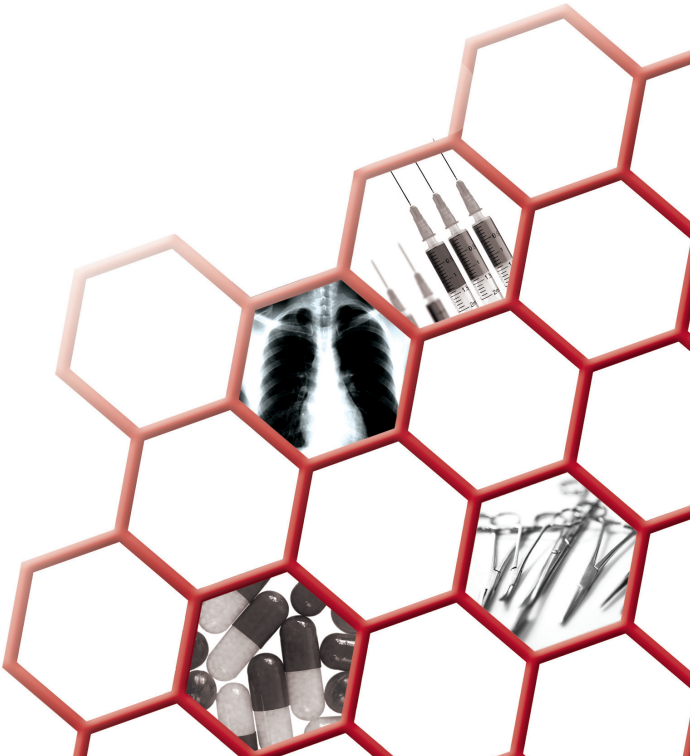
BAKER & MCKENZIE

Promoting Medical Products Globally

Handbook of Pharma and MedTech Compliance



Promoting Medical Products Globally

Global Handbook of Pharmaceutical and MedTech Compliance

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Table of Contents

Introduction

Asia Pacific

Australia **2**
Elisabeth White

China **15**
Clement Ngai, Jingyan Wei

Hong Kong **28**
Isabella Liu

India **41**
Shishir Jose Vayttaden, Vinay Subramanian, Adrika Ray
Luthra & Luthra

Japan **79**
Kengo Nishigaki, Ryosuke Tateishi

Malaysia **106**
Kherk Ying Chew

Philippines **120**
Maria Christina J. Macasaet-Acaban, Alain Charles J. Veloso, Eleanor
R. Mateo

Singapore **145**
Andy Leck, Ren Jun Lim

Taiwan **169**
Grace Shao, Belle Chiou

Thailand **203**
Peerapan Tungsuwan, Praween Chantanakomes, Prim Uditananda

Vietnam **225**
Vu Minh Ha

Europe

Austria **235**
Daniel Larcher, Agata Wolinska

Belgium **285**
Annabelle Bruyndonckx

Czech Republic **307**
Patrik Kastner

France **355**
Thomas Devred

Germany **433**
Thilo Räpple, Frank Pflüger

Hungary **495**
Helga Bíró, Berekméri-Varró Réka

Italy **553**
Pierfrancesco Federici, Aurelio Giovannelli, Francesco Goisis, Roberto Cursano, Matthew Davidson Mario Cigno

The Netherlands **587**
Misha lutje Beerenbroek, Emma Runia, Eline van Nimwegen

Poland **619**
Paulina Kieszkowska-Knapik, Magdalena Bąkowska

Russia **663**
Alexey Trusov, Sergei Lomakin

Spain **703**
Montserrat Llopart, Ester Navas, Cecilia Pastor, Ariadna Casanueva

Sweden **757**
Stefan Brandt, Jenny Lundberg

Switzerland **785**
Peter Reinert

Turkey **829**
Hasmet Ozan Guner

Ukraine **858**
Olga Shenk

United Kingdom **870**
John Leadley, Richard Davies

North America

Canada **892**
Kanta Wadhwan, Lisa Douglas, Jonathan Tam

United States of America **917**
Neil F. O'Flaherty, Tish E. Pahl, Evan P. Phelps
Olsson Frank Weeda Terman Matz PC
John P. Rowley III, Marc Litt, Catherine O Suilleabhain
Baker & McKenzie

Latin America

Argentina **987**
Vanina Caniza, Camila Pampuro

Brazil **1001**
Esther Flesch, Heloisa Uelze, Henrique Frizzo

Chile **1033**
Rafael Pastor, Sebastian Doren

Colombia **1045**
Georgette Olga Otero

Mexico **1071**
Adriana Ibarra-Fernandez, José Hoyos Robles, Pedro Tapia Juárez

Venezuela **1103**
María Fernanda Zajía, Dianne Phoebus, Martha Cohen

Introduction

Welcome to the third edition of the popular legal guide "*Promoting Medical Products Globally: Handbook of Pharma and MedTech Compliance*".

When planning cross-border advertising campaigns, pharmaceutical and medical device companies must ensure that they observe all the applicable laws of the countries where they intend to do business. As might be expected, there are differing legal requirements in the various regions of the world when it comes to cooperation between the industry and physicians. In some countries for instance, approval by a competent authority must be secured before a specific advertising campaign can be launched. In other countries, legal reviews are limited to the aftermath of various advertising activities. There are also very different ways of bringing legal action against improper advertisements. Additionally, it must be noted that medical professionals employed by public hospitals are treated as public officials in numerous countries. Consequently, relevant anti-bribery laws must also be taken into account. Since some jurisdictions provide for strict rules which prohibit corrupt behaviour in other countries, the assessment and legal evaluation of compliance issues can become extremely complex for multinationals.

Due to the many legal developments intended to promote ethical business practices in relation to interaction between medical companies and healthcare professionals around the world, it has become necessary to release an updated edition of this book.

We have updated this handbook to expand beyond Europe and North America, to now include country reports from the Asia Pacific region (Australia, China, Hong Kong, Japan, Malaysia, Philippines, Singapore, Taiwan, Thailand and Vietnam), Latin America (Argentina, Brazil, Chile, Columbia, Mexico and Venezuela) as well as India and Turkey. The book now covers all regions of the world.

Most of the authors of the country reports in this handbook are attorneys-at-law with a special focus on healthcare law issues and who work with the international law firm Baker & McKenzie. Their daily practice includes advising pharmaceutical and medical device companies on all of the above issues, and helping them construct agreements covering every specific form of cooperation.

Special thanks are owed to Shishir Jose Vayttaden, Vinay Subramanian and Adrika Ray from the law firm Luthra & Luthra, with its offices in New Delhi,

Mumbai and Bangalore, who put the India chapter together. The US chapter has been revised and written by Neil F. O'Flaherty, Tish E. Pahl and Evan P. Phelps from the law firm Olsson Frank Weeda Terman Matz PC in Washington DC; in conjunction with John Rowley, Marc Litt and Catherine O Suilleabhain of Baker & McKenzie. We are grateful for these contributions which showcase the expertise of these lawyers in the compliance field and from which the reader will certainly benefit.

We trust that this book is a useful resource for lawyers and medical industry specialists in assessing the legal impact on their promotion and marketing activities involving health professionals or medical institutions. This book must be on the shelf of all compliance officers of multinational medical companies.

Thilo Räpple, Frankfurt
September 2012

Asia Pacific

Australia

Elisabeth White

Introduction

In Australia, the advertising of pharmaceutical products and medical devices to consumers and health professionals is administered via a co-regulatory system.

The Therapeutic Goods Administration ("TGA"), a division of the Federal Government Department of Health and Ageing, is the key authority regulating pharmaceutical products and medical devices in Australia, including their advertising and promotion.

The TGA is supported in its regulatory activities by a number of industry organizations which have implemented and enforce codes of conduct applicable to member countries.

The advertising and promotion of pharmaceutical products and medical devices is monitored fairly actively in Australia. In addition to review by regulators, it has been the subject of media coverage and commentary.

Regulatory Framework

The primary regulatory instrument is the Therapeutic Goods Act 1989 ("TG Act") and associated subordinate regulations which include the following:

- Therapeutic Goods Regulations 1990 ("Regulations")
- Therapeutic Goods (Medical Devices) Regulations 2002
- Therapeutic Goods Advertising Code 2007 ("TGA Code")

Compliance with the Regulations and the TGA Code is mandatory under the TG Act. The TGA Code regulates advertising to consumers (not to healthcare practitioners).

In Australia, voluntary industry codes govern the conduct of member pharmaceutical and medical technology companies, in particular interactions between sponsors and healthcare practitioners, including advertising and promotion. These industry codes include the following:

- Medicines Australia Code of Conduct ("MA Code")
- Medical Technology Association of Australia Code of Practice ("MTAA Code")
- Australian Self-Medication Industry ("ASMI") Code of Practice
- Complementary Health Council ("CHC") Code of Practice for the Marketing of Complementary Healthcare Products
- IVD Australia Code of Conduct

The codes are not legally binding, but operate as industry standards, and members of the relevant industry organizations may be subject to penalties if their conduct infringes a relevant code.

The promotion of pharmaceutical products and medical devices is also subject to general trade practices and consumer protection laws set out in the Australian Consumer Law (part of the Competition and Consumer Act 2011). Relevant provisions include the following:

- Section 18: a general prohibition on conduct by a corporation, in trade or commerce, which is misleading or deceptive or likely to mislead or deceive
- Sections 29 and 33: prohibit specific types of false representations, including false representations as to the standard, quality, value or grade of a product; as to sponsorship, approval, performance characteristics, uses or benefits; or the need for particular goods or services

The TG Act defines advertisement broadly as: "any statement, pictorial representation or design, however made, that is intended whether directly or indirectly to promote the use or supply of therapeutic goods."

This definition is adopted in the Regulations, the TGA Code, and industry codes.

The TG Act and the TGA Code define health professionals to include: medical practitioners, psychologists, dentists, veterinary surgeons, pharmacists, physiotherapists, dieticians, scientists working in medical laboratories or nurses; wholesalers and purchasing officers of therapeutic goods; herbalists, homeopathic practitioners, chiropractors, naturopaths, nutritionists, traditional Chinese medicine practitioners, podiatrists or osteopaths.

For the purposes of industry codes, "healthcare practitioner" is defined slightly more broadly.

Permitted and Prohibited Practices

Advertising to Consumers

In Australia, all pharmaceutical products and medical devices must be included on the Australian Register of Therapeutic Goods ("ARTG"), unless exempt, before they can be supplied, promoted and advertised in Australia.

The TG Act provides that:

- unregistered goods must not be advertised in Australia to consumers or healthcare professionals; and
- pharmaceutical products and medical devices must not be advertised for any indication which has not been accepted and included on the ARTG in relation to that product or device.

The TG Act also provides that all advertisements must comply with the Regulations and the TGA Code. The object of the TGA Code is to ensure that the marketing and advertising of therapeutic goods to consumers is conducted in a socially responsible manner that promotes the quality use of therapeutic goods and does not mislead or deceive consumers.

Significantly:

- advertising prescription-only and certain pharmacist-only medicines to the general public is prohibited; and
- advertising over-the-counter (OTC) medicines, complementary medicines and devices is generally permitted.

Advertising to consumers may take a range of forms, including:

- magazines or newspapers;
- television, radio or cinema;
- the internet;
- billboards or public transport;
- leaflets, flyers, brochures, catalogues, letterbox drops; and
- medical journals

Prior approval is required for advertisements to consumers in the form of broadcast media (television and radio), print media (newspapers and

magazines, including inserts) and outdoor media (billboards, bus shelters, sides and interiors of buses, and taxi displays). The approval process has been delegated by the Federal Department of Health and Ageing to the ASMI and the CHC.

No prior approval is required for advertisements relating to medical devices.

The TGA Code includes a range of additional requirements and prohibitions in relation to advertising including the following:

- Minimum product information requirements - All advertisements (apart from limited point of sale material) must contain:
  - the trade name of the goods;
  - a reference to approved / permitted indications for the use of the goods;
  - where applicable, a list of ingredients or a prominent "ALWAYS READ THE LABEL" statement; and
  - a prominent "USE ONLY AS DIRECTED" statement.

  Direct marketing and internet advertising must contain additional product information, as must pharmacist-only medicines and radio advertising where claims are made in relation to symptoms of diseases or conditions. Print advertisements must also include ARTG numbers.

- Prohibited representations, including as to the treatment of sexually transmitted diseases, HIV / AIDS or mental illness.
- Prior approval must be obtained to use certain restricted representations in relation to particular diseases (see TGA Code, Appendix 6).
- An advertisement for therapeutic goods must not:
  - be likely to arouse unwarranted and unrealistic expectations of product effectiveness;
  - be likely to lead to consumers self-diagnosing or inappropriately treating potentially serious diseases;
  - mislead, or be likely to mislead, directly or by implication or through emphasis, comparisons, contrasts or omissions;
  - abuse the trust or exploit the lack of knowledge of consumers or contain language which could bring about fear or distress;
  - contain any matter which is likely to lead persons to believe that they are suffering from serious ailment or that harmful consequences may result from the therapeutic good not being used;

    - encourage, or be likely to encourage, inappropriate or excessive use;
    - contain any claim, statement or implication that it is infallible, unfailing, magical, miraculous, or that it is a certain, guaranteed or sure cure;
    - contain any claim, statement or implication that it is effective in all cases of a condition; or
    - contain any claim, statement or implication that the goods are safe or that their use cannot cause harm or that they have no side-effects.
- Scientific information must be presented in a manner that is accurate, balanced and not misleading.
- Requirements in relation to comparative advertising.
- Endorsements are strictly regulated.
- Testimonials must be documented, genuine, not misleading and illustrate typical cases only.
- Samples must not be offered.
- Specific requirements in relation to the advertising of analgesics, vitamins and weight management.

The MA Code also regulates interactions with consumers in relation to pharmaceutical products and prescribes mandatory requirements in relation to:

- product media releases;
- educational materials;
- disease education activities; and
- patient support programs.

Finally, the Australian Consumer Law Act will apply to any and all promotional claims and advertising to consumers. As a general rule, companies should avoid claims which are unduly broad, vague, ambiguous or exaggerated. In order to meet any allegation of breach, companies should ensure that they are in a position to substantiate claims by reference to appropriate factual and scientific data.

Advertising to Healthcare Practitioners

Advertisements directed to healthcare practitioners are regulated by the MA Code (for pharmaceutical products) and the MTAA Code (for medical devices and technology).

Pharmaceutical Products

For prescription medicines, inclusion on the ARTG is subject to a condition that promotional material must comply with the MA Code. Non-prescription medicines, OTC and complementary medicines are also regulated by the ASMI and the CHC.

The MA Code sets out the following requirements for educational and promotional material directed to healthcare practitioners:

- All material must be current, balanced, accurate and fully supported by product information.
- Material must not mislead directly or by implication or omission.
- Materials must be in good taste.
- Unqualified superlatives are prohibited.
- A product may only be described as "new" for the first 12 months it is available in Australia.
- Comparative statements must properly reflect the body of evidence and not mislead, must be factual and fair, must be capable of substantiation and must not be disparaging.
- Materials must include product information and PBS information.
- There are mandatory type and size requirements for print media.
- Specific requirements apply to primary advertisements, secondary advertisements and short advertisements.
- Specific requirements apply to advertorials and company-commissioned articles.
- Mandatory information, type and font size requirements apply to leave-behinds, sales aids and leaflets.
- There are mandatory requirements for audiovisual material, restricted access television and advertising on the internet, including close circuit websites for healthcare professionals, social media and e-newsletters.

Medical Devices and Technology

The MTAA Code requires the following:

- Advertisements to health care practitioners must contain:
    - the brand name of the product;
    - the name and contact details of the product sponsor;
    - claims consistent with the intended purpose of the product; and
    - all such other information required by law or as a condition of grant of a license.

- Advertisements must:
  - not be misleading or deceptive or likely to mislead;
  - reflect a high standard of social responsibility and conform to standards of good taste;
  - not claim that a device or technology has some special merit, quality or property unless the claim can be substantiated;
  - not use the term "safe" without appropriate qualification; and
  - not describe a product as "new" after 12 months without appropriate qualification.
- Member companies must be able to substantiate all claims in an advertisement by reliable technical, scientific or other support, and provide substantiation of claims upon any request by third parties.
- The name or photograph of a healthcare practitioner must not be used without his/her written permission, nor in any way that is contrary to ethical guidelines or likely to mislead, deceive or confuse.
- Advertisements must not unfairly denigrate a competitor's product. Comparative advertising must be based upon comparative testing of the relevant products, the outcomes must be reported in a fair and balanced manner, and each outcome must be referenced and consistent with the body of evidence.

Other Promotional Activities

Competitions

The MA Code regulates competitions directed to healthcare practitioners, requiring as follows:

- Competitions must be based upon medical knowledge.
- The prize must be relevant to the practice of medicine.
- Individual prizes must be of low monetary value or educational.
- Entry to the competition must not be dependent on prescribing, ordering or recommending a product.
- Competitions must be appropriately documented and comply with all relevant laws.

The MTAA Code includes provisions in relation to competitions directed to healthcare practitioners and consumers.

In relation to consumers, the MTAA Code provides that:

- a competition must not be directed to consumers in relation to any medical device which is used or intended to be used or administered by a medical practitioner; and
- entry to a competition must not, as a condition of entry, require a consumer to use or purchase a product.

The MTAA Code provides, in relation to healthcare practitioners, that:

- a competition must be based entirely on medical or other specialist healthcare knowledge or the acquisition of that knowledge;
- prizes must be directly relevant to the practice of medicine or field of the specialist healthcare and of minimal monetary value; and
- entry into a competition must not be dependent on ordering, recommending, using or prescribing a product.

Gifts

The MA Code only permits gifts to healthcare professionals which consist of brand name reminders, educational material, a competition prize or a sponsorship arrangement. Gifts must not be given to induce recommendations or prescriptions.

The MTAA Code permits companies to provide a gift of appreciation to a healthcare professional in very limited circumstances. The gift must be of minimal value (i.e., no more than AUD100) and serve a genuine educational function for the healthcare practitioner or a consumer. Medical textbooks, anatomical models and branded promotional items of limited value may also be provided.

The MTAA Code permits philanthropic gifts or donations to charitable or philanthropic organizations for educational or research purposes, provided that donations or philanthropic grants must not be made for the purpose of inducing a healthcare practitioner to purchase, lease, recommend or use particular products.

Sample Products

The MA Code permits the provision of "starter packs" which are one-third the size of retail or trade packs, bear compliant labeling and include relevant product information. Starter packs must be provided to healthcare professionals (not directly to patients), and companies must keep records.

The MTAA Code acknowledges the legitimate practice of providing healthcare practitioners with appropriate sample products for genuine training, educational or product evaluation purposes.

Entertainment

Both the MA Code and MTAA Code expressly provide that interactions with healthcare practitioners must not include entertainment (including sporting events, musicals and other forms of entertainment).

Hospitality

Both the MA Code and MTAA Code regulate the provision of hospitality to healthcare practitioners.

Hospitality must only be provided in the context of an educational conference or meeting, in an environment which is conducive to enhancing education and learning. The venue must not be chosen for its leisure or recreational facilities.

The MTAA Code further provides that, where hospitality is provided at a third party educational conference (such as a conference hosted by a medical society), the hospitality must be available to all attendees or a specialty sub-group; be subordinate to the educational and technical purposes of the conference; and be appropriate in value.

Sponsorship for Training, Research, Employee Positions or Events

Both the MA Code and the MTAA Code permit certain types of sponsorship subject to specific requirements, as follows:

- Training, education and product demonstrations conducted by or on behalf of companies

  MA Code: There must be objective evidence as to the educational value of the event; the venue must be chosen for the provision of education, not for its leisure or recreational facilities; meals and beverages must not be excessive; travel must be in economy class; no entertainment may be provided; delegates must not be paid; and the attendance of partners or other family members must not be funded.

  MTAA Code: The program must be conducted in a clinical, educational, conference or other setting conducive to the effective transmission of knowledge; any hospitality must be modest in value

and subordinate in time and focus to the education / training; and the program must be recorded in a detailed agenda or written agreement.

- Sponsorship or grants for third party educational conferences

  MA Code: The primary objective of the conference must be the enhancement of medical knowledge and improving the quality use of medicine; the third party organizer must independently determine educational content, speakers and attendees; there must be no payment for entertainment, attendance or family members. The Code also permits companies to sponsor a particular healthcare practitioner to attend an educational event directly related to their area of expertise provided there are clear guidelines for the grant of such sponsorships, it is recorded in a formal agreement and the sponsorship is not linked to prescribing.

  MTAA Code: The conference must be primarily dedicated to promoting objective medical, scientific and educational activities; the sponsorship or grant must be proportionate to the overall cost of the conference; the conference sponsor must control the program, select the sponsorship recipient and make necessary payments; the sponsorship must not be conditional; and the sponsorship or grant must be recorded in a written agreement.

- Grants or donations for educational or research purposes (which may include, by way of example, a fellowship position)

  The types of organizations which may receive donations are those established to advance medical education, research with scientific merit or public education.

Contracts with Healthcare Professionals and Medical Institutions

The MA Code permits companies to legitimately seek the services of suitably qualified and experienced healthcare practitioners to provide services, advice and guidance. These arrangements may include consulting agreements and appointments to advisory boards. There must be a written agreement between the company and healthcare practitioner and the remuneration paid to the healthcare practitioner must be commensurate with the services provided. MA Code provisions in relation to sponsorships, grants and financial support may also apply.

The MTAA Code also provides that companies may engage healthcare practitioners to provide valuable genuine consulting services provided that such an engagement may take place only where a legitimate need and purpose of the services is identified in advance and product promotion is not a purpose for the engagement. MTAA Code provisions relating to training, education and product demonstrations may also apply.

Both codes permit companies to enter into appropriate arrangements with medical practices, hospitals, medical institutions and health research organizations.

Consequences of Breach

Liability Under Civil and Criminal Law

The TG Act provides a range of offenses relating to failure to comply with the TGA Code and other misrepresentations in the context of advertising. The maximum penalty for each offense is currently AUD66,000 for corporations; though a misrepresentation regarding a device being listed on the ARTG may result in a maximum penalty of AUD5.5 million.

Any person may take civil action for breach of the TG Act or the Australian Consumer Law, seeking remedies including declarations or injunctions.

The remedies for breach of the Australian Consumer Law also include corrective advertising, damages and related remedies. If the regulator, which is the Australian Competition and Consumer Commission, takes action, a Court may also award fines.

Australia, like many other jurisdictions, also has anti-bribery legislation with local and potentially extraterritorial effect. The legislation is relevant to dealings with individuals who may be public officials (foreign or local), such as doctors or employees of government-owned hospitals.

Under the Australian Criminal Code Act 1995 (Cth), it is a criminal offense to bribe a foreign public official. Bribery is providing, causing, offering, or promising to provide a benefit to a foreign public official that is not legitimately due with the intention of influencing the foreign public official in order to obtain or retain business or a business advantage that is not legitimately due.

As the definition of "benefit" includes any advantage and is not limited to property, this means that the provision can apply to hospitality and entertainment, as well as to gifts.

Similar provisions apply at a state level in relation to local public officials.

Even where doctors or other individuals are not considered public officials, it can also be an offense to offer or give a corrupt commission, reward, or other undisclosed benefit to an agent as an inducement to act / not act or favor/disfavor any person in relation to the affairs or business of the agent's principal, whether or not a public official is involved. It also is a criminal offense for an agent (or related party) to receive or solicit such an undisclosed benefit.

Some Australian companies may also be subject to provisions of the UK Bribery Act 2010 if they carry on a business or part of a business in the UK. Similarly the United States Foreign Corrupt Practices Act ("FCPA") has a wide geographical reach and will apply, for example, to Australian subsidiaries of US companies.

Professional Codes of Conduct

The sanctions for breach of the MA Code include cessation of conduct and withdrawal, corrective action and monetary fines ranging from a minimum of AUD100,000 for a technical or minor breach to AUD250,000 for a severe and unremedied breach.

The sanctions for breach of the MTAA Code depend upon the severity of the breach and include recalls, retraction notices, fines (AUD40,000 for a severe breach) and expulsion from the MTAA.

In practice, large fines are not typically imposed.

Recommendations

As indicated above, the advertising and promotion of pharmaceutical products and medical devices is monitored relatively actively in Australia. The advertising and promotion of products by sponsor companies to healthcare professionals has, in particular, been the subject of media coverage and commentary.

We recommend that manufacturers and sponsors put in place appropriate internal codes of conduct and associated guidelines in relation to the

advertising and promotion of products in Australia, ensuring these are adapted to comply with local regulations.

We also recommend conducting regular training sessions for local company representatives (including sales teams) to ensure awareness and compliance with internal codes of conduct and regulatory requirements. This is critical in order to minimize any potential exposure, including, significantly, under anti-bribery legislation, including the FCPA. It is also a mandatory requirement for member organizations of local industry organizations, including Medicines Australia and the Medical Technology Association of Australia.

At a practical level, it is critical to distinguish between advertising and promotional materials which are directed to consumers (where permissible) and those which are directed to healthcare professionals. As outlined in this chapter, differing considerations will apply.

Finally, Australian regulators including the TGA and the Australian Consumer and Competition Commission (which administers the Australian Consumer Law) have wide-ranging investigation and enforcement powers. Companies should take care and seek advice in relation to their dealings with regulators, including as to representations made in response to any regulatory enquiries and the disclosure of commercially sensitive, confidential and potentially privileged material.

China

Clement Ngai, Jingyan Wei

Introduction

Advertising and promotion of pharmaceuticals and medical devices are subject to strict regulations in China. Approval requirements for advertisements and strict product labeling requirements are issues that multinational pharmaceutical and medical device manufacturers often contend. On top of that, laws of anti-unfair competition and anti-bribery, together with the US Foreign Corrupt Practices Act, make marketing and promotion of pharmaceutical and medical device products particularly difficult in China.

The pharmaceutical and medical device distribution sector has been undergoing changes and consolidation. Authorities have been targeting bribery activities in the sector and there has been strong emphasis by foreign companies to implement strict compliance policies in all business activities including advertising and promotion. Apart from internal policy, the professional industry body has also promulgated ethical industry codes of conduct on business activities.

The Regulatory Framework

In China, there is no one comprehensive law or regulation that governs the conduct of advertising and promotion of pharmaceutical products and medical devices. The relevant legislation that govern advertisement and promotional activities concerning medical products and services are found in both national and local level laws, administrative regulations and orders.

The main laws and regulations include the following:

Laws governing general advertising

- Advertising Law of the People's Republic of China (1995)
- Detailed Implementing Rules of Advertising Law of the PRC (2005)

Laws governing pharmaceuticals generally

- Law for the Administration of Pharmaceuticals (2001)
- Implementing Regulations for the Pharmaceuticals Law (2002)

Laws relating to advertising of pharmaceuticals

- Measures for the Examination of Pharmaceutical Advertisements (2007)
- Standards for the Examination and Publication of Pharmaceutical Advertisements (2007)

Laws governing medical devices generally

- Regulations on Supervision and Administration of Medical Device (2000)
- Measures for the Administration of Medical Device Registration (2004)

Laws relating to advertising of medical devices

- Measures for Examination of Advertisement for Medical Device (2009)
- Standards for Examination and Release of Medical Device Advertisements (2009)
- Measures for the Administration of User Manuals for, Labels of, and Markings of Packages of Medical Devices (2004)
- Warning System for Illegal Advertisements for Pharmaceuticals, Medical Devices and Health Foods (Trial regulations, issued 2006)

Under the Advertising Law, the term "advertising" or "advertisement" is defined as "commercial advertising or commercial advertisement by which a dealer in merchandise or a provider of services directly or indirectly introduces, at his own expense, through a certain medium and in a certain form, merchandise marketed or services provided by him."

Consistent with the general broad definition of "advertisement," "pharmaceutical advertisement," as defined in the Measures for the Examination of Pharmaceutical Advertisements, also covers a potentially wide range of activities, particularly, "any advertisement published through various media or forms which contain the name of a pharmaceutical product, indications (functions) or other relevant contents of a pharmaceutical product."

Likewise, in the Measures for the Examination of Medical Device Advertisements, "medical device advertisement" is defined as "any advertisement published through a certain medium and in a certain form

which contain a medical device's name, scope of use, components and physical make-up, or mechanism of a medical device product."

The broad definition of "advertising / advertisement" implies that the scope is wide and it should be assumed that any or all advertising or promotional activities of pharmaceutical products and medical devices regardless of the form and media in which it is released, published, or delivered, could be subject to the control and restrictions of the above mentioned regulations on medical advertising.

However, it should be noted that the above advertising regulations do not readily govern product promotional activities targeting medical institutions and practitioners. Instead, these advertising and promotional activities are regulated under local anti-unfair competition laws and anti-bribery laws and regulations.

The following are laws relating to unfair competition / anti-bribery:

- Anti-Unfair Competition Law of the People's Republic of China (1994)
- Several Provisions on Countering Unfair Competition in the Medical Industry (1993)
- Provisional Regulations on Prohibition of Commercial Bribery (1996)
- Provisional Measures for the Administration of the Acceptance by Medical and Health Institutions of Private Donations (2007)
- Measures on Establishing Bad Record for Commercial Bribery in the Purchase and Sale of Medical Products (2007)
- Opinions on Several Issues Concerning the Application of the Law in the Handling of Criminal Cases of Commercial Bribery (2008)
- Notice on Strengthening the Regulations on Commercial Bribery in the Purchase and Sale of Medical Products (2010)

General Requirements

The general regulatory framework on the advertisement of pharmaceuticals and medical devices can be summarized as follows:

Pharmaceuticals

- Publication, release or other forms of dissemination of pharmaceutical advertisements requires a "Pharmaceutical Advertisement Permit" from the relevant local food and drug administration authority.
- The advertisement permit is valid for one year.

- Publication or release of a drug advertisement in locations other than where the advertisement permit is issued requires a pre-publication recordal with the local food and drug administration authority of the target advertisement location.
- Pre-approval is not required if the advertisement promotes only the name of an over-the-counter ("OTC") drug, or if the advertisement only promotes the name of a prescription drug and is published in designated medical professional journals.
- Advertisement of certain drugs, including narcotics, psychotropic drugs, radiopharmaceuticals, specialty drugs used by the military and drugs only permitted for trial use, is strictly prohibited.
- Advertisement of prescription drugs is only permitted for medical professional journals, and is strictly prohibited for the general public.

Medical Devices

- Publication, release or any form of dissemination of advertisements on medical devices requires a "Medical Device Advertisement Permit" from the relevant local food and drug administration authority.
- The advertisement permit is valid for one year.
- Pre-release approval is not required if the advertisement contains only the name of the medical device and includes the medical device registration number.
- Advertisements of certain medical devices, including unregistered medical devices (where product registration is required), devices for trial use in clinical studies, devices under trial production, devices manufactured without requisite manufacturing license, or other devices that run afoul of social conventions or moral principles are strictly prohibited.

Permitted and Prohibited Practices - Advertisements

The following is a summary and an illustrative list of the main dos and don'ts for conducting advertising activities for medical products in China.

Pharmaceuticals

- Obtain pre-publication approval unless exemptions apply.
- Be truthful and not misleading.
- List product name, required legends, advertisement permit number, product manufacturing permit number and the drug manufacturer/distributor.

- Always use generic product name in advertisements (i.e., cannot use brand name only in advertisements); generic product names must be displayed more prominently than brand names.
- Do not use unscientific assertions or claims regarding efficacy or usage claims.
- Do not conduct comparative advertising with similar products, or conduct "before and after" references for own product.
- Do not use superlative language.
- Do not use references to cure rate, efficacy rate or product awards.
- Do not use the name or images of medical institutions, academic institutions, doctors, and patients as testimonials to the advertised claims.
- Do not publish advertisements on publications or press media that target minors or otherwise to appeal to minors, or advertise in the name of a minor.
- Do not advertise for narcotics, psychotropic drugs, poisons for medical use, radiopharmaceuticals or drugs specially needed by the army.
- Do not use unregistered trademark in drug advertisements; use registered trademarks together with generic product name.
- Only licensed drug manufacturers or distributors can apply for drug advertisement permits.

Specifically, for advertising of prescription drugs:

- Advertise only in medical and pharmaceutical industry publications - not in mass media or media of general distribution.
- Include the legend "for medical science and pharmaceutical professionals only."
- If product name is the same as a trademark or a trade name, do not conduct "disguised advertising" by using the trademark / trade name in advertisements of general distribution.

For advertising of OTC drugs:

- Advertise in general media and in medical and professional publications.
- Include the legend "please purchase and use the product in accordance with instructions or under the guidance of a pharmacist."
- Include the "OTC" marking in the packaging.
- Do not use misleading language, including technical medical terms that may be difficult for the general public to understand.

Medical Devices

- Obtain pre-publication approval unless exemptions apply.
- Be truthful, scientific, accurate and not misleading.
- List product name, advertisement permit number, product registration number and the manufacturer.
- Include the legend "please read the product excerpts carefully or purchase and use under the guidance of medical professionals" if the product is recommended for use by individuals.
- Do not use unscientific assertions or promises regarding efficacy or usage claims.
- Do not conduct comparative advertising with similar products, or conduct "before and after" references for own product.
- Do not use superlative language.
- Do not use language such as "must have for the family".
- Do not use references to cure rate, efficacy rate or product awards.
- Do not use the name or images of medical institutions, academic institutions, doctors, and patients as testimonials to the advertised claims.
- Do not publish advertisements on publications or press media that are targeted at minors or otherwise to appeal to minors, or advertise in the name of a minor.
- Do not advertise using non-medical device product names in place of medical device product names.
- Only licensed medical device manufacturers or distributors can apply for medical device advertisement permits.

Permitted and Prohibited Practices – Other Promotional Activities

Under the Several Provisions on Countering Unfair Competition in the Medical Industry, companies may not entice buyers to purchase their products by providing money, goods, free trips, reimbursements of costs or other means that are considered as "bribery." In general, "bribery" is defined by whether its purpose is to solicit business.

The Provisional Regulations on Prohibition of Commercial Bribery further recognizes that payments made in the guise of covering marketing or publicity expenses, sponsorship fees, R&D costs, service or consulting fees, sales commissions and the like may be deemed "commercial bribery" if they are made in order to induce purchases or sales of goods.

Gifts

Gifts to healthcare professionals and medical institutions may be permissible if such gifts are of "modest value" and given in accordance with customary business practices. Generally, the following two types of gifts are viewed as permissible in China:

- Gifts in kind (not cash) with the company name/logo printed or engraved on the gift item, such as a pen; under PRC law, this sort of gifts will be treated as a form of advertising by the company.
- Gifts made in connection with major events or festivals, such as birthday parties, funerals, the Spring Festival or the Mid-Autumn Festival.

In practice, one should generally keep the unit value of promotional gift items below RMB100, and gifts in connection with holidays below RMB200.

Sample Products

Sample products of "modest value" that are provided for promotional purposes should not be problematic.

Commercial bribery rules only prohibit the act of giving items of value for the purpose of soliciting purchases. "Hospitality" (e.g., meals and accommodation provided to healthcare professionals during business events) does not fall within this definition if it is incidental to business activities and is not intended to influence the purchasing decision. The hospitality should be directly related to the business event and the expense should not exceed reasonable amounts.

Lavish meals, meals outside the agenda of the business event, or reimbursing personal room charges such as room service or telephone calls, would likely be viewed as inappropriate.

Entertainment

The entertainment should be incidental to business activities and not intended to influence decisions. Furthermore, it should be directly related to the business event and the expense should not exceed reasonable amounts. Golf outings or performances by celebrities would likely be viewed as inappropriate.

Sponsorship for Training, Research, Employee Positions or Events

Sponsorship for training or events provided by medical device companies to employees of medical institutions may be prohibited as "commercial bribery," if they are provided to influence the purchasing decision and they provide a benefit for the employee. Otherwise, they may be analyzed in the context of "donations" (see below) or "discounted items."

Discounted Products

Under the Anti-Unfair Competition Law of the People's Republic of China, discounts have to be "above board" and have to be properly recorded on the books of both parties. A secret, off-the-book rebate to a business unit or an individual will be treated as a "bribe."

Donations

Charitable donations to hospitals are governed by the Provisional Measures for the Administration of the Acceptance by Medical and Health Institutions of Private Donations. These provisional measures require, *inter alia*, that the donation not be made for any profit-making purpose, not be linked to any conditions, and be made for the benefit of the public.

If a donation does not satisfy the above criteria, it may be analyzed under the same structure as discounted products. The arrangement has to be "above board," i.e., it has been properly documented and recorded in the books of both parties.

Consequences of Breach

The liabilities for violations of applicable advertising regulations vary depending on the type of conduct and violation. However, they mainly include the following types of penalty:

- Revocation of the related (drug or medical device) advertisement permits
- A ban (up to three years) for a new (advertising) permit
- Suspension of the advertisement in question
- Suspension of manufacturing, sale and use of the product
- Administrative fine (from RMB10,000 to RMB30,000)

Professional Codes of Conduct

The R&D Based Pharmaceutical Association of China ("RDPAC"), which is an industry body in the pharmaceutical industry, promulgated and issued the Code of Practice on the Promotion of Pharmaceutical Products ("RDPAC Code") in 2003, which set forth standards for the ethical promotion of pharmaceutical products to healthcare professionals and for the interactions of the medical industry with them.

The latest version of the RDPAC Code was issued in 2010, with 37 pharmaceutical companies member signatories, all of which are major multinational, research-based companies with substantial investment in China.

The general principles on the promotion of medical products and services set out by the RDPAC Code are as follows:

- Purpose of interaction - Interactions with healthcare professionals are intended to benefit patients and enhance the quality of medical services by providing the professionals with product information and scientific and educational information, among others.
- Independence of healthcare professionals - No financial benefit or benefit-in-kind may be offered to healthcare professionals in exchange for prescribing, recommending, purchasing, supplying or administering products, or to cause inappropriate influence on the prescribing practices of the professional.
- Appropriate use - Promotion should encourage the appropriate use of pharmaceutical products through objective introduction.
- Chinese laws and other local regulations - In all cases, all applicable Chinese laws and regulations must be observed and checked in advance of promotional actions.
- Transparency of promotion - Promotion should not be disguised. Clinical assessments, post-marketing surveillance and experience programs and post-authorization studies must not be disguised promotion.
- Pre-approval communications - No pharmaceutical product shall be promoted for use in China until drug registration approval for marketing purposes has been granted.

Promotional Practices

In accordance with the RDPAC Code, promotional information should be:

- Consistent with product information approved by Chinese drug administration authorities;
- Clear, legible, accurate, balanced, fair, objective and sufficient enough to enable the recipient to form his or her own opinion of the therapeutic value of the products concerned; and
- Can be substantiated either by reference to approved product excerpts or by scientific evidence.

Seminars, Meetings, or Other Promotional Events

Seminars, meetings, or other promotional scientific or professional events for healthcare professionals sponsored or organized by the medical industry shall focus on providing information about the products and scientific developments, among others.

Events should be held in an appropriate venue that is conducive to the objectives and purpose of the event; extravagant venues should be avoided.

Events held outside of China are allowed only if a significant portion of the invited professionals are from overseas and it is feasible to hold the event in another country, or if the resource or expertise in relation with the subject matter of the event is located outside of China.

Companies are permitted to sponsor healthcare professionals' attendance to medical events. However, the support is strictly limited to the payment of travel, meals, accommodation and registration fees. Payment to professionals for the time spent in attending the event is strictly prohibited, except for reasonable fees and reimbursement paid to the speakers or presenters at the event.

Sponsored meal expenses should be incidental to the main purpose of the event, subject to moderate and reasonable local standards, and not be more than RMB300 per person per meal.

For events involving overnight stay, it should be ensured that the healthcare professionals spend a majority of the time on scientific or educational activities.

Entertainment will only be allowed only if it is secondary to the main purpose of the event and is provided during or directly before or after the meal or refreshment.

There should be no sponsorship of entertainment or other leisure or social activities unrelated to the events, such as sports contests, sightseeing, excursions, theatre or opera trips.

In all events, the recipient of all allowed sponsorship by the industry shall be healthcare professionals who attend the event and it should not extend to guests who accompany the professionals, such as relatives and friends.

Gifts

In principle, gifts for personal use, cash or cash equivalents should not be offered to healthcare professionals, except for the following items:

- Promotional aids or souvenirs of minimal value which are relevant to the practice of the healthcare professional (e.g., pens, notepads and surgical gloves)
- Items of medical utility of modest value that are beneficial to the provision of medical services and for patient care (e.g., medical books and anatomical modes)
- Gifts with value of no more than RMB200 given on an infrequent basis in acknowledgment of official holidays in China

Samples

Free samples of a medical product of a limited quantity may only be supplied to healthcare professionals for the purpose of familiarization with the product and further enhancement of patient care. Samples should be clearly identified as “Sample” or “Not for Sale” and should not be resold or otherwise misused.

Criminal and Civil Liabilities

Liabilities for Violation of Anti-Bribery Laws

The liabilities applicable to violations of anti-commercial bribery laws include the following:

- Administrative fine in the range of RMB10,000 to RMB200,000
- Confiscation of illegal gains
- Criminal liabilities (for parties that commit bribery acts)

Public Procurement and Fraud

Public medical institutions in China are mostly government-owned. Procurement of drugs and medical device products is done under a centralized system of public procurement and tending.

Medical products purchased by public medical institutions (including non-profit medical institutions that are state-owned) are subject to public procurement and tendering rules.

In the process of bidding for government tenders, the following acts will likely be deemed as violation:

- Committing acts of false advertising, commercial bribery or other anti-fair competition acts
- Providing bids in bad faith (e.g., bids with prices lower than costs)
- Colluding with other bidders on bidding prices to disrupt the order of the procurement process
- Offering bribes to procuring entities, medical institutions or individuals for illegal gains
- Providing fraudulent documentation or commit fraud by other means
- Refusing to enter into sales and procurement contracts within a prescribed timeline or failing to perform obligations under the agreements
- Raising the price of selected products without approval or raising the price in a disguised form
- Refusing to deliver or failing to deliver on time selected products and in so doing causing product shortage at the medical institution

Any violation will be published on the website of the local health authority, and companies with such adverse records will be barred from bidding for other government tenders for two years.

Contracts with Healthcare Professionals and Medical Institutions

There are no express laws or regulations that govern contracts with healthcare professionals and medical institutions.

However, the RDPAC Code provides that, for arrangements for health professionals to give speech or presentations at events or to provide other consultancy services, medical companies should enter into written

agreements with the said professionals, and that the agreements should set out clear provisions regarding compensation and other reasonable reimbursements.

Recommendations

The following are rules of thumb when conducting advertising and promotional activities concerning medical products in China:

- Follow the rules on general adverting of medical products – observe the dos and don'ts (see section on permitted and prohibited practices).
- Do not use laudatory language or references to medical professionals or entities.
- Rx and OTC advice must always be included.
- For OTC drugs, language must be simple and non-technical.
- Watch the use of ®, "TM", brand name, trademarks or trade names.
- Watch for kickback arrangements involving suppliers/distributors.
- Do not enter into bribe/kickback arrangements disguised as sponsorships.
- Do not enter into agreements where there is potential ambiguity on fees and payment.
- Observe overseas anti-bribery laws such as the US Foreign Corrupt Practices Act.

Hong Kong

Isabella Liu

Introduction

There are no specific laws or regulations in Hong Kong governing the promotion of pharmaceuticals or medical devices (together, "medical products").

Advertising Legislation

Regulatory Framework

Hong Kong does not have a general advertising law. There is no relevant legislation governing medical devices and the Trade Descriptions Ordinance (Cap. 362) ("TDO") applies. In relation to drugs, the Public Health and Municipal Services Ordinance (Cap. 132) ("PHMSO") is specifically applicable.

Trade Descriptions Ordinance

The Trade Descriptions Ordinance (Cap. 362) ("TDO") provides the overriding principle that all product descriptions must be true and not misleading. The TDO is broadly applicable to all goods.

"Trade description" is broadly defined to cover indications, direct or indirect, and given by whatever means, of various matters with respect to goods or parts of goods, including quantity, composition and fitness for purpose, strength, performance, behavior and accuracy.

The penalty for non-compliance is, on conviction on indictment, a fine of HKD100,000 and imprisonment for five years and, on summary conviction, a fine of HKD200,000 and imprisonment for two years.

Public Health and Municipal Services Ordinance

False labeling and advertisement of drugs is an offense under Hong Kong law. If any person gives with any drug sold by him, or displays with any drug exposed for sale by him, a label which falsely describes the drug or is calculated to mislead as to its nature, substance or quality, he will be guilty of an offense under section 61(1) of the PHMSO, unless he did not know of or could not with reasonable diligence have ascertained the false character of

the label. The maximum penalty for non-compliance is a fine of HKD50,000 and imprisonment for six months.

Undesirable Medical Advertisements Ordinance

Separately, there are statutory stipulations over medical claims under the Undesirable Medical Advertisements Ordinance (Cap. 231) ("UMAO") that are relevant to medical products. The UMAO is very broad and wide-catching, and prohibits advertisements likely to lead to the use of any medicine, surgical appliance or treatment for the purpose of preventing or treating certain diseases or conditions detailed in Schedules 1 and 2 of the UMAO. The purpose of the legislation is to protect the public from being induced by advertisements to seek improper self-medication or treatment. "Advertisement" includes the labels on product containers but excludes package inserts.

However, the interpretation of the UMAO by the Department of Health ("DOH") in its Guidelines on the Undesirable Medical Advertisements Ordinance is much narrower than the statutory wording. Under the DOH's current practice, advertisements will generally only be forbidden if they claim that a product has curative or preventive effects on the specified diseases. The appearance of the name of the product and the name or logo of the pharmaceutical company is generally permissible in advertisements, as long as there is no specific reference to curative or preventive purposes of the product for the specified medical diseases and conditions. While the enforcement risk is apparently manageable given the DOH's current approach, advertising medical products may still be found to be in breach of the UMAO given its broad application.

Any person who contravenes the UMAO is liable upon first conviction to a fine of HKD10,000 and, upon a second or subsequent conviction, to a fine of HKD25,000 and imprisonment for one year. However, it is a defense if the advertisement was made only in a publication of a technical character intended for circulation mainly among certain medical professionals.

Television and Radio Codes

Depending on the media used for advertising medical products, further regulations may be applicable. For example, advertisements on broadcast media must also comply with the Generic Code of Practice on Television Advertising Standards ("TV Code"). Advertisements for "unacceptable products or services" (e.g., smoking cessation and pregnancy testing services) cannot be advertised on broadcast media.

The TV Code also strictly controls the design and content of medical product advertisements, and prohibits impressions of professional advice and support from medical professionals, appeals to fear or exploitation of credulity, encouragement of excess, and exaggerated claims using superlative or comparative adjectives such as "the most successful" or "quickest."

Advertisements over the radio are required to comply with the Radio Code of Practice on Advertising Standards of Ancillary Visual Service.

Permitted and Prohibited Practices – Advertisements

The promotion of off-label use of pharmaceuticals is prohibited in Hong Kong. Under the Pharmacy and Poisons Regulations (Cap. 138A), pharmaceutical products sold in Hong Kong must be registered with the Drug Office of the DOH. The particulars of the product are registered, including its proposed indication, dosage and route of administration. If any of the particulars are changed without approval, the product will not be regarded as registered.

Although the Hong Kong Association of the Pharmaceutical Industry ("HKAPI") Code of Pharmaceutical Marketing Products ("HKAPI Code") acknowledges that pharmaceuticals should not be promoted for use until requisite approval for marketing for such use has been granted, it states that this should not abridge the right of the scientific community and the public to be fully informed concerning scientific and medical progress.

Permitted and Prohibited Practices – Other Promotional Activities

Prevention of Bribery Ordinance

The Prevention of Bribery Ordinance (Cap. 201) ("PBO") governs both the public and private sectors, and sets the standards of behavior for agents conducting their principals' business. In relation to the public sector, the Hospital Authority ("HA"), the statutory body in charge of all public hospitals in Hong Kong, is considered a public body for the purposes of the PBO.

The following are prohibited under the PBO:

- Solicitation or acceptance of an advantage by a prescribed officer or public servant in relation to his official duties without the permission of the Chief Executive of Hong Kong / relevant public body;

- Offering of an advantage to a prescribed officer or public servant in relation to his official duties where the prescribed officer / public servant does not have the permission of the Chief Executive / relevant public body;
- Solicitation or acceptance of an advantage by an agent when conducting his principal's affairs or business without the permission of his principal (this would cover doctors in private hospitals); and
- Offering of an advantage to an agent in the conduct of his principal's affairs or business where the agent does not have the permission of his principal.

The definition of "advantage" under the PBO is very wide and would include gifts and free participation in seminars without payment of registration or entry fees.

"Prescribed officers" are members of the civil service (government employees/officials). It is not a defense to claim that any advantage accepted or offered is customary in any profession, trade, vocation or calling. The maximum penalty for breach is a fine of HKD500,000 and imprisonment for seven years.

As stated above, offering and accepting advantages is allowable where permission is obtained. Permission must be sought before the advantage is accepted; or as soon as reasonably possible after such offer or acceptance, provided that all relevant circumstances have been considered. For doctors employed in public hospitals, permission from the HA or the hospitals must be in writing. For doctors in private hospitals, it is advisable but not required for the employer's permission to be in writing.

Gifts, Seminars, Hospitality, Entertainment

The PBO governs such activities, and as discussed previously, where a healthcare professional seeks to accept an advantage from a pharmaceutical company, permission of the principal must first be obtained.

Under the HA's Code of Conduct, employees shall avoid obligations to customers or business associates resulting from advantages, gifts or entertainment received in or due to their official capacity which could compromise their position in any way or be perceived by a third party to potentially compromise themselves or the HA.

Gifts

Under section 3 of the PBO, prescribed officers are prohibited from soliciting or accepting any advantage without the general or specific permission of the Chief Executive.

The Acceptance of Advantages (Chief Executive's Permission) Notice 2010 states that prescribed officers may accept gifts of value under HKD250 from any one person on any one occasion, provided the person has no official dealings with the department or organization in which the prescribed officer works, and the prescribed officer does not attend the occasion on which the gift is given in his official capacity or by virtue of the official position he holds.

Under the HKAPI Code, no financial benefit or benefit-in-kind may be provided or offered to a healthcare professional in exchange for prescribing, recommending, purchasing, supplying or administering products, or for a commitment to continue to do so.

Promotional Items of Nominal Value

Pursuant to the HKAPI Code, promotional items of nominal value are permissible. However, they must be provided free of charge and only on an infrequent basis, relate to the healthcare professional's work, and/or entail a benefit to patients.

Text, Reference Books, Magazines, Journals, etc.

Pursuant to the HKAPI Code, such items may only be given to hospitals or private group practices when they serve a genuine educational purpose and can only be provided on an infrequent basis. The monetary limit is HKD5,000 per hospital department or group practice per year. Maximum expenditure of these items per company should be of a modest amount per calendar year.

Seminars and Hospitality

The HKAPI Code provides rules on sponsorship of symposia, congresses or other promotional, medical/healthcare or educational programs.

- For events over three hours, a minimum of two-thirds of the time must be devoted to the scientific agenda.
- Hospitality must be reasonably related to the event, reasonable by local standards (maximum of HKD400 for breakfast or lunch and maximum

of HKD700 per attendee for dinner), and in any event limited to travel, meals, accommodation and genuine registration fees.
- Entertainment of "modest" nature by reasonable local standards and which is secondary to refreshments and/or meals is allowed.
- No stand-alone entertainment or other leisure or social activities should be provided or paid for by member companies at events.
- Payments to compensate healthcare professionals for time spent attending such events are strictly prohibited.

Entertainment

"Entertainment" is defined under the PBO as food and drink provided for consumption on the occasion when it is provided and any other entertainment connected with or provided at the same time. Entertainment is specifically excluded from the PBO's definition of "advantage."

The Civil Service Regulations state that government employees may not, without the permission of the head of his department, accept entertainment that is likely to lead to the embarrassment of the officer in the discharge of his functions, or bring the officer or the public service into disrepute.

Samples

Samples would be considered an "advantage" under the PBO and any healthcare professional that seeks to accept samples can only do so with the permission of his principal.

Under the HKAPI Code:

- the distribution of product samples is permissible as long as the samples are intended for the use of physicians to gain patient experience with a particular drug;
- each sample pack should clearly indicate that it is intended for physician use only;
- the frequency and volume of the provision of samples should be reasonable given the doctor's experience with the products and in any event limited both in size and face value; and
- samples cannot be included or used as part of any sale and purchase transaction of any products with any healthcare professional.

Sponsorship

Pursuant to the Code of Professional Conduct for the Guidance of Registered Medical Practitioners ("Professional Code"), commercial organizations may sponsor healthcare professionals to participate in scientific meetings or for educational and charitable services. The amount sponsored must be reasonable.

According to HA's internal Guidelines on Acceptance of Donation and Sponsorship (not available to the public), a sponsor should not designate any specific candidate for attending any conference. The hospital should nominate a candidate for the sponsorship and seek prior written consent of the Hospital Chief Executive to accept the sponsorship for conference attendance.

Under the HKAPI Code:

- in relation to symposia and congresses, member companies may sponsor healthcare professionals to attend such events, but sponsorship must not be conditional upon an obligation to prescribe, recommend or promote any medical product;
- companies should not pay any costs associated with individuals accompanying healthcare professionals invited to attend symposia and congresses;
- payments of professional fees in the form of honoraria and reimbursement of out-of-pocket expenses may be provided to healthcare professionals providing genuine services such as chairs, moderators, speakers or presenters on the basis of a written contract with the company; and
- companies should not organize or sponsor an event for healthcare professionals (including sponsoring individuals to attend such an event) that takes place outside their home city, unless it is appropriate and justified to do so from a logistical or security point of view (e.g., international scientific congresses and symposia that derive participants from many countries).

Consequences of Breach

Please see above regarding the consequences of breaching the various legislation which may affect the promotion of medical products.

Professional codes of conduct, as will be discussed below, are non-statutory in nature but often stipulate specified consequences upon breach. For

example, although the HKAPI Code is voluntary in nature, it is binding upon members of the HKAPI and breach can result in a monetary fine or suspension or expulsion from HKAPI.

Professional Codes of Conduct

HKAPI Code

The HKAPI Code sets out principles and guidelines for its member pharmaceutical companies and organizations to follow regarding their marketing activities. The 15th edition of the HKAPI Code came into effect in April 2011, and the draft 16th edition is currently undergoing review to be aligned with the latest version of the International Federation of Pharmaceutical Manufacturers & Associations ("IFPMA") Code of Practice. While the HKAPI Code is not legally enforceable in Hong Kong and is only binding upon its members, it nevertheless serves as a useful reference of acceptable local market practices for non-member companies.

The HKAPI Code operates under the general principle that member companies' relationships with healthcare professionals are intended to benefit patients and enhance the practice of medicine, and that interactions should be focused on informing healthcare professionals about products, providing scientific and educational information, and supporting medical research and education.

Code of Professional Conduct for the Guidance of Registered Medical Practitioners

The Professional Code issued by the Medical Council of Hong Kong sets out acceptable professional conduct expected of registered medical practitioners (including doctors working for both private and public hospitals) in Hong Kong. The code embodies two cardinal values of the medical profession – maintaining high standards of proper conduct, and good practice to fulfill doctors' moral duty of care.

The Professional Code also upholds a robust professional culture to support self-governing through identifying role-specific obligations and virtues of the medical profession. The overriding consideration is whether any act is done in the best interest and benefit of patients. Breach of the Professional Code could lead to disciplinary hearings which may result in de-registration from the registered medical practitioners list or suspension from practice.

HA Code of Conduct

As the statutory body that manages all public hospitals in Hong Kong, the HA plays a very significant role in relation to local healthcare professionals. In Hong Kong, there are currently 39 public hospitals and 12 private hospitals. Public hospitals provide over 85 percent of all hospital beds in Hong Kong.

The code of conduct of the HA includes the philosophies, values and guiding principles that establish a set of benchmark standards of ethical behavior expected of every staff member of the HA. Compliance with the code is an integral part of its employment terms and conditions.

Code of Professional Conduct and Code of Ethics for Nurses in Hong Kong

The Code of Professional Conduct and Code of Ethics for Nurses in Hong Kong issued by the Nursing Council of Hong Kong aims to make explicit the standards for professional conduct that nurses shall comply with at all times in their course of duty. The code highlights eight aspects of professional conduct that nurses are to comply with in discharging their professional duties.

Code of Practice for Private Hospitals, Nursing Homes and Maternity Homes

The DOH's Code of Practice for Private Hospitals, Nursing Homes and Maternity Homes sets out the standards of good practice for health care institutions to adopt in order to provide quality care to patients. Requirements are set out to be adopted in the management of staff, management of the premises and services, setting out policies and procedures, and setting up a system to deal with complaints. In assessing the suitability for registration and re-registration of health care institutions, compliance with the requirements under the code will be taken into account.

Integrity in Practice: A Practical Guide for Medical Practitioners on Corruption Prevention

The Independent Commission Against Corruption ("ICAC") has published a document entitled Integrity in Practice: A Practical Guide for Medical Practitioners on Corruption Prevention ("Integrity in Practice"). Despite not being a professional code of conduct as such, it remains relevant to medical professionals in light of the fact that the ICAC enforces the PBO. Integrity in

Practice discusses legal and integrity issues faced by medical practitioners and suggests action plans for corruption prevention.

Codes for Media Providers and Advertising Agencies

As discussed previously, there are further codes of conduct issued by the Communications Authority of Hong Kong that may be applicable depending on the media used in advertising.

In addition, the Association of Accredited Advertising Agencies of Hong Kong ("AAAA") has issued a voluntary Code of Practice ("4As Code"). The 4As Code is intended to reassure advertisers of the business ethics of agencies, ensure the continuation of the advertising agency as a professional and profitable enterprise, and provide a basis for standards and business practices such as remuneration, import duties, statutory charges and taxation that are common to both Hong Kong and the PRC. Although compliance with the 4As Code is voluntary, such may be considered "best practice" in Hong Kong.

Criminal and Civil Liability

Please refer to "Permitted and Prohibited Practices – Other Promotional Activities" above, regarding the PBO.

Public Procurement and Fraud

The spirit of the PBO is to maintain fair play in the procurement of contracts with public bodies. Section 5 of the PBO makes it an offense for a public servant, without permission of the public body, to solicit or accept an advantage for giving assistance in securing contracts from the public body. Any person who offers such an advantage commits an offense of corruption. The maximum penalty for non-compliance is a fine of HKD500,000 and imprisonment for 10 years.

Furthermore, it is an offense under section 9(3) of the PBO for an agent, with intent to deceive his principal, to use any receipt, account or other document in respect of which the principal is interested, which contains any statement which is false or erroneous or defective in any material way, and which to his knowledge is intended to mislead the principal. This offense carries a maximum penalty of a fine of HKD500,000 and imprisonment for seven years.

The more general anti-bribery provisions discussed in "Permitted and prohibited practices – Advertisements" above may also be relevant in the context of public procurement fraud, depending on the circumstances.

Contracts with Healthcare Professionals and Medical Institutions

There is no specific prohibition against a pharmaceutical company signing a service contract with healthcare professionals, for example, for speaking and chairing at meetings, translating medical documents, writing medical articles or giving medical training. However, the PBO should be observed since a service contract may be considered an "advantage" under the PBO. Due authorization from the employer/principal should be acquired to minimize the risk of violating the PBO.

Public vs. Private

It is important to distinguish between doctors in public hospitals and doctors in private hospitals, as different provisions of the PBO may apply. Moreover, as discussed above, healthcare professionals in public hospitals will require further determination as to whether they are "prescribed officers" (holding an office of emolument under the government) or "public servants" (any prescribed officer and any employee of a public body).

Financial or Other Inducements

The Professional Code states that doctors should not accept any financial or other inducement from healthcare organizations which may compromise, or may be regarded by others as likely to compromise, the independent exercise of their professional judgment. Doctors who have any kind of financial or professional relationship with, use the facilities of, or accept patients referred by, health care and health product organizations must exercise due diligence to ensure that the organization does not advertise in contravention of the principles and rules applicable to individual doctors.

Although the Professional Code acknowledges that the medical professional and the pharmaceutical industry have close ties as they both have common interests in the research and development of new therapies, drugs and the like, doctors must choose drugs or appliances which, in their independent professional judgment and having due regard to cost effectiveness, will serve the medical interests of their patients.

Recommendations

It is key for pharmaceutical companies to avoid contravening the PBO. Companies must therefore ensure that the permission of the public body or principal has been obtained in relation to any "advantage" offered to healthcare professionals.

Advertising:

- Drugs cannot be labeled or advertised in a manner that falsely describes the drug or is calculated to mislead as to its nature, substance or quality.
- Product descriptions for medical products must be true and not misleading.
- Advertisements that claim a product has curative or preventive effects on diseases and conditions specified under the UMAO are prohibited.
- Off-label use of pharmaceuticals cannot be promoted, although the HKAPI Code states that this should not affect the right of the scientific community and public to be informed about scientific and medical progress.

Other promotional activities:

- Public servants and agents should obtain permission from their principal before accepting any "advantage."
- Gifts should not be offered to healthcare professionals to influence them in the purchase, supply or prescription of medical products.
- Promotional items of nominal value and educational items such as texts and reference books may only be given on an infrequent basis.
- Prescribed officers may only accept gifts of value under HKD250.
- For symposia and congresses, hospitality must be reasonable, any entertainment must be "modest," and compensation for participation is prohibited.
- Samples can only be distributed in reasonable quantities, and only if it will allow the physician to gain patient experience with a particular drug.

भारत

शिशिर जोस वाईटाडन, विनय सुब्रमण्यम, आद्रिका रे
लूथरा और लूथरा

परिचय

भारत एक क्वासी फेडरल (संघ राज्यवत) गणराज्य है, जहां पर स्वास्थ्य सेवा उद्योग का नियमन केंद्रीय सरकार तथा उसके 28 राज्यों की सरकारों के बीच विभाजित है। यहां पर दवा उत्पादों के प्रचार पर लागू किए जाने वाले अधिकतर नियम बनाए तो केंद्र में जाते हैं, लेकिन इनका पालन आधा केंद्र सरकार द्वारा तथा आधा राज्य सरकारों द्वारा करवाया जाता है।

दवाओं के विज्ञापन के लिए कानून

नियामक ढाँचा

एकमात्र कानून, जिसकी समीक्षा यहाँ की जा रही है, जो कि विशेष तौर पर दवा उद्योग तथा चिकित्सकों के बीच सम्बन्धों को नियंत्रित करता है, वह केंद्रीय एजेंसी द्वारा जारी किया जाता है, तथा सभी राज्यों पर लागू होता है। भारतीय चिकित्सा परिषद अधिनियम, 1956 (एमसीआई एक्ट) के तहत जारी भारतीय चिकित्सा परिषद (व्यवसायिक आचरण, शिष्टाचार तथा नीतियां) नियमन 2002 (एमसीआई नियमन) भारत में चिकित्सा व्यवसाय के मानकों को निर्धारित करते हैं। ये नियम चिकित्सकों पर लागू होते हैं, न कि दवा उद्योग पर। एमसीआई एक्ट, जो कि पूरे भारत में लागू होता है, के अतिरिक्त कुछ राज्यों में ठीक ऐसे ही कानून हैं, जो कि सिर्फ उन्हीं राज्यों में लागू होते हैं। इनमें से कुछ राज्यों में चिकित्सीय व्यवसाय में नैतिक आचरण के लिए नियम राज्य चिकित्सा परिषदों द्वारा जारी किए जाते हैं। न तो राज्य अध्यादेशों का, और न ही राज्य चिकित्सीय नियमों का इस पाठ में वर्णन किया गया है, क्योंकि यह अधिकतर एमसीआई विनियमों के ही संपूरक हैं।

औषधि तथा जादुई उपचार अधिनियम, (आपत्तिजनक विज्ञापन), 1954 (आपत्तिजनक विज्ञापन अधिनियम) एक संक्षिप्त अध्यादेश है, जिसमें कि दवाओं के विज्ञापन सम्बन्धित विशेष नियमों का उल्लेख है। यह अध्यादेश कुछ दवाओं के सम्बन्ध में सभी प्रकार के विज्ञापनों पर, तथा अन्य दवाओं के सम्बन्ध में भ्रामक विज्ञापनों पर रोक लगाता है। यह

India

Shishir Jose Vayttaden, Vinay Subramanian, Adrika Ray
Luthra & Luthra

Introduction

India is a quasi-federal republic where the regulation of the medical care industry is divided between the central government and the governments of its 28 states. Most rules applicable to the promotion of pharmaceutical products are centrally legislated but administered partially by the central government and partially by the state governments.

Pharmaceutical Advertising Legislation

Regulatory Framework

The only law reviewed here which specifically regulates the relationship between medical practitioners and the pharmaceutical industry is issued by a central agency and applies to all states. The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations 2002 (the "MCI Regulations") issued under the Medical Council of India Act, 1956 ("MCI Act") prescribes standards for the medical profession in India. It applies to doctors and not to the pharmaceutical industry. Apart from the MCI Act, which applies throughout India, some states have similar laws which apply only within those states. In some of these states, regulations for the ethical practice of the medical profession have been issued by state medical councils. Neither the state statutes nor the state medical regulations are explained in this chapter as these tend mostly to supplement the MCI Regulations only.

The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 ("Objectionable Advertisements Act") is a brief statute with some very specific rules in relation to the advertisement of drugs. The statute prohibits all advertising in relation to some drugs and prohibits misleading advertisements in relation to other drugs. It applies to the whole of India except the state of Jammu and Kashmir, and it applies to persons domiciled in the territories to which it applies when they are outside those territories.

On 2 June 2011, the Department of Pharmaceuticals under the Ministry of Chemicals and Fertilizers of the central government introduced a voluntary

जम्मू कश्मीर को छोड़कर पूरे भारत में लागू होता है तथा जिस क्षेत्र में यह लागू है, उस क्षेत्र में निवास करने वाले व्यक्तियों पर तथा वहां आकर बसने वाले अन्य व्यक्तियों पर भी यह नियम लागू होता है।

रसायन तथा उर्वरक मंत्रालय, भारत सरकार, के अधीन आने वाले औषधीय विभाग (डिपार्टमेंट ऑफ फार्मास्युटिकल्स) ने 2 जून 2011 को भारतीय दवा उद्योग के लिए, एक स्वैच्छिक विपणन कोड (मार्केटिंग कोड) प्रस्तुत किया है। यह दवाओं के प्रचार तथा चिकित्सकों के साथ दवा कंपनियों के परस्पर व्यवहार से सम्बन्धित है। जब विपणन कोड की घोषणा की गई थी, तब सरकार ने ये संकेत दिए थे, कि यदि इसका कार्यान्वयन अप्रभावी पाया जाएगा, तो इसको वैधानिक प्रभाव दिया जा सकता है। हालांकि मार्केटिंग कोड के लिए औपचारिक आदेश तथा आगे होने वाले संशोधन अभी तक अटके हुए हैं। अतः, 31 जुलाई 2012 तक मार्केटिंग कोड स्वैच्छिक ही रहा। फिर भी, इस बात की संभावना को देखते हुए कि इसे जल्द ही अनिवार्य कर दिया जाएगा, इसका संक्षिप्त विवरण ''व्यवसायिक आचरण संहिता'' के बजाए ''औषधि विज्ञापन कानून'' में शामिल किया गया है।

औषधि व सौंदर्य प्रसाधन अधिनियम, 1940 तथा औषधि व सौंदर्य प्रसाधन नियम, 1945, भारत में दवा उत्पादों, सौंदर्य प्रसाधनों तथा होम्योपैथिक दवाओं की लैबलिंग तथा ब्राण्डिंग को नियंत्रित करते हैं।

सरकारी स्वास्थ्य सुविधाएं, ख़रीद प्रक्रिया तथा राज्य द्वारा वेतन पाने वाले स्वास्थ्य अधिकारियों आदि से सम्बन्धित प्रचार गतिविधियों के संदर्भ में भारतीय भ्रष्टाचार निरोधी कानून प्रासंगिक हैं। इस कानून के महत्वपूर्ण घटक हैं:

- एक केन्द्रीय विधान जिसे भ्रष्टाचार निवारण अधिनियम, 1988 (पीसीए) कहा जाता है तथा जो सम्पूर्ण भारत में लागू होता हैः
- एक नियमों का संग्रह, जो कि केन्द्र सरकार के सिविल सेवकों पर लागू होते हैं तथा इन्हें केंद्रीय सिविल सेवाएं (आचरण) नियम 1964 (सीसीएस रूल्स) कहा जाता है: तथा

marketing code for the Indian pharmaceutical industry (the "Marketing Code"). It relates to the promotion of pharmaceutical products and the interaction of pharmaceutical companies with healthcare professionals. When the Marketing Code was announced, the Government had indicated that it could be given statutory effect if its implementation was found to be ineffective upon review. From subsequent news reports, it appears that a decision has been taken to give the Marketing Code mandatory effect. However, a formal notification to this effect and the consequent amendments to the Marketing Code are still pending. Therefore, as of 31 July 2012, the Marketing Code remains voluntary. Nevertheless, given the probability that it may soon be made mandatory, a summary of this is included under "Pharmaceutical advertising legislation" (below) and not under "Professional codes of conduct."

The Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945 regulate labeling and branding of pharmaceutical products, cosmetics and homeopathic medicines in India.

Indian anti-corruption law is relevant in the context of promotional activities concerning government health facilities, public procurement processes and health officers on the state's payroll, etc. The most relevant constituents of this law are:

- a central statute called the Prevention of Corruption Act 1988 (the "PCA"), which applies throughout India;
- a set of rules applicable to civil servants of the central government called Central Civil Services (Conduct) Rules 1964 (the "CCS Rules"); and
- different rules prescribed by the different state governments which are applicable to their respective civil servants[1].

The Foreign Contribution (Regulation) Act, 1976 (the "FCRA") regulates the acceptance and utilization of foreign contribution and foreign hospitality by government workers and those working in "important areas of national life" including editors and publishers of medical journals, among others.

[1] Due to space constraints, these states rules are not explained in this chapter.

- विभिन्न राज्य सरकारों द्वारा निर्धारित किए गए विभिन्न नियम जो कि उन राज्यों के लोकसेवकों पर लागू होते हैं।[1]

विदेशी अंशदान (नियमन) अधिनियम, 1976 (एफसीआरए), राष्ट्रीय महत्व के महत्वपूर्ण पदों पर काम कर रहे व्यक्तियों तथा संगठनों को मिलने वाले विदेशी अंशदान तथा विदेशी सत्कार को नियंत्रित करता है।

अनुमति प्राप्त तथा निषिद्ध पद्धतियां

एमसीआई विनियमन

एमसीआई नियमों में नीतिगत आचरण के लिए कुछ महत्वपूर्ण बातों का समावेश है, जो कि चिकित्सकों तथा दवा उद्योग के आपसी सम्बन्धों को अप्रत्यक्ष रूप से प्रभावित करती हैं। उदाहरण के लिए, इसके अनुसार चिकित्सक के व्यक्तिगत वित्तीय हितों से मरीज़ों के चिकित्सीय हित प्रभावित नहीं होने चाहिए।[2] अतः, एमसीआई नियम चिकित्सकों को बाध्य करते हैं कि ''... दवा उद्योगों से व्यवहार करते वक्त हमेशा यह सुनिश्चित किया जाना चाहिए कि उनकी व्यवसायिक स्वायत्तता तथा चिकित्सा संस्थान की स्वायत्तता तथा स्वतंत्रता के साथ कभी भी कोई समझौता न किया जाए'' ।[3]

किंतु चिकित्सकों तथा स्वास्थ्य सेवा उद्योग के मध्य सम्बन्धों से सीधे तौर पर जुड़ा नियम 6.8 जुड़ा हुआ है, जो कि विशेष तौर पर कुछ आचरणों को निषिद्ध करता है। इनकी व्याख्या नीचे की गई है;

क) चिकित्सक दवा उद्योग तथा संबद्ध स्वास्थ्य सेवा उद्योगों के सदस्यों से उपहार नहीं ले सकते हैं।

ख) वे दवा तथा सम्बद्ध स्वास्थ्य सेवा उद्योगों की ओर से दी जाने वाली घरेलू अथवा अंतर्राष्ट्रीय यात्राओं की सुविधा भी ग्रहण नहीं कर सकते हैं। इस निषेध के अंतर्गत

[1] जगह की कमी की वजह से यहां पर ये सभी नियम नहीं दिए जा रहे हैं।

[2] नियमन 1.8 एमसीआई रेग्युलेशंस

[3] नियमन 6.8.1 (एफ), एमसीआई रेग्युलेशंस

Permitted and Prohibited Practices

MCI Regulations

The MCI Regulations contain some broad wording on ethical conduct that may indirectly affect the relationship of medical practitioners with the pharmaceutical industry. For example, it says that the personal financial interests of medical practitioners should not conflict with the medical interests of patients[2]. Again, the MCI Regulations oblige medical practitioners to "…always ensure that there shall never be any compromise either with his / her own professional autonomy and / or with the autonomy and freedom of the medical institution"[3] when dealing with pharmaceutical companies.

More directly relevant to the relationship between medical practitioners and the healthcare industry is Regulation 6.8, which specifically prohibits certain conduct. These prohibitions are summarized below:

- Medical practitioners are prohibited from receiving gifts from members of the pharmaceutical industry or allied healthcare industry.
- They are also barred from accepting domestic or international travel facilities from the pharmaceutical or allied healthcare industry. Cruise tickets and paid vacations are examples of facilities that are specifically enumerated as being covered by the prohibition. The prohibition applies equally to facilities made available to their family members and applies irrespective of whether it is for the purpose of a vacation or for attending Continuing Medical Education ("CME") programs as delegates.
- Medical practitioners are also prohibited from accepting hospitality like hotel accommodation for themselves or for their family members.
- Medical practitioners are prohibited from receiving cash or monetary grants from the pharmaceutical or allied healthcare industry "for individual purpose in individual capacity"[4] (*sic*.). The regulations provide that funding for medical research and study can only be received through approved institutions after complying with the modalities laid down either by law or by the guidelines of these

[2] Regulation 1.8, MCI Regulations.
[3] Regulation 6.8.1(f), MCI Regulations.
[4] Regulation 6.8.1(d), MCI Regulations

क्रूज़ टिकिट तथा पूर्व भुगतान की गई छुट्टियां विशेष तौर पर उल्लेखित है। यह सभी निषेध चिकित्सकों के परिजनों को उपलब्ध कराई गई सुविधाओं पर भी समान रूप से लागू हैं। भले ही वे छुट्टियां मनाने गए हों अथवा कंटीन्युइंग मेडिकल एजुकेशन कार्यक्रमों में प्रतिनिधि के तौर पर गए हों।

ग) चिकित्सकों तथा उनके परिजनों के लिए होटल में रुकना तथा आतिथ्य सत्कार ग्रहण करना भी निषिद्ध है।

घ) चिकित्सकों के लिए ''व्यक्तिगत हितों हेतु व्यक्तिगत क्षमता से[4] '' दवा तथा सम्बद्ध स्वास्थ्य सेवा उद्योगों से नकद अथवा मौद्रिक अनुदान लेना निषिद्ध है। नियमों के तहत यह भी तय किया गया है कि चिकित्सीय अनुसंधान तथा अध्ययन हेतु धन अधिकृत संस्थानों द्वारा प्राप्त किया जा सकता है, वह भी कानून अथवा इन संस्थानों द्वारा बनाए गए दिशानिर्देशों को पारदर्शी ढंग से पालन करने के पश्चात। इस नियम के तहत धनप्राप्ति का खुलासा करना भी ज़रूरी है, परंतु इस खुलासे के लिए तरीका, समय अथवा सटीक विषयवस्तु के बारे में निर्धारण नहीं है।

ङ) एक चिकित्सक को दवा तथा स्वास्थ्य सेवा उद्योगों द्वारा वित्त पोषित अनुसंधानों में भाग लेने अथवा काम करने की अनुमति है। हालांकि, इसके लिए इस प्रकार की परियोजनाओं हेतु नियमों में सात शर्तें निर्धारित की गई हैं, जिनका पालन करने पर चिकित्सक इनमें सहभागिता निभा सकता है। यह शर्तें इस प्रकार हैं:

(1) अनुसंधान प्रस्ताव सभी सम्बन्धित अधिकारियों द्वारा विधिवत रूप से अनुमोदित होना चाहिए।
(2) परियोजना राष्ट्रीय/राज्य/संस्थागत नीति समितियों/निकायों द्वारा पारित किया जाना चाहिए।
(3) इसे चिकित्सा अनुसंधान के लिए निर्धारित सभी कानूनी ज़रूरतों को पूरा करना चाहिए।
(4) अनुसंधान हेतु लगने वाले धन के स्त्रोत तथा मात्रा का खुलासा प्रारंभ में ही कर देना चाहिए।

[4] रेग्युलेशंस 6.8.1 (डी), एमसीआई रेग्युलेशंस

institutions, in a transparent manner. The regulations also appear to impose a duty to disclose the funding but do not prescribe the form, timing or precise contents of such disclosure.

- A medical practitioner is allowed to carry out, participate in or work in research projects funded by pharmaceutical and allied healthcare industries. However, the regulations prescribe seven conditions with which such assignment or project must comply before a medical practitioner is allowed to participate. These conditions are as follows:
  - The research proposal(s) should be duly approved by the authorities concerned.
  - The project(s) should have been cleared by national / state / institutional ethics committees / bodies.
  - It should fulfill all the legal requirements prescribed for medical research.
  - The source and amount of funding should have been publicly disclosed at the beginning.
  - If human volunteers are necessary for the research project, proper care and facilities should be provided to them.
  - The project should not involve undue animal experiments and when these are necessary, they must be done in a scientific and humane way.
  - Most importantly, the regulations stipulate that while accepting such an assignment, the medical practitioner should retain the freedom to publish the results of the research "…in the greater interest of the society."[5] Medical practitioners are obliged to procure a provision to this effect in the agreement pursuant to which they undertake such assignments.
- The MCI Regulations allow medical practitioners to work for pharmaceutical and allied healthcare industries in advisory capacities, as consultants, as researchers, as treating doctors or in any other professional capacity. However, they oblige them to always ensure that:
  - their professional integrity and freedom are maintained;
  - patients' interests are not compromised in any way;
  - such affiliations are within the law; and
  - such affiliations / employments are fully transparent and disclosed.

[5] Regulation 6.8.1(e)(vii), MCI Regulations.

(5) यदि अनुसंधान हेतु स्वयंसेवकों की आवश्यकता हो, तो उन्हें समुचित सुविधाएं उपलब्ध कराई जानी चाहिए तथा देखरेख की जानी चाहिए।

(6) परियोजना में पशुओं पर गैरज़रूरी प्रयोग नहीं किए जाने चाहिए यदि ऐसे प्रयोग आवश्यक हों तो ये प्रयोग वैज्ञानिक तथा मानवोचित तरीके से किया जाना चाहिए।

(7) सबसे महत्वपूर्ण बात यह है कि नियमों के अनुसार यह शर्त होती है कि ऐसी परियोजना स्वीकार करने के दौरान चिकित्सक ''....समाज के हित हेतु[5] '' अनुसंधान के परिणामों को प्रकाशित करने की स्वतंत्रता सुरक्षित रखेंगे। चिकित्सकों को अनुसंधान प्रारंभ होने से पूर्व अनुबंध में ही इस प्रकार का प्रावधान दिया जाता है।

च) एमसीआई नियमन चिकित्सकों को अनुमति देता है, कि वे औषधि तथा सम्बद्ध स्वास्थ्य सेवा उद्योगों के लिए सलाहकार के रूप में, अनुसंधानकर्ता के रूप में चिकित्सक के रूप में अथवा किसी अन्य व्यवसायिक सेवा प्रदाता के रूप में कार्य कर सकते हैं। हालांकि, वे उन्हें यह सुनिश्चित करके दें कि:

(1) उनकी व्यवसायिक ईमानदारी तथा स्वतंत्रता बनाकर रखी जाएगी;

(2) मरीज़ों के हितों के साथ किसी भी प्रकार का समझौता नहीं किया जाएगा;

(3) ऐसे सम्बन्ध समुचित विधि के अनुसार हों; तथा

(4) ऐसी सम्बद्धता/नियुक्तियां पूर्णतः पारदर्शी तथा स्पष्ट हों।

(छ) चिकित्सकों हेतु किसी भी औषधि अथवा दवा उत्पाद का जनसामान्य में प्रचार करने की मनाही है। इसमें उल्लेख किया गया है कि उत्पादों पर किए गए किसी भी प्रकार के अध्ययन के परिणामों को समुचित वैज्ञानिक निकायों द्वारा प्रदर्शित किया जाना चाहिए अथवा समुचित वैज्ञानिक पत्रिकाओं में प्रकाशित किया जाना चाहिए।

एमसीआई रेग्युलेशंस किसी भी अन्य प्रकार के आचरण को व्यवसायिक गलत आचरण ठहराने की शक्ति रखता है, भले ही उनकी गणना ऐसे आचरणों में न होती हो। एमसीआई रेग्युलेशंस के उल्लंघन की दशा में चिकित्सक पर अनुशासनात्मक कार्रवाई की जा सकती है जिसमें कि ''....आवश्यक समझा जाने वाला कोई दण्ड दिया

[5] रेग्युलेशंस 6.8.1 (ई), (vii), एमसीआई रेग्युलेशंस

- Medical practitioners are barred from publicly endorsing any drug or pharmaceutical product. Any study on products may be presented to or through appropriate scientific bodies or published in appropriate scientific journals in a proper way.

The MCI Regulations reserve the power to treat other forms of conduct as professional misconduct even when they are not specifically enumerated as such. A violation of the MCI Regulations makes the medical practitioner liable for disciplinary proceedings which may result in "…such punishment as deemed necessary or may direct the removal[6] altogether or for a specified period."[7]

Labeling Rules

The provisions of the Drugs and Cosmetics Rules, 1945 relating to the labeling and branding of pharmaceutical products are applicable to imported drugs as well as drugs manufactured in India. A limited exemption is provided for exported drugs and drugs made up ready for treatment. Also, drugs that are not meant for medicinal use are not bound by the labeling rules provided they are clearly marked as such.

Labels that comply with the stipulated rules are required to appear on the innermost container as well as every other covering in which the container is packed. The proper name of the drug along with the name of the manufacturer and place of manufacture must always be mentioned. If the drug has a trade name, it may be mentioned only after the proper name on the label. A correct statement of the net contents in terms of weight, measure and volume should also be mentioned. Also, to avoid false inducement, the active ingredients present in the drug are required to be mentioned on the label. Specifications are provided for disclosure of the quantity of the active ingredient based on the nature and type of drug. For instance, for drugs in solid form intended for parental administration, the quantity of the specific ingredients has to be disclosed in terms of units or weight per milligram or gram. The label must mention the batch number, which by further reference will provide details relating to the manufacture of the drug.

[6] This is a reference to the register of licensed medical practitioners maintained by each state medical council. A removal from this register debars the concerned individual from practicing modern medicine in any part of India.
[7] Regulation 8.2, MCI Regulations.

जा सकता है अथवा उन्हें निष्कासित[6] करने के निर्देश दिए जा सकते हैं, पूर्णरूपेण अथवा एक तय समय के लिए।[7]"

लेबलिंग के नियम

भारत में बने अथवा आयातित दवा उत्पादों की लेबलिंग तथा ब्राण्डिंग पर औषधि तथा सौंदर्य प्रसाधन नियम, 1945 के प्रावधान लागू होते हैं। हालांकि निर्यात के लिए बनाई गई दवाओं तथा उपचार हेतु तैयार दवाओं के लिए सीमित छूट प्रदान की जाती है। इसके साथ ही ऐसी दवाएं जो चिकित्सीय उपयोग हेतु नहीं हैं, उन पर लेबलिंग नियम लागू नहीं होते हैं, परंतु उन पर स्पष्ट तौर पर यह अंकित होना चाहिए कि वे चिकित्सीय उपयोग हेतु नहीं हैं।

नियमों के अधीन आने वाले लेबल्स दवाओं के सबसे अंदरूनी डब्बों तथा हर उस आवरण पर लगे होना ज़रूरी है जिसमें उन डब्बों को पैक किया गया है। दवा का समुचित नाम, उत्पादक के नाम तथा उत्पादन की जगह के नाम के साथ हमेशा उल्लेखित होना चाहिए। यदि दवा का कोई व्यवसायिक नाम है, तो वह हमेशा दवा के मूल नाम के बाद ही छपा होना चाहिए। दवा के निर्माण में लगी शुद्ध सामग्री का सही विवरण दिया जाना चाहिए, जिसमें उनका वज़न, माप तथा परिमाण उल्लेखित हो। साथ ही, झूठे प्रलोभनों से बचने के लिए, दवा में मौजूद सभी सक्रिय संघटकों के बारे में लेबल पर उल्लेख किया जाना चाहिए। दवा की प्रकृति तथा प्रकार के अनुसार उसमें मौजूद सक्रिय संघटकों की मात्रा के खुलासे के बारे में विनिर्देश उपलब्ध कराए जाते हैं। उदाहरण के लिए, ऐसी दवाओं के लिए जो कि आंत्रेतर उपयोग हेतु है तथा ठोस प्रकार की है, संघटकों की मात्रा यूनिट्स में अथवा प्रति मिलीग्राम अथवा ग्राम वज़न में उल्लेख कीजानी चाहिए। लेबल में बैच नंबर, उल्लेखित होना चाहिए जिससे कि दवा के उत्पादक से सम्बन्धित जानकारी विस्तार से उपलब्ध हो सके।

[6] यह प्रसंग लायसैंस प्राप्त चिकित्सकों के रजिस्टर सम्बन्ध में है, जो कि प्रत्येक राज्य चिकित्सा परिषद द्वारा बनाया जाता है। इस रजिस्टर से नाम हटने पर चिकित्सक भारत में किसी भी स्थान पर आधुनिक चिकित्सा की प्रैक्टिस नहीं कर सकता है।

[7] रेग्युलेशंस 8.2, एमसीआई रेग्युलेशंस

In case of distribution of drugs as free samples, the label on the container must contain the words "Physician's sample-Not to be sold".[8] Furthermore, different disclosures have been prescribed for certain specified drugs. For instance, labels of certain drugs should mention the date of expiry of potency as determined by the company.

The rules also prohibit any person from altering, obliterating or defacing any inscription made by the manufacturer on the container or label of the drug. Companies are prohibited from making any representation which claim or purports to claim that their drug can cure or prevent certain specified diseases or ailments such as AIDS.

Two of the grounds on which a drug may be deemed to be "misbranded[9]" are that it is not labeled as per the rules or its label bears a statement or design which makes any false claim about the drug. The import of any misbranded pharmaceutical product is punishable with imprisonment for a term extending to six months and/or with a fine extending to INR500. Furthermore, the consignment would also be subject to confiscation on commission of the offense. On commission of any subsequent offense, the punishment is increased to imprisonment for a term extending to one year and/or with fine extending to INR1,000. For the manufacture, sale or distribution of a misbranded pharmaceutical product, the person responsible is punishable by imprisonment for a term between one and two years and/or with a fine of at least INR20,000. For any subsequent offense committed, the punishment is increased to imprisonment for a term between two and four years and/or a fine of at least INR50,000.

Specific provisions have been provided for "spurious"[10] drugs. A drug is held to be spurious if it is imported/manufactured under a name which belongs to another drug; if it is an imitation or resembles another drug which is likely to deceive an individual, specifically based on its label or container; or if the label or container bears the name of a fictitious manufacturer, or claims to be of a manufacturer but is not.

The import of spurious drugs is punishable with imprisonment for a term extending to three years and a fine extending to INR5,000. Such punishment is increased to a period of imprisonment extending to five years and/or fine extending to INR10,000 if the offense is repeated.

[8] Rule 96(1)(viii), Drugs and Cosmetics Rules, 1945.
[9] Section 9 and Section 17, Drugs and Cosmetics Act, 1940.
[10] Section 9-B and Section 17-B, Drugs and Cosmetics Act, 1940.

यदि दवा नमूने के तौर पर वितरित की जानी हो तो लेबल पर इसका उल्लेख करना आवश्यक है, ''फिज़िशियंस सैम्पल-नॉट टू बी सोल्ड।[8] '' इसके अतिरिक्त कुछ विशेष दवाओं हेतु अलग-अलग प्रकार के निर्देश लिखना आवश्यक होते हैं। उदाहरण के लिए कुछ दवाओं के लेबल पर कंपनी द्वारा निर्धारित दवा की शक्ति की समाप्ति की तारीख का उल्लेख होना चाहिए।

नियमों के अनुसार दवाओं के लेबल अथवा डब्बे पर दवा निर्माता द्वारा प्रकाशित की गई जानकारी में कोई भी व्यक्ति फेरबदल नहीं कर सकता है और न ही उसे मिटा अथवा नष्ट कर सकता है। कंपनियों के लिए ऐसा कोई भी दावा करना अथवा दावा करने का संकेत देना कि उनकी दवा से किसी विशिष्ट बीमारी, जैसे एड्स का ईलाज अथवा उससे रक्षा हो सकती है, मना है।

वे दो आधार, जिन पर किसी भी दवा को ''मिस ब्राण्डेड''[9] करार दिया जा सकता है, वे हैं वह नियमों के अनुसार लेबल नहीं की गई हो; अथवा उसके लेबल में ऐसा कोई कथन या डिजाईन हो जो कि दवा के बारे में कोई झूठा दावा करता हो| किसी भी मिस ब्रांडेड दवा उत्पाद का आयात करने पर छः महीने तक की सज़ा तथा/अथवा 500 रुपये तक जुर्माना हो सकता है| इसके साथ ही, ऐसे किसी भी माल को जब्त किया जा सकता है| पहली बार के बाद हर अगले जुर्म पर सज़ा की मियाद एक साल तक बढ़ाई जा सकती है तथा/अथवा जुर्माने की रकम 1000 रुपये तक बढ़ाई जा सकती है| मिस ब्रांडेड दवा उत्पाद के उत्पादन, बिक्री अथवा वितरण करने की दशा में दोषी व्यक्ति को एक व दो साल की कैद की सजा तथा/अथवा कम से कम 20,000 रुपये तक जुर्माना किया जा सकता है| पहली बार के बाद सज़ा की मियाद बढाकर २ से ४ साल तथा/अथवा जुर्माने की रकम 50,000 रुपये तक बढ़ाई जा सकती है|

"नकली"[10] दवाओं हेतु विशेष प्रावधान किये गए हैं| एक दवा नकली ठहराई जा सकती है, यदि वह किसी अन्य दवा के नाम पर उत्पादित/आयातित की गई हो; यदि वह किसी अन्य दवा की नक़ल हो अथवा उस जैसी हो जिससे कि किसी व्यक्ति को

[8] रूल 96(1)(viii), ड्रग्स एंड कॉस्मेटिक्स रूल्स, 1945

[9] सेक्शन 9 तथा सेक्शन 17, ड्रग्स एंड कॉस्मेटिक्स एक्ट, 1940

[10] सेक्शन 9-B**B** तथा सेक्शन 17-BB, ड्रग्स एंड कॉस्मेटिक्स एक्ट, 1940

For the manufacture, sale and/or distribution of spurious drugs, if such drug is likely to cause death or harm amounting to grievous hurt, the manufacturer and/or any person responsible may be punished with imprisonment of a term between 10 years to life and/or a fine not less than INR1,000,000 or three times the value of drugs confiscated, whichever is higher. In other cases, the punishment prescribed is imprisonment for a term extending from seven years to life and a fine ranging from INR300,000 or three times the value of drugs confiscated, whichever is higher. This imprisonment term is increased to a minimum period of 10 years if the offense is repeated.

The Objectionable Advertisements Act

This legislation prohibits any advertisement of a drug in terms which suggest or which is calculated to lead to the use of that drug for: the procurement of miscarriage or prevention of conception in women; the maintenance or improvement of the capacity of human beings for sexual pleasure; the correction of menstrual disorder in women; or the diagnosis, cure, mitigation, treatment or prevention of certain specific diseases that are mentioned in a schedule or which may be notified by the Government.

Separately, it prohibits advertisements which: directly or indirectly give a false impression regarding the true character of the drug; make a false claim about the drug; or is otherwise false or misleading in any material particular way.

Importing products into or out of any territory to which the Objectionable Advertisements Act applies is a separate offense in itself.

Designated officers of the state government are empowered to seize any advertisement that contravenes the Objectionable Advertisements Act. Upon a finding that there has been a violation, the court may also direct that anything gained by the violation should be forfeited.

The central government is empowered to exempt specific drugs or specific classes of drugs from the applicability of the relevant provisions of the statute.

Violations of the Objectionable Advertisements Act are punishable: in the case of the first conviction, with imprisonment which may extend to six months or with a fine or both; and in the case of a subsequent conviction, with imprisonment which may extend to one year and/or with a fine.

धोखा हो विशेष तौर पर उसके लेबल तथा डब्बे के आधार पर|; यदि लेबल अथवा डब्बे पर किसी नकली उत्पादक का नाम हो अथवा उत्पादक होने का दावा करता हो लेकिन हो नहीं|

नकली दवाओं का आयात सज़ा योग्य अपराध है जिसमें कि 3 साल तक कैद की सज़ा तथा रु. 5000 तक का जुर्माना हो सकता है| यदि अपराध दोहराया जाता है तो सज़ा की मियाद बढ़कर 5 साल तक हो सकती है तथा/अथवा जुर्माने की रकम रु. 10000 तक बढ़ाई जा सकती है|

नकली दवाओं के उत्पादन, बिक्री अथवा/तथा वितरण करने पर, यदि इस दवा से किसी की मृत्यु हो जाती है अथवा गंभीर क्षति पहुंचती है, तो निर्माता अथवा/तथा किसी भी जिम्मेदार व्यक्ति को 10 साल से लेकर आजीवन कैद की सज़ा तथा/अथवा रु. 1,000,000 तक का जुर्माना अथवा जब्त किये गए माल की कीमत का तीन गुना जुर्माना, जो भी अधिक हो, किया जा सकता है| अन्य मामलों में, निर्धारित की गई सज़ा की अवधि 7 साल से लेकर आजीवन तक तथा जुर्माने की रकम रु. 3,000,000 अथवा जब्त की गई दवाओं की कीमत की तीन गुना रकम, जो भी अधिक हो वसूल की जा सकती है| यदि अपराध दोहराया जाता है तो सज़ा की मियाद १० साल से लेकर आजीवन तक बढ़ाई जा सकती है|

आपत्तिजनक विज्ञापन अधिनियम

यह अधिनियम ऐसे किसी भी विज्ञापन पर निषेध लगाता है, जो कि संकेत करते हों अथवा दवाओं को इन कारणों के लिए इस्तेमाल करने की सलाह देते हों महिलाओं को गर्भपात करने हेतु अथवा गर्भाधान से बचाव हेतु; मानवों में यौन सुख कीक्षमता को बढाने अथवा सक्षम करने हेतु; महिलाओं में मासिक धर्म विकार को ठीक करने हेतु; अथवा सरकार द्वारा अधिसूचित अथवा अनुसूची में उल्लेखित किसी विशेष बीमारी के निदान, इलाज, शमन, उपचार अथवा बचाव हेतु|

इसके अलावा, यह ऐसे विज्ञापनों पर रोक लगाता है जो कि प्रत्यक्ष या अप्रत्यक्ष रूप से दवा के असल गुण के बारे में गलत अवधारणा देता हो, दवा के बारे में झूठा दावा करता हो, अथवा जो कि किसी अन्य प्रकार से गलत हो अथवा किसी सामग्री के विषय में भ्रामक जानकारी देता हो|

The Marketing Code

A summary of all the provisions of the Marketing Code would be beyond the scope of this document. Some of its stipulations are mentioned below:

- Medicinal products are not permitted to be promoted before they have received product authorizations. Then, all promotional materials should be consistent with the terms of the authorization granted. All information about medicinal products, in addition to being accurate, balanced, fair, objective and not misleading, is also required to be capable of substantiation. The Marketing Code requires that substantiation should be provided without delay to any member of the medical or pharmacy profession upon demand.
- The Marketing Code maintains that the word "safe"[11] should not be used unqualifiedly and it should not be stated categorically that the medicine has no side effects, toxic hazards, and that it does not carry the risk of addiction. Again, the word "new"[12] cannot be used to describe medicinal products which have generally been available for more than 12 months.
- The Marketing Code provides that comparisons of medicinal products should be factual, fair and capable of substantiation, and that no comparison should mislead by distortion, undue emphasis, omission or by any other way. Brand names of products of other companies may not be used in comparison except with the prior consent of the companies concerned. Other companies, their products, services or promotions must not be disparaged either directly or by implication.
- The Marketing Code stipulates the minimum information that promotional material should contain when provided to persons qualified to prescribe medicines. These include but are not limited to: the name and list of active ingredients; the recommended dosage; method of use; and method of administration, unless that is obvious.
- Promotional material appearing in print and paid for by pharmaceutical companies should not resemble editorial matter.
- The Marketing Code prohibits names or photographs of healthcare professionals from being used in promotional material.

[11] Para 2.2, Marketing Code.
[12] Para 2.3, Marketing Code.

आपत्तिजनक विज्ञापन अधिनियम के अधिकार क्षेत्र में दवा का आयात या निर्यात करना स्वतः ही एक अलग जुर्म है|

राज्य सरकार द्वारा निर्दिष्ट अधिकारियों को यह अधिकार रहता है कि वे आपत्तिजनक विज्ञापन अधिनियम की अवहेलना करने वाले विज्ञापनों पर रोक लगाएं| यह पाए जाने पर कि उल्लंघन हुआ है, कोर्ट उस उल्लंघन से सम्बंधित किसी भी वस्तु को जब्त करने के लिए निर्देश दे सकती है|

केंद्रीय सरकार के पास किसी विशेष दवा अथवा विशिष्ट वर्ग की दवाओं को इस विधान के प्रासंगिक प्रावधानों से छूट देने का अधिकार होता है|

आपत्तिजनक विज्ञापन अधिनियम का उल्लंघन दंडनीय है, (a) पहली बार दोषी सिद्ध होने पर छः महीने की कैद की सज़ा अथवा जुर्माना अथवा दोनों; तथा (b) हर आगामी अपराध पर एक साल तक कैद की सज़ा अथवा जुर्माना अथवा दोनों|

विपणन कोड

विपणन कोड के सभी प्रावधानों का वर्णन करना इस दस्तावेज़ की क्षमता से बाहर है| इसके कुछ नियम निम्नलिखित हैं:

- औषधीय उत्पादों का प्रचार उनके उत्पाद अधिकृत होने से पूर्व नहीं किया जा सकता है| इसके बाद सभी प्रचार सामग्रियां दिए गए प्राधिकरण के अनुसार होनी चाहिए| दवा उत्पादों के बारे में सभी जानकारियाँ सटीक, संतुलित, निष्पक्ष, स्पष्ट होने तथा भ्रामक न होने के साथ ही साथ प्रमाणीकरण हेतु सक्षम होना भी आवश्यक है| विपणन कोडहेतु आवश्यक है कि चिकित्सीय तथा औषधीय व्यवसाय के किसी भी सदस्य को मांगे जाने पर प्रमाणीकरण बिना देर किये उपलब्ध कराया जाए|
- विपणन कोड सुनिश्चित करता है कि "सुरक्षित"[11] शब्द का उपयोग अनावश्यक रूप से ना किया जाए तथा यह विशेष तौर पर यह दर्शाने के लिए इस्तेमाल ना किया जाए कि दवा के दुष्प्रभाव तथा ज़हरीले प्रभाव नहीं हैं, तथा इसके सेवन से लत लगने की

[11] अनुच्छेद 2.2 मार्केटिंग कोड

- It stipulates that promotional material should not imitate the devices, copy the slogans or general layout adopted by other companies in a way that is likely to mislead or confuse. It also exhorts companies to avoid extremes of format, size or cost in their promotional material. It also discourages the posting of material on postcards, other exposed mailings, envelopes or wrappers which might be regarded as advertising to the lay public or which could be considered unsuitable for public view. The Marketing Code makes companies liable for the acts of employees who draw up promotional material and obliges them to ensure that they are familiar with the requirements of the Marketing Code. It also obliges them to ensure that third parties (such as advertising agencies, consultants and market research companies) understand the Marketing Code.
- The Marketing Code has fairly detailed provisions dealing with the conduct of medical representatives of pharmaceutical companies. They are prohibited from employing any inducement, subterfuge tactics or payments to gain access to a healthcare professional.
- The Marketing Code also contains provisions on the distribution of free samples. Illustratively, these provisions limit the number of free samples that can be provided; require that these be given only to persons who are qualified to prescribe the medicine (and even to them only against a written request); and prohibit free samples of certain products (antidepressant, hypnotic, sedative or tranquilizer). Pharmaceutical companies are barred from providing, offering or promising gifts, pecuniary advantages or benefits in kind to persons qualified to prescribe or supply pharmaceutical products. The Marketing Code clarifies that gifts for the personal benefit of healthcare professionals (such as tickets to entertainment events) are also covered by the prohibition.
- The Marketing Code has fairly detailed provisions on the sponsorship of CME and other events by pharmaceutical companies. It acknowledges that companies may legitimately provide assistance in the education of healthcare professionals. There is also some admission that they may undertake measures that facilitate attendance of professionals at such events in India. For events organized in India, the Marketing Code allows companies to bear actual travel expenses, meals, refreshments, accommodation and registration fees. Companies are urged to not organize meetings to coincide with sporting, entertainment or other leisure events or activities, and to avoid venues

संभावना नहीं है| साथ ही, "नया"[12] शब्द का उपयोग ऐसे औषधीय उत्पादों के बारे में न किया जाए जो सामान्य तौर पर 12 महीनों से अधिक समय से उपलब्ध है|

- मार्केटिंग कोड के माध्यम से यह सुनिश्चित किया जाता है कि औषधीय उत्पादों की तुलना तथ्यपरक, निष्पक्ष तथा प्रामाणिक हो तथा विकृति, अनावश्यक महत्व, जानबूझकर छोड़ दी गई जानकारियों अथवा अन्य किसी भी प्रकार से किसी तुलना के माध्यम से भ्रम की स्थिति नहीं बननी चाहिए| दूसरी कंपनियों के उत्पादों के नामों का उपयोग उन कंपनियों की अनुमति के बिना नहीं करना चाहिए| दूसरी कंपनियों को तथा उनके उत्पादों को प्रत्यक्ष अथवा अप्रत्यक्ष रूप से अपमानित नहीं करना चाहिए|
- विपणन कोड में यह शर्त रखी गई है कि दवा उत्पाद की प्रचार सामग्री में तथा लेबल में आवश्यक न्यूनतम जानकारियाँ होनी चाहिए| इनमें शामिल हैं पर इन पर ही सीमित नहीं (aa) सक्रिय संघटकों का नाम तथा सूची, (b) सुझाई गई खुराक, (c) इस्तेमाल का तरीका, तथा (d) ग्रहण करने का तरीका, जब तक कि स्पष्ट न हो|
- प्रकाशित होने वाले विज्ञापन में तथा फार्मा कंपनियों द्वारा भुगतान किये जाने वाले विज्ञापनों में एक ही प्रकार का मजमून नहीं होना चाहिए|
- विपणन कोड के अनुसार विज्ञापनों में चिकित्सकों के नाम तथा चित्रों का उपयोग निषिद्ध है|
- इसमें यह शर्त रहती है कि विज्ञापनों में यंत्रों की, स्लोगन की, तथा सामान्य रूपरेखा की नक़ल दूसरी कंपनियों द्वारा उस तरह नहीं की जानी चाहिए जिससे कि उपभोक्ताओं को भ्रमित किया जा सकता हो| यह सामग्रियों को डाक के माध्यम से, लिफाफों में, पैकेट में, जो कि आम जनता को विज्ञापन के लिए भेजे जाते हों, अथवा जो जनता के मध्य देखे जाने योग्य नहीं हो, भेजने से निषिद्ध करता है| विपणन कोड कंपनियों कोऐसे कर्मचारियों के प्रति जवाबदेयता तय करने हेतु बाध्य करता है जो कि प्रचार अभियानों से सम्बंधित हैं तथा उन्हें यह सुनिश्चित करने के लिए भी बाध्य करता है कि वे कर्मचारी विपणन कोड की सभी आवश्यकताओं से परिचित हों| यह बाध्य करता

[12] अनुच्छेद 2.3 मार्केटिंग कोड

that are "renowned for their entertainment or leisure facilities or are extravagant."[13] Compensation for time spent at conferences is not permitted. In a provision which is not always easy to reconcile with the Marketing Code's emphasis on organizing all CME events in India, it permits "promotional, scientific or professional meetings, congresses, conferences, symposia, and other similar events (including, for example, advisory board meetings, visits to research or manufacturing facilities, and planning, training or investigator meetings for clinical trials and non-interventional studies)"[14] to be held outside India provided that the country where it is held is the appropriate venue that is conducive to the main purpose of the event. Companies are mandated to maintain detailed records of their expenditures incurred during events.

- The Marketing Code creates a self-regulatory mechanism whereby associations representing pharmaceutical companies enforce the Marketing Code. They are empowered by the Marketing Code to undertake any or all of the following measures against errant companies that are their constituents:
    - Suspend or expel the company from the association.
    - Reprimand the company and publish details of that reprimand.
    - Suspend or expel the company from the association.
    - Reprimand the company and publish details of that reprimand.
    - Require the company to issue a corrective statement; details of the proposed content and mode and timing of dissemination of the corrective statement must be provided to a committee of the association for approval and it has to be displayed on the website of the association.
    - Ask the company to take steps to recover items given in connection with the promotion of a medicine provided to health professionals and members of the public and the like; details of the action taken must be provided in writing to a committee of the association and also be uploaded on the website of the association.

[13] Para 7.3, Marketing Code.
[14] Para 7.6, Marketing Code.

है कि उनका प्रचार अभियान देख रही थर्ड पार्टीज़ जैसे विज्ञापन एजेंसीज़, परामर्शदाता तथा मार्केट रिसर्च कंपनियां विपणन कोड को समझे|

- विपणन कोड में चिकित्सीय प्रतिनिधियों तथा दवा कंपनियों के आचरण सम्बंधित प्रावधानों का स्पष्ट विवरण दिया गया है| कंपनियों के लिए चिकित्सकों को लुभाने के लिए प्रलोभन देना, जोड़-तोड़ करना, अथवा घूस देना मना है|
- विपणन कोड में मुफ्त नमूने वितरित करने को लेकर भी कुछ प्रावधान हैं| उदाहरण के तौर पर, यह प्रावधान जारी किये जाने वाले मुफ्त नमूनों की संख्या निर्धारित करते हैं, सुनिश्चित करते हैं कि नमूने उन्ही व्यक्तियों को दिए जाएँ, जो कि उन दवाओं को लिखने के लिए योग्य हों (वह भी तभी जब वे लिखित मांग दें), तथा कुछ दवाइयों जैसे तनाव निरोधी, कृत्रिम निद्रादायक, दर्द निवारक तथा शांतिदायक दवाओं के नमूने देना निषिद्ध है|
- फार्मा कंपनियों के लिए ऐसे किसी व्यक्ति को जो कि फार्मा उत्पादों की आपूर्ति तथा प्रेस्क्रिप्शन हेतु योग्य हो, उपहार देना, उपहार की पेशकश करना अथवा उपलब्ध करवाना तथा धन सम्बन्धी लाभ देना निषेध है| विपणन कोड यह स्पष्ट करता है कि चिकित्सकों के व्यक्तिगत लाभ हेतु दिए जाने वाले उपहार जैसे, मनोरंजक कार्यक्रमों के टिकिट भी इस निषेध के अंतर्गत आते हैं|
- विपणन कोड में फार्मा कंपनियों द्वारा सीएमई तथा अन्य आयोजनों को प्रायोजित करने के सम्बन्ध में भी स्पष्ट प्रावधान किये गए हैं| यह निर्धारित करता है, कि कंपनियां चिकित्सकों के शिक्षण के लिए मदद वैधानिक तरीके से ही कर सकती हैं |इसमें यह भी स्वीकारा गया है कि भारत में इस प्रकार के आयोजनों में चिकित्सकों की उपस्थिति उपलब्ध करवाने हेतु कंपनियां कुछ उपाय कर सकती हैं| भारत में होने वाले आयोजनों हेतु विपणन कोड कंपनियों को अनुमति देता है कि वे यात्रा का खर्च, भोजन, नाश्ता, ठहरने की सुविधा तथा रजिस्ट्रेशन फीस आदि का खर्च वहन करें| इसके लिए कंपनियों से आह्वान किया जाता है कि वे ऐसे आयोजनों में खेल, मनोरंजन तथा अन्य आयोजनों का समावेश न करें तथा ऐसे स्थलों का चुनाव न करें जो कि "अपनी मनोरंजन सुविधाओं के लिए जाने जाते हों तथा शाही हों|"[13] कोंफ्रेन्सेस में बिताये गए समय का मुआवजा देने की अनुमति नहीं है |एक प्रावधान के अनुसार यदि सभी सीएमई आयोजनों को भारत में ही आयोजित करने के विपणन कोड की

[13] अनुच्छेद 7.3 मार्केटिंग कोड

Professional Codes of Conduct

Of the various organizations in India representing pharmaceutical companies, the Organization of Pharmaceutical Producers of India (the "OPPI") and the Indian Drug Manufacturers' Association are known to have codes on marketing for their constituents. Some of the important provisions of OPPI's code (the "OPPI Code") are mentioned in this section.

The OPPI Code

The OPPI Code is based on the code of the International Federation of Pharmaceutical Manufacturers and Associations. It deals with only those marketing and promotion activities that are directed at healthcare professionals. For example, it does not apply to the promotion of self-prescription pharmaceutical products or of prescription drugs if such marketing is targeted directly at consumers. Clinical trials are specifically excluded from the purview of the OPPI Code.

The OPPI Code contains some general principles for companies to follow in their relationships with healthcare professionals and in respect of product promotions. Separately, it contains specific rules, some of which are already contained in the MCI Regulations. The following are some examples of these rules:

- The OPPI Code lays out the specific information about a drug that all printed promotional materials (other than the so-called "reminder"[15] advertisements) and electronic promotional materials must contain. These include the names of active ingredients, name and address of the pharmaceutical company or its agent responsible for marketing the product, approved indications for use together with the dosage and method of use, and a brief statement of the contraindications, precautions and side effects.
- It requires promotions to avoid undue exaggeration of the properties or benefits. The OPPI Code also stipulates that promotions should not be disguised as clinical assessments or post-marketing surveillance, which should only be conducted for objective scientific purposes. It stipulates specific standards for any promotional material, such as consistency with product information, accurate representation reflective of the evaluation of all up-to-date evidence, and being substantiated either by reference to approved labeling or by scientific evidence.

[15] Para 5.2, OPPI Code.

बाध्यता के साथ सामंजस्य नहीं बैठ पा रहा हो ,तब ऐसे कोई आयोजन जैसे "प्रचार , वैज्ञानिकअथवा व्यावसायिक मीटिंग ,कोंग्रेसेस ,कांफ्रेंसेस ,सिम्पोसिया तथा अन्य इसी प्रकार के आयोजन) जिनमें शामिल हैं ,उदाहरण के लिए ,सलाहकार बोर्ड मीडिंग , अनुसन्धान तथा उत्पादन यूनिट्स तक मुआयना ,तथा क्लिनिकल ट्रायल्स व अहस्तक्षेपनीय अध्ययन हेतु योजना बनाने ,प्रशिक्षण लेने अथवा खोज करने हेतु कोई मीटिंग("1429 भारत के बाहर भी किये जा सकते हैं ,बशर्ते वह देश इस प्रकार के आयोजनों हेतु उपयुक्त तथा मीटिंग के मुख्य उद्देश्य के प्रति सहायक हो |कंपनियों के लिए आवश्यक है कि वे ऐसे आयोजनों के दौरान होने वाले खर्च का पूरा हिसाब रखे|

- विपणन कोड एक आत्म नियंत्रित तंत्र बनाता है जिससे कि दवा कंपनियों का प्रतिनिधित्व करने वाले संगठन, विपणन कोड का पालन करने के लिए बाध्य करते हैं| विपणन कोड उन्हें सक्षम करता है कि वे उनके अधीन आने वाली गलत कंपनियों पर निम्न में से कोई या सभी कार्रवाइयां कर सके:
  - कंपनी को संगठन से निष्कासित या निलंबित करे|
  - kampanकंपनी को फटकार लगाए तथा उस चेतावनी को विस्तार से प्रकाशित करे|
  - कंपनी को दोष निवारण वक्तव्य जारी करने को कहे; प्रस्तावित सामग्री की विस्तार से जानकारी, माध्यम, तथा उस वक्तव्य को जारी करने का समय संगठन की एक समिति को अनुमति के लिए उपलब्ध कराया जाना चाहिए तथा इसे संगठन की वेबसाइट पर भी प्रकाशित किया जाना चाहिए|
  - कंपनियों को आदेशित करना चाहिए कि वे उन सभी दवाओं को पुनः इकठ्ठा करें जो उन्होंने विज्ञापन तथा प्रचार के दौरान चिकित्सकों को तथा सम्बन्धित व्यक्तियों को दी हैं तथा की जाने वाली कार्यवाहियों की विस्तृत जानकारी लिखित में संगठन की समिति को दी जानी चाहिए तथा संगठन की वेबसाइट पर भी अपलोड की जानी चाहिए|

[14] अनुच्छेद 7.6 मार्केटिंग कोड

- The OPPI Code stipulates certain conditions which have to be satisfied for promotional information at international scientific events to refer to pharmaceutical products that are not registered in the country where the event takes place. For example, it requires that a significant proportion of the speakers and attendees be from countries other than the country where the event takes place, that such promotional material indicate the countries where the product is registered, and clarify that the product is not available locally.
- It prohibits travel facilities and hotel accommodation from being extended to healthcare professionals visiting as delegates. However, speakers and presenters may reimburse their expenses and may be paid a reasonable fee. It clarifies that hospitality should be limited to refreshments and meals incidental to the main purpose of the event, that it should only be provided to the participants and not their guests, be moderate and reasonable as judged by local standards, and should not exceed what the recipients would normally be prepared to pay for themselves. It prohibits stand-alone entertainment or other leisure or social activities other than events of "modest nature"[16] which is secondary to the refreshments or meals.
- Companies are not allowed to provide gifts, cash or monetary grants in individual capacities to healthcare professionals. In a rule similar to that found in the MCI Regulations, the OPPI Code stipulates that funding for research and other activities can be routed only through approved institutions.
- The OPPI Code permits companies to retain healthcare practitioners in advisory capacities as consultants, researchers, treating doctors or any other professional capacity.
- It also mandates that pharmaceutical companies establish and maintain adequate procedures to ensure compliance with it and designate a suitable employee to approve all promotional communications of the company. The OPPI Code contains a detailed procedure for admitting and addressing complaints. The penalties for non-compliance range from publishing the violation and the key facts on the OPPI website, requiring an undertaking to cease any such irregular practice, requiring the issue of retraction statements, or finally the expulsion from the OPPI.

[16] Para 7.5.3, OPPI Code.

व्यावसायिक आचरण संहिताएं

भारत में फार्मा कंपनियों का प्रतिनिधित्व करने वाले कई संगठनों में से ऑर्गनाइज़ेशन ऑफ फार्मास्युटिकल प्रोड्यूसर्स ऑफ इंडिया ("ओपीपीआई") तथा इंडियन ड्रग मेन्यूफेक्चरर्स असोसिएशन का अपने संघटकों के लिए विपणन कोड है| ओपीपीआई के कोड के कुछ महत्वपूर्ण प्रावधानों का वर्णन इस भाग में किया गया है|

ओपीपीआई कोड

ओपीपीआई कोड इंटरनेशनल फेडरेशन ऑफ फार्मास्युटिकल मेन्यूफेक्चरर्स एंड एसोसिएशंस के कोड पर आधारित होने का दावा करता है| यह सिर्फ उन्ही प्रचार गतिविधियों से सम्बंधित है जो कि चिकित्सकों से व्यवहार से सम्बंधित हैं| उदाहरण के लिए, यह सेल्फ प्रेस्क्रिप्शन फार्मा उत्पाद अथवा ऑफ प्रेस्क्रिप्शन दवाओं के प्रचार पर लागू नहीं होता है, यदि ऐसा प्रचार सीधे उपभोक्ताओं को लक्षित हो तो| विशेष तौर पर क्लिनिकल ट्रायल्स ओपीपीआई कोड की परिधि से बाहर हैं|

ओपीपीआई कोड में कंपनियों के लिए चिकित्सकों से सम्बन्ध रखने तथा उत्पाद के प्रचार से सम्बंधित कुछ सामान्य सिद्धांत हैं| इसमें पृथक रूप से कुछ ऐसे विशेष नियम हैं जो कि पहले से ही एमसीआई रेग्युलेशंस में शामिल हैं| इन नियमों के कुछ उदाहरण निम्न हैं :

(a) ओपीपीआई कोड दवाओं के बारे में कुछ विशेष जानकारियाँ निर्धारित करता है जो कि हर प्रकाशित प्रचार सामग्रियों (तथाकथित "रिमाइन्डर"[15] विज्ञापनों के अलावा) तथा इलेक्ट्रॉनिक विज्ञापनों में होनी ज़रुरी है| इसमें शामिल है सभी सक्रिय संघटकों के नाम, फार्मा कम्पनी का नाम तथा पता अथवा इसकी मार्केटिंग के लिए जवाबदार एजेंट, इस्तेमाल करने का सही ढंग खुराक तथा ग्रहण करने के तरीके सहित, तथा मतभेदों, एहतियातों तथा दुष्प्रभावों से सम्बंधित एक संक्षिप्त कथन|

(b) दवा की विशेषताओं तथा लाभों को अनावश्यक रूप से बढ़ा-चढा कर बताया ना जाए, इसके लिए प्रचार आवश्यक है| ओपीपीआई कोड यह सुनिश्चित करता है कि प्रचार को क्लिनिकल मूल्यांकन अथवा विपणन के बाद निगरानी आदि के छद्म आवरणों से न

[15] अनुच्छेद 5.2 ओपीपीआई कोड

Criminal and Civil Liability

The PCA

The PCA is the primary Indian legislation on bribery. It applies to all Indian states except Jammu and Kashmir and to all citizens of India outside India. It is also one of the few statutes in India the violation of which every person who learns of it is legally obliged to report. Therefore, when a pharmaceutical company learns of a violation of PCA, it becomes legally obliged to report the relevant facts to Indian authorities.

Mentioned below are some of the acts, which may be relevant to the relationship of pharmaceutical companies with government healthcare professionals, the procurement process, government hospitals, etc., and which are criminalized by the PCA.

Firstly, the PCA criminalizes the accepting, obtaining or agreeing of, or attempting to accept or obtain, any gratification which is not legal remuneration "…as a motive or reward for doing or forbearing to do any official act or for showing or forbearing to show, in the exercise of his official functions, favour or disfavour to any person or for rendering or attempting to render any service or disservice to any person[17] ."

Secondly, it makes it unlawful for a public servant to accept, obtain, agree to accept, or to attempt to obtain, any valuable thing without consideration (or for a consideration which he knows to be inadequate), from any person whom he knows to have been, to be, or to be likely to be concerned in any proceeding or business transacted or about to be transacted by such public servant, or having any connection with his official functions or the official functions of any public servant to whom he is subordinate, or from any person whom he knows to be interested in or related to the person so concerned.

Both these offenses, as well as the abetment of them (which would include pharmaceutical companies offering such bribes), are punishable with imprisonment of between six months and five years and a fine.

The PCA provides increased penalties for habitually committing the violations described above.

[17] Section 7, PCA

छुपाया जाए; इन्हें सिर्फ स्पष्ट वैज्ञानिक उद्देश्यों हेतु ही संचालित किया जाए| यह प्रचार सामग्रियों के लिए स्पष्ट मानक निर्धारित करता है जैसे उत्पाद की नियमित जानकारी, सभी अप टू डेट प्रमाणों के मूल्यांकन को दर्शाते हुए सटीक प्रतिनिधित्व तथा वैज्ञानिक प्रमाणों अथवा अनुमति प्राप्त लेबलिंग के माध्यम से प्रामाणिक बनाना|

(c) किसी ऐसे देश में हो रहे अंतरराष्ट्रीय वैज्ञानिक आयोजन में, जहाँ पर कंपनी का उत्पाद पंजीबद्ध नहीं है, प्रचार करने हेतु ओपीपीआई कोड में कुछ शर्तें हैं जिनका पालन करने पर ही उत्पाद का प्रचार किया जा सकता है| उदाहरण के लिए, यह आवश्यक है कि उस आयोजन में अन्य देशों के भी पर्याप्त सहभागी तथा वक्ता हों उस देश के अतिरिक्त, जिस देश में वह आयोजन हो रहा है, कि प्रचार सामग्री में उन देशों का उल्लेख हो जहाँ पर उत्पाद पंजीबद्ध है, तथा स्पष्ट किया जाए कि उत्पाद स्थानीय तौर पर उपलब्ध नहीं है|

(d) यह प्रतिनिधि के तौर पर आये हुए चिकित्सकों की यात्रा सुविधाओं तथा होटल में ठहरने की अवधि बढाने से निषिद्ध करता है| हालाँकि, इसके अनुसार वक्ताओं तथा प्रस्तोताओं को किये गए खर्चे की प्रतिपूर्ति की जानी चाहिए तथा समुचित शुल्क दिया जाना चाहिए| यह स्पष्ट करता है कि, आतिथ्य की सीमा आयोजन के मुख्य उद्देश्य के अलावा नाश्ते तथा भोजन तक होनी चाहिए तथा वह भी सिर्फ प्रतिभागियों को उपलब्ध कराया जाना चाहिए, उनके साथ आने वाले मेहमानों को नहीं, स्थानीय मानकों के अनुसार संयमित तथा वाजिब रहना चाहिए, तथा कभी भी उस श्रेणी से बढ़ना नहीं चाहिए जिस श्रेणी तक भुगतान करने के लिए प्रतिभागी मानसिक रूप से तैयार रहें| भोजन तथा नाश्ते के बाद "मर्यादित प्रकृति"[16] के कार्यक्रमों के अलावा, किसी भी प्रकार के मनोरंजन, अथवा अन्य सामाजिक गतिविधियां इसके तहत निषिद्ध है|

(e) कंपनियों द्वारा चिकित्सकों को व्यक्तिगत रूप से उपहार, नकद, मौद्रिक अनुदान देने की मनाही है| एमसीआई रेग्युलेशंस में वर्णित एक इसी प्रकार के नियम के अनुसार ओपीपीआई कोड अनुसन्धान आदि के लिए दिए जाने वाले धन को अधिकृत संस्थानों के द्वारा ही दिया जान प्रस्तावित करता है|

(f) ओपीपीआई कोड कंपनियों को यह अनुमति देता है कि वे चिकित्सकों को सलाहकार के रूप में जैसे, परामर्शदाता, अनुसंधानकर्ता, उपचार करने वाले चिकित्सक अथवा अन्य किसी व्यावसायिक रूप में रखें|

[16] अनुच्छेद 7.5.3 ओपीपीआई कोड

The Central Civil Services (Conduct) Rules, 1964

The Central Civil Services (Conduct) Rules, 1964 regulate the conduct of central government employees. Among the many subjects on which detailed rules are provided is that of accepting gifts. "Gift[18]" has been defined widely and includes free transport, boarding, lodging or any pecuniary advantage provided by a person other than a near relative or personal friend. Even when gifts are received from a near relative or personal friend, disclosure has to be made if the gift from the near relative or personal friend exceeds the threshold limits specified for different categories of employees.

Specific structures have also been laid down for acceptance of gifts from foreign dignitaries and firms. Government employees can accept such gifts only on grant of approval by the Government. These approvals are granted only in exceptional cases. For this, the employee has to demonstrate that the firm has no official dealings with any department of the Government and that the gift is absolutely *bona fide* in nature. Furthermore, there is an absolute prohibition on such employees accepting any cost of passage to foreign countries and hospitality by way of free board and lodging if such offers are made by foreign firms contracting with the Government directly or indirectly.

The FCRA

The Foreign Contribution (Regulation) Act 2010 came into effect on 1 May 2011. The act regulates the acceptance and utilization of foreign contribution and foreign hospitality by certain individuals. Under the Act, foreign contribution means donation, delivery or transfer of articles, currency (both Indian and foreign) or any security (both Indian and foreign) by any foreign source. Fees paid by foreign delegates and participants for participation in a conference/seminar, and which is utilized for meeting the expenditure of hosting the conference/seminar has been excluded from the said definition.

"Foreign source"[19] is defined broadly and includes foreign companies, foreign governments and Indian companies more than half of whose shares are held, either singly or in the aggregate, by foreign governments, citizens, corporations, companies, trusts and/or societies. "Foreign hospitality[20] "

[18] Explanation to Rule 13, Central Civil Services (Conduct) Rules, 1964.
[19] Section 2(1)(j), FCRA.
[20] Section 2(1)(i), FCRA.

(g) ओपीपीआई कोड यह भी निर्धारित करता है कि कंपनियां अधिकतम प्रक्रियाओं के माध्यम से इसका पालन करें तथा कंपनी के सभी प्रचार कार्यक्रमों को इसके अनुसार ढालने के लिए एक सक्षम कर्मचारी कि नियुक्ति करें| ओपीपीआई कोड में शिकायतों को मानने तथा निवारण करने के लिए विस्तृत प्रक्रिया है| इनका पालन न करने की दशा में दंड का भी प्रावधान है जो कि हो सकता है, ओपीपीआई की वेबसाइट पर उल्लंघनों का तथा मुख्य तथ्यों का प्रकाशन, ऐसी अनियमित गतिविधियों को रोकने हेतु दायित्व लेना अनिवार्य करना तथा अंततः ओपीपीआई से निष्कासन|

<u>आपराधिक तथा नागरिक दायित्व</u>

<u>पीसीए</u>

पीसीए घूसखोरी के लिए प्राथमिक भारतीय कानून है| यह जम्मू कश्मीर के अलावा भारत के सभी राज्यों में तथा भारत के तथा भारत से बाहर के सभी नागरिकों पर लागू होता है| यह उन चुनिन्दा कानूनों में से एक है, जिसका उल्लंघन होने की दशा में, प्रत्येक वह व्यक्ति, जो उल्लंघन के बारे में जानता हो, कानूनी रूप से इसकी जानकारी देने के लिए बाध्य है| अतः, जब किसी फार्मा कंपनी को पीसीए के उल्लंघन के बारे में पता चलता है, तो उसके लिए कानूनी बाध्यता है कि वह उसके बारे में प्रासंगिक तथ्यों से भारतीय अधिकारियों को अवगत कराये|

नीचे कुछ कार्यों का वर्णन किया गया है, जो कि फार्मा कंपनियों के सरकारी स्वास्थ्य सेवा अधिकारियों, खरीद प्रक्रिया, सरकारी अस्पताल इत्यादि से संबंधों हेतु प्रासंगिक हैं तथा पीसीए के अंतर्गत अपराध की श्रेणी में आते हैं|

पहला यह कि, ऐसा कोई भी उपहार स्वीकार करना, प्राप्त करना अथवा प्राप्त करने के लिए राज़ी होना, अथवा स्वीकार करने अथवा प्राप्त करने का प्रयास करना, जो कि कानूनी पारिश्रमिक नहीं है, तथा जो कि "....लोक सेवक होते हुए या ने की प्रत्याशा रखते हुए, वैध पारिश्रमिक से भिन्न प्रकार का भी कोई परितोषण, किसी बात करने के प्रयोजन से या ईनाम के रूप में किसी व्यक्ति से प्रतिग्रहीत या अभिप्राप्त करेगा या करने को सहमत होगा, या करने का प्रयत्न करेगा,कि वह लोक सेवक, कोई पदीय कार्य

refers to any offer, except those that are of a purely casual nature, made in cash or kind by a foreign source to any individual providing him with costs of travel to any foreign country or with free boarding, lodging, transport or medical treatment.

Among the classes of persons prohibited from accepting foreign contributions are editors and publishers of registered newspapers (medical journals are frequently such) and (except pursuant to a prior registration with the central government) persons having a "definite cultural economic, educational, religious or social program…"[21] Again, no employee of a corporation or a body controlled or owned by a government is permitted to accept foreign hospitality unless the government's prior permission has been obtained.

Violations of the FCRA are punishable, *inter alia*, with imprisonment of up to five years.

Recommendations on Contracts with Healthcare Professionals and Medical Institutions

Indian medical practitioners working on research projects funded by pharmaceutical companies are obliged by MCI Regulations to contractually reserve the right to publish the research results in certain circumstances. Companies would be well-advised to seek local counsel to protect their intellectual property rights in relation to such projects when faced with such provisions.

The engagement of healthcare professionals to provide genuine consultancy or other genuine services to a member company is excluded from the scope of the OPPI Code. Rulings from countries on similar provisions in the code of the International Federation of Pharmaceutical Manufacturers and Associations may provide guidance on what elements would support a finding of genuineness in such agreements.

[21] Section 11(1), FCRA.

करे या पदीय कार्य करने का लोप करे या किसी व्यक्ति को अपनी पदीय कार्यों के प्रयोग से कोई अनुग्रह करे या करने से प्रतिविरत करे|"[17]

दूसरा, लोकसेवक के लिए यह गैर कानूनी है, यदि वह अपने लिए या किसी अन्य के लिए कोई मूल्यवान वस्तु प्रतिफल के बिना या ऐसे प्रतिफल के लिए जिसका पर्याप्त होना वह जानता है, किसी ऐसे व्यक्ति से, जिसका अपने द्वारा की गई, या की जाने वाली किसी प्रक्रिया, या कारोबार से संबंध रहा होगा, या हो सकता हो, अथवा अपने या किसी ऐसे लोक सेवक जिसका वह अधीनस्थ है, पदीय कार्यों से कोई संबद्ध होना वह जानता है, अभ्यासतः प्रतिग्रहीत या अभिप्राप्त करता है या प्रतिग्रहीत करने के लिए सहमत होता है, या अभिप्राप्त करने का प्रयत्न करता है|

इन दोनों अपराधों की दशा में, तथा इन्हें करने के उकसावे में आने की दशा में (जिसमें ऐसी रिश्वत फार्मा कंपनियों द्वारा दिया जाना सामने आये), दंडनीय अपराध है तथा इसके लिए छः महीने से 5 साल तक की कारावास की सज़ा तथा जुर्माना हो सकता है|

उपरोक्त वर्णित अपराधों के दोहराव की दशा में पीसीए के तहत सज़ा एवं/अथवा जुर्माना बढ़ाया जा सकता है|

केंद्रीय लोकसेवा (आचरण) नियम, 1964

केंद्रीय लोकसेवा (आचरण) नियम, 1964, केंद्र सरकार के कर्मचारियों के आचरण को नियंत्रित करते हैं| ऐसे कई विषयों पर, जिनकी इन नियमों में विस्तृत जानकारी दी गई है, एक है उपहार लेना| "उपहार"[18] को इसमें वृहत तौर पर परिभाषित किया गया है, तथा इसमें शामिल है, मुफ्त यात्रा, ठहरने तथा खाने का खर्च, अथवा अन्य कोई वित्तीय लाभ, जो कि लोकसेवकों को किसी व्यक्ति द्वारा, जो कि करीबी रिश्तेदार अथवा परिचित न हो, उपलब्ध कराया जाता है| यहाँ तक कि रिश्तेदार अथवा परिचितों से भी मिलने वाले उपहारों की जानकारी सार्वजनिक करना आवश्यक है यदि वह उस कर्मचारी के निर्धारित वर्ग की सीमा से अधिक हो तो|

[17] भाग 7, पीसीए

[18] नियम 13 का विस्तारण, केंद्रीय लोकसेवा (आचरण) नियम, 1964

Companies operating in India should have systems within their human resource management and sales functions to ensure that their medical representatives and other employees (particularly those responsible for marketing materials) are acquainted with the Marketing Code. Equally important, third parties working for or on behalf of pharmaceutical companies or commissioned to engage in activities covered by the Marketing Code should have a good working knowledge of the Marketing Code.

Companies that have disclosure obligations in their home jurisdictions under anti-bribery statutes such as the Foreign Corrupt Practices Act, 1977 may need to promptly take counsel in both India and in their home country upon learning of any violation of the PCA by their Indian affiliates. The time within which disclosures may have to be made (and the contents of such disclosures) under the two legal systems may not be easily reconciled. There may be similar implications under the securities law of multiple jurisdictions if the company is listed on exchanges in more than one country.

विदेशी प्रतिनिधियों तथा कंपनियों से उपहार ग्रहण करने पर भी कड़े प्रतिबन्ध लगाए गए हैं| सरकारी कर्मचारी इस प्रकार के उपहार सिर्फ सरकार द्वारा अनुमति दिए जाने पर ही ग्रहण कर सकते हैं| इस प्रकार की अनुमतियाँ विशिष्ट मामलों में ही दी जाती है| इसके लिए कर्मचारी को यह जताना होता है कि कंपनी का सरकार के किसी भी विभाग के साथ कार्यालयीन व्यवहार नहीं है, तथा उपहार सिर्फ सदाशयता प्रदर्शित करने के लिए दिया जा रहा है| इसके अलावा, ऐसी विदेशी कंपनियों से, जो कि सरकार के साथ प्रत्यक्ष अथवा अप्रत्यक्ष रूप से अनुबंधित है, कर्मचारियों को मुफ्त में ठहरने तथा विदेशी राष्ट्र की यात्रा, आतिथ्य सत्कार ग्रहण करना सख्त मना है|

एफसीआरए

विदेशी अंशदान (नियमन) अधिनियम, 2010, 1 मई 2011 से प्रभावशील हुआ है| यह अधिनियम विशिष्ट व्यक्तियों द्वारा विदेशी अंशदान तथा विदेशी आतिथ्य ग्रहण करने तथा इस्तेमाल करने पर नियंत्रण लगाता है| अधिनियम के अंतर्गत, विदेशी अंशदान का मतलब दान तथा किसी विदेशी स्रोत द्वारा वस्तुओं का, मुद्रा का (भारतीय तथा विदेशी) अथवा कोई प्रतिभूति (भारतीय व विदेशी) वितरण व हस्तांतरण है| किसी विदेशी प्रतिनिधि तथा प्रतिभागी द्वारा किसी कांफ्रेंस/सेमिनार में भाग लेने के लिए दी जाने वाली फीस जिसका उपयोग कांफ्रेंस/सेमिनार के खर्चों को वहन करने के लिए हो रहा हो, इस परिभाषा के बाहर है|

"विदेशी स्रोत"[19] के दायरे में मुख्यतः विदेशी कम्पनियाँ, विदेशी सरकारें तथा ऐसी भारतीय कंपनियां जिनके आधे से अधिक शेयर एकल रूप में अथवा सकल रूप से विदेशी सरकारों, नागरिकों, निगमों, कंपनियों, ट्रस्टों तथा/अथवा संस्थाओं द्वारा धारण किये गए हों, आती हैं| "विदेशी आतिथ्य"[20] का मतलब ऐसा कोई प्रस्ताव, उनके अलावा, जो कि नैमित्तिक प्रकृति के हों, जो कि नकद अथवा उस प्रकार, किसी विदेशी स्रोत द्वारा किसी व्यक्ति को विदेश यात्रा, मुफ्त ठहरना, खाना, परिवहन तथा इलाज कराने हेतु दिया जाए|

[19] भाग 2 (1)(j), एफसीआरए

[20] भाग 2 (1)(i), एफसीआरए

उस वर्ग के व्यक्तियों में जो कि विदेशी अंशदान ग्रहण करने हेतु प्रतिबंधित नहीं हैं, शामिल है पंजीकृत अखबारों (बहुधा मेडिकल जर्नल्स) के संपादक तथा प्रकाशक तथा ऐसे व्यक्ति जिनका एक "तय सांस्कृतिक, शैक्षणिक, धार्मिक अथवा सामाजिक कार्यक्रम हो..."[21] | परन्तु, सरकार द्वारा नियंत्रित अथवा स्वामित्व वाली किसी भी संस्था, निगम या निकाय के कर्मचारी हेतु विदेशी आतिथ्य स्वीकार करने की मनाही है जब तक कि सरकार से उसके लिए अनुमति ना ली गई हो|

एफसीआरए का उल्लंघन दंडनीय अपराध है तथा इसके तहत 5 साल तक की कैद की सजा हो सकती है|

चिकित्सकों तथा चिकित्सीय संस्थानों के साथ अनुशंसा तथा अनुबंध

फार्मा कंपनियों द्वारा प्रायोजित तथा धन प्राप्त अनुसंधानों में काम कर रहे भारतीय चिकित्सक एमसीआई नियमों के तहत अनुबंध की शर्तों के अनुसार विशिष्ट परिस्थितियों में अनुसन्धान के परिणामों को प्रकाशित करने का अधिकार रखते हैं| ऐसे प्रावधानों से सामना होने पर कंपनियों को सलाह दी जाती है कि वे अपने बौद्धिक सम्पदा अधिकारों को सुरक्षित रखने के लिए स्थानीय अभिभावक की सलाह लें|

चिकित्सक की किसी सदस्य कंपनी के साथ वास्तविक परामर्श अथवा अन्य वास्तविक सेवाओं हेतु संलग्नता ओपीपीआई कोड के दायरे के बाहर है| चूँकि इसकी उत्पत्ति का स्रोत इंटरनेशनल फेडरेशन ऑफ फार्मास्युटिकल मेन्यूफेक्चरर एंड एसोसिएशन का कोड है, अतः इसी प्रकार के प्रावधानों पर बाहरी देशों में लिए गए फैसलों को अनुबंधों में वास्तविकता की जांच हेतु मार्गदर्शन के तौर पर इस्तेमाल किया जा सकता है|

भारत में कार्यरत कंपनियों के लिए यह आवश्यक है कि उनके मानव संसाधन प्रबंधन में तथा बिक्री कार्यों में ऐसे तंत्र हों जो सुनिश्चित करते हों कि उनके प्रतिनिधि तथा वे कर्मचारी जो प्रचार से जुड़े हुए हैं, मार्केटिंग कोड से भली भांति परिचित हों| इसके साथ ही यह भी महत्वपूर्ण है कि, मार्केटिंग कोड में सम्मिलित गतिविधियों में संलग्न थर्ड पार्टीज़ जो कि कंपनियों के लिए या उनकी ओर से काम करती हों, को मार्केटिंग कोड का बेहतर कार्यानुभव हो|

[21] भाग 11(1), एफसीआरए

ऐसी कम्पनियां, जिनका उनके गृह न्यायिक क्षेत्र में रिश्वत निरोधी कानून जैसे विदेशी भ्रष्ट आचरण अधिनियम, 1977, के तहत प्रकटीकरण दायित्व हो, उन्हें किसी भी भारतीय सहभागी द्वारा पीसीए का उल्लंघन किये जाने की जानकारी लगते ही भारत तथा अपने गृह देश में तुरंत ही न्यायिक सलाह लेना चाहिए| ऐसे प्रकटीकरण करने की समयसीमा तथा उनकी विषयवस्तु का दोनों देशों के न्यायिक तंत्र में सामंजस्य बैठना आसान नहीं है| यदि कंपनियां एक से अधिक देश के एक्सचेंज में सूचीबद्ध हैं तो विभिन्न न्यायिक क्षेत्रों के प्रतिभूति कानूनों के एक सामान निहितार्थ हो सकते हैं|

日本

西垣建剛、立石竜資

医薬・医療機器広告規制

はじめに

以下に述べるとおり、医薬、医療機器業界における広告及びプロモーション活動に対する規制は多岐にわたっている。これらの業界の製品を取り扱う企業は、関連規制の内容を十分に理解する必要がある。

広告

広告規制に関しては、薬事法、適正広告基準、プロモーションコード等の数多くの規制がある。医薬、医療機器を扱う企業は、これらの多岐にわたる法規、規制を遵守する仕組みを構築する必要がある。

昨今、製薬企業によるオフラベルプロモーション（適応外使用に関するプロモーション）の問題が提起されつつあり、業界団体（日本製薬団体連合会等）は、各企業が適正な手続によりこれを規制することを求めている。例えば、日本製薬団体連合会は、プレスリリース、医師との対談記事、疾病啓発広告等の形態をとりながら、適応外情報を提供するケースが散見されると指摘している。製薬企業は、オフラベルプロモーションに関する規制の強化の動きに十分に配慮する必要がある。

プロモーション

プロモーションに関する規制については、医療従事者と製薬・医療機器企業との間の不適切な関係について社会的関心が高まっていることに留意が必要である。このような状況において、製薬、医療機器業界では、自主規制（公正競争規約）を強化してきている。例えば、製薬企業は、医療従事者に提供される飲食や接待の金額を明示する新たなルールを採択しており[1]、医療機器業界も同様の規制を採用している

[1] 医療用医薬品公正競争規約では、講演会等の懇親行事における飲食の提供は2万円以下、医薬情報活動に伴う飲食の提供は5千円以下、説明会に伴う茶菓・弁当の提供は3千円以下と規制される。

Japan

Kengo Nishigaki, Ryosuke Tateishi

Introduction

As stated below, there are multiple regulations which govern advertising and promotional activity in the pharmaceutical drug and medical device industries in Japan. Medical product companies must ensure that they understand the details of these rules and regulations.

Advertising

With regard to advertising regulations, there are a lot of rules, including, but not limited to, the Pharmaceutical Affairs Act, the Advertisement Adequacy Standards and the Promotion Code. Pharmaceutical drug and medical device companies should have adequate procedures to ensure compliance with the multiple rules and regulations.

Off-label promotion by pharmaceutical companies is gradually becoming an issue, and industry groups (e.g., the Japan Federation of Pharmaceutical Organizations ("JFPO")) are requesting that companies establish adequate rules to regulate it. For example, the JFPO has expressed the view that some companies convey off-label information under the pretense of press releases, articles containing interviews with doctors, and disease education advertisements. Pharmaceutical drug companies should heed the current movement to strengthen control of off-label promotion.

Promotional Activities

With regard to promotional regulations, it is worth noting that a great deal of public concern and attention has recently been focused on improper interactions between pharmaceutical or medical device companies and healthcare practitioners ("HCPs"). In order to respond to this severe public concern, the pharmaceutical and medical device industries have been strengthening their self regulatory codes (i.e., the Fair Competition Code). For example, the pharmaceutical industry group has decided to adopt a new rule which stipulates clear limits on the prices of meals and receptions that

[2]。また、いずれの業界も公正競争規約違反に対しては厳格な態度をとるようになってきている。

以上の状況に鑑みると、製薬・医療機器業界の企業は、医療従事者との関係に関する最新の法規、規制の同行について熟知し、社会的非難や信用の失墜という事態を招かないためにも、これらの全ての規制を遵守する必要がある。

規制の概要

関連法規

日本では、医薬品又は医療機器の広告を統一的に規制する法律はなく、以下の個別の法律、ルールによって、広告活動、プロモーション活動が規制されている。

広告に関する一般規制

- 薬事法（誇大広告等の禁止、特定疾病用の医薬品の広告の制限、承認前の広告の禁止）
- 薬事法施行令

広告に関する行政指導

- 医薬品等適正広告基準[3]

医薬品の広告、プロモーションに関する業界自主規制

- 医療用医薬品プロモーションコード[4]（日本製薬工業協会）
- 医療用医薬品製品情報概要記載要領
- 医療用医薬品製造販売業公正競争規約（不当景品類および不当表示防止法第11条に基づき制定）

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[2]医療機器業公正競争規約では、講演会等の懇親行事における飲食の提供は2万円以下、医療機器の情報活動に伴う飲食の提供は1万円以下、説明会に伴う茶菓・弁当の提供は3千円以下と規制される。

[3] 昭和55年10月9日薬発第1339号各都道府県知事あて厚生省薬務局長通知　改正平成14年3月28日医薬発第0328009号

[4]「医療用医薬品プロモーションコード」2008年3月19日改定（2008年5月23日実施）日本製薬工業協会

may be provided to HCPs[1]. The medical device industry group has decided to adopt similar rules[2]. Both industry groups have become more strict in their treatment of violations of the Fair Competition Code.

Given these circumstances, companies involved in these industries should pay keen attention to the latest laws and regulations regarding interactions with HCPs and should abide by every rule in order to avoid public censure and damage to reputation.

The Regulatory Framework

Relevant Regulations

In Japan, there is no law that generally applies in regard to advertising medicines and medical devices. The following laws and rules individually/independently regulate advertising and promotional activities.

General Regulations Regarding Advertising

- The Pharmaceutical Affairs Act (Prohibition on misleading advertising and others, restriction on advertising medicines for specified diseases, prohibition on advertising prior to approval)
- Order for Enforcement of the Pharmaceutical Affairs Act

Administrative Guidance Related to Advertising

- Appropriate Advertising Standards for Pharmaceuticals, etc.[3]

[1] For example, meals provided to HCPs in connection with a lecture must cost less than JPY 20,000, meals provided in connection with the provision of medical information to HCPs must cost less than JPY 5,000 and light meals provided during explanatory meetings must cost less than JPY 3,000 under the new Fair Competition Code rules for the Ethical Pharmaceutical Drug Marketing Industry.
[2] For example, meals provided to HCPs in connection with a lecture must cost less than JPY 20,000, meals in connection with the provision of medical device information to HCPs must cost less than JPY 10,000 and light meals provided during explanatory meetings less than JPY 3,000 under the new Fair Competition Code rules for the Medical Device Industry.
[3] 9 October 1980, *YakuHatsu* No. 1339, Notice by Chief of Pharmaceutical Bureau, Ministry of Health, Labour and Welfare to Governors of all Administrative Division (*todofuken*), Amendment 28 March 2002 *IYakuHatsu* No. 0328009

医療機器の広告、プロモーションに関する業界自主規制

- 医療機器業プロモーションコード[8]（日本医療機器産業連合会）
- 医療機器業公正競争規約（不当景品類および不当表示防止法第11条に基づき制定）

汚職、談合に関する法律

- 刑法
- 独占禁止法
- 国家公務員倫理法
- 国家公務員倫理規程

広告の定義

広告の定義については、厚労省の通達により、(i)顧客を誘引する（顧客の購入意欲を昂進させる）意図が明確であること、(ii)特定医薬品等の商品名が明らかにされていること、(iii)一般人が認知できる状態であることの3つの要件を全て満たす場合に、広告に該当するとの考え方が示されている[6]。

規制概要

医薬品及び医療機器に対する広告についてのルールの骨子は以下のとおりである。

- がん、肉腫、白血病の3疾病に使用されることが目的とされている医薬品であって、政令で指定されているものについては、医薬関係者以外の一般人を対象とする広告が禁止されている（薬事法第67条第1項、薬事法施行令第64条）。
- その他の医薬品、医療機器についても、医師の処方を有するものについては、医薬関係者以外の一般人を対象とする広告は行ってはならない（適正広告基準第3-5）。
- 医薬品又は医療機器の名称、製造方法、効能、効果又は性能に関して、虚偽又は誇大な記事を広告し、記述し、又は流布して

[8]「医療機器業プロモーションコード」2010年6月30日改定（2010年10月1日実施）日本医療機器産業連合会
[6]平成10年9月29日医薬監第148号都道府県衛生主管部（局）長あて厚生省医薬安全局監視指導課長通知

Industry Self-Regulation Related to Advertising and Promotion of Medicines

- Promotion Code of Ethical Pharmaceutical Drugs[4] (Japan Pharmaceutical Manufactures Association)
- Entry Guideline for Outlines of Ethical Pharmaceutical Drugs Information
- Fair Competition Code in Ethical Pharmaceutical Drugs Marketing Industry (Based on Article 11 of the Act against Unjustifiable Premiums and Misleading Representations)

Industry Self-Regulation Related to Advertising and Promotion of Medical Devices

- Promotion Code in the Medical Devices Industry[5] (The Japan Federation of Medical Devices Association)
- Fair Competition Code for the Medical Devices Industry (Based on Article 11 of the Act against Unjustifiable Premiums and Misleading Representations)

Laws Related to Corruption and Bid Rigging

- Penal Code
- Antimonopoly Act
- National Public Service Ethics Act
- National Public Service Ethics Code

Definition of Advertisement

The Ministry of Health, Labour and Welfare has officially given notice that "advertisement" is defined by the following three characteristics: there is a clear intent to stimulate customers' desire to purchase products or services; names of specific pharmaceutical products and the like are clearly revealed; and the general public may perceive it.[6]

[4] Japan Pharmaceutical Manufactures Association, "Promotion Code in Ethical Pharmaceutical Drugs," Amended 19 March 2008 (Implemented 23 May 2008).
[5] The Japan Federation of Medical Devices Association, "Promotion Code in the Medical Devices Industry," Amended 30 June 2010 (Implemented 1 October 2010).
[6] *Iyakukan* Notification No. 148 dated September 29, 1998 issued by Director of Compliance Department, Pharmaceutical and Medical Safety Division, the Ministry of Health and Welfare to health directors of prefectural governments.

はならない。効能、効果又は性能について医師その他の者がこれを保証したものと誤解されるおそれがある記事を広告し、記述し、又は流布することも禁止されている。また、堕胎を暗示し、又はわいせつにわたる文書又は図画を用いてはならない（薬事法66条）。

- 未承認の医薬品の名称、製造方法、効能、効果又は性能に関する広告をしてはならない（薬事法68条）。
- 一般人向け広告、医療療従事者向けプロモーション資料については、プロモーションコード、医療用医薬品製品情報概要記載要領等の自主規制を遵守した表現、内容によらなければならない。

許容される行為、禁止される行為 – 広告

医薬品の広告

医療用医薬品（医師の処方を要するもの）

- 医師の処方を要する医療用医薬品については、一般人向けの広告を行ってはならない。
- 医療従事者向けプロモーション資料については、医療用医薬品プロモーションコードを遵守しなければならない。プロモーションコードの骨子は以下のとおりである。
    - 効能、効果、用法、用量は、承認を受けた範囲を逸脱して記載しない。
    - 有効性、安全性については、虚偽、誇大な表現又は誤解を招く表現を用いない。
    - 有効性に偏ることなく、副作用等の安全性に関する情報も公平に記載する。
    - 他剤との比較は、客観性のあるデータに基づき、原則として一般名称をもって行う。
    - 他社及び他社品を中傷、誹謗した記載をしてはならない。
    - 例外的なデータを取り上げて、これが一般的事実であるかのような印象を与える表現をしない。
    - 誤解を招いたり、医薬品としての品位を損なうような写真、イラスト等を用いない。
    - 品名のみを主体とする広告では、記載事項は、名称（販売名）、薬効分類名（製品タイトル）、規制区分、一般名

General Requirements

The key rules on advertising medicines and medical devices are described below.

- With regard to medicines intended to treat cancer, sarcoma and leukemia and identified by government ordinances (i.e., Enforcement Order of Pharmaceutical Affairs Act), advertisements are only permitted to target medical personnel and not the general public pursuant to Article 67-1 of the Pharmaceutical Affairs Act and Article 64 of the Order for Enforcement of the Pharmaceutical Affairs Act.
- With regard to medicines that require a prescription, advertisements may only target healthcare professionals under the Appropriate Advertising Standards No. 3-5.
- With regard to medical devices that are intended to be used by healthcare professionals and that may cause harm when used by general public, advertisements may only target healthcare professionals under the Appropriate Advertising Standards No. 3-5.
- Article 66 of the Pharmaceutical Affairs Act prohibits advertising, writing or circulating false or misleading articles regarding the name, manufacturing methods, efficacy/effectiveness and nature of any medicines and medical devices. Additionally, Article 66 of the Act prohibits advertising, writing or circulating articles that misleadingly convey that some doctors or healthcare practitioners have certified the efficacy/effectiveness and nature of certain medicines or medical devices. Furthermore, it prohibits the usage of words or pictures that are obscene or suggest abortion.
- Article 68 of the Pharmaceutical Affairs Act prohibits advertising the name, manufacturing methods, efficacy/effectiveness and nature of any unapproved medicines.
- The expressions and contents of advertisements for the general public and promotional materials for medical personnel must follow Promotion Codes, Entry Guideline for Outlines of Ethical Pharmaceutical Drugs Information, and other relevant self-regulations.

称、薬価基準等収載の有無とし、併せて製品に関する資料請求先を明示する。

- 医療用医薬品のプロモーション資料の具体的な記載方法については、製品情報概要記載要領等の自主規範に従い、科学的根拠に基づく正確、公平かつ客観的なものとする。

OTC医薬品の広告

- 一般人向けの広告については、適正広告基準を遵守しなければならない。適正広告基準の骨子は以下のとおりである。
    - 虚偽の表現、不正確な表現を用いて、効能効果又は安全性について事実に反する認識を得させるおそれのある広告をしてはならない。
    - 効能効果又は安全性を摘示し、これが確実である保証をするような表現はしてはならない。
    - 本来の効能効果等とは認められない効能効果を表現することの禁止
    - 過量消費又は乱用助長を促すおそれのある広告をしてはならない。
    - 他社の製品を誹謗するような広告をしてはならない。
    - 医療関係者等が推薦している等の広告は行ってはならない。
    - ゆきすぎた懸賞、賞品等射幸心をそそる方法に拠る広告は行わない。懸賞、賞品として医薬品を授与する旨の広告は原則として行ってはならない。医薬品等の容器、被包等と引き換えに医薬品を授与する旨の広告は行わないものとする。
    - 不快又は不安恐怖の感じを与えるおそれのある表現を用いた広告は行わない。不快や迷惑等の感じを与えるような広告は行わない。
    - 電子メールに拠る広告については、(i)販売業者等の電子メールアドレス等の連絡先を表示する、(ii)消費者の請求または承諾を得ずに一方的に電子メールにより医薬品等の広告を送る場合、メールの件名欄に広告であることを表示する、(iii)消費者が電子メールによる広告の受取を希望しない場合、その旨の意思を表示するための方法を表示し、意思表示を示した者に対しては、電子メールに拠る広告の提供を行わない。

Permitted and Prohibited Practices – Advertisements

Advertisements for Drugs

Ethical Pharmaceutical Drugs (Require a Prescription)

- Advertisements for ethical pharmaceutical drugs that require a prescription are not permitted to target the general public.
- Promotional materials for pharmaceutical professionals must follow the Promotion Code of Ethical Pharmaceutical Drugs. The main points of the Promotion Code are as follows:
    - The expressions of efficacy/effectiveness, nature, dose and dose regimen of drugs shall not go beyond the scope for which approval was obtained.
    - Use of false, excessive or misleading expressions regarding safety and efficacy is not allowed.
    - Along with information on efficacy, information on the side effects and others related to the safety of the drugs must also be noted as well.
    - Comparison with other drugs must be based on objective data, and in principle, should use generic names.
    - Defamation of other companies or their products is not allowed.
    - Giving the wrong impression by conveying exceptional data as if it represents a common fact is not allowed.
    - Use of photographs or illustrations that would mislead and hurt the dignity of the drug is not allowed.
    - Advertisements that are mainly constituted by the name of the product must mention the name (used for distribution), the efficacy classification names, regulatory classifications, generic name, contact information for requests for more informational materials, and whether the advertised drug is covered by the Japanese social health insurance.
- More specific methods of writing promotional materials of ethical pharmaceutical drugs must follow the Entry Guideline for Outlines of Ethical Pharmaceutical Drugs Information and other relevant self-regulations, and must be scientifically objective, fair and accurate.

- テレビ、ラジオの提供番組において、出演者が特定の医薬品等の品質、効能効果等、安全性その他について言及し、又は暗示する行為はしてはならない。また、子供向け提供番組における広告については、誤った認識を与えないよう特に注意をすること。
- 医薬品につき化粧品的若しくは食品的用法、医療機器につき美容器具的、健康危惧的用法を強調して、安易な使用を助長するような広告はしてはならない。
- 医薬品等の品位を損ない、信用を傷つけるおそれのある広告は行わない。

医療機器の広告

- 医師の処方を要する医療機器については、一般人向けの広告を行ってはならない。
- 広告の規制内容は、1. の医薬品と同様である。

許容される行為、禁止される行為 – その他のプロモーション

公務員に対するプロモーション

刑法は、公務員に対する贈賄を禁止する。したがって、医療従事者が公務員に該当する場合（国公立医療機関の医師等）には、医療従事者に対して賄賂を提供することができない。「賄賂」とは、人の需要又は欲望を満たすに足りる一切の利益を指す。また、公務員は、国家公務員倫理法に基づく国家公務員倫理規程および条例等により、利害関係者から利益供与を受けることが禁じられている。例えば、国家公務員倫理規程は、利害関係者と公務員の関係について以下の通り規定する。

- 国家公務員は、利害関係者からの供応接待、利害関係者の遊技又はゴルフ、利害関係者との旅行（公務のための旅行を除く）はできない。
- 国家公務員が例外的に許容されているのは、多数の者が出席する立食パーティーにおける飲食物、職務として出席した会議等における茶菓の提供、職務として出席した会議における簡素な飲食物の提供である。また、贈答品については、宣伝用物品又

Advertisements for OTC Drugs

Advertisements of OTC drugs intended for the general public must follow the Appropriate Advertising Standards for Pharmaceuticals, etc. The main points of the Appropriate Advertising Standards are as follows:

- Advertisement using misleading expressions that may suggest false information regarding the efficacy/effectiveness and safety of the drugs is not allowed.
- Using expressions guaranteeing the efficacy/effectiveness, nature and safety of drugs is prohibited.
- Noting the efficacy/effectiveness, etc., of drugs that is not acknowledged as innate is prohibited.
- Encouraging overdose or abuse of the drugs is prohibited.
- Defaming other companies' products is prohibited.
- Mentioning that medical personnel or another similar professional recommends a product is prohibited.
- Excessive prizes that would appeal to gambling tendencies is prohibited. In principle, advertisements shall not state that medicines are given out as prizes or promotional gifts. Advertisements shall not convey that medicines will be handed out in exchange for containers, wrappers, etc., of drugs.
- Using expressions that may convey discomfort, concern and fear is prohibited. Advertisements shall also not create discomfort, nuisance, etc.
- When advertising through emails:
    - show contact information (email address, etc.) of the distributor, etc., of the drug;
    - the subject line of an email with the advertisement must indicate that it is an advertisement if the email was sent unilaterally without the request or consent of the consumer; and
    - the advertisement email must set forth an option and procedure to refuse further advertisement emails, and such refusal request must be followed.
- In sponsored programs on television or radio, people on the programs may not comment on or suggest certain drugs' quality, efficacy, safety and other related qualities. Advertisements for sponsored programs for children require special attention not to induce wrong perception of the drugs.

は記念品であって広く一般に配布するためのもの、立食パーティーにおける記念品等の提供のみが許容されている。

医療用医薬品製造販売業公正競争規約

医薬品等公正競争規約は、事業者が、医療機関等に対し、医療機器の取引を不当に誘引する手段として景品類を提供することを禁止している。主たる規制は以下の通りである。

贈答

社会的儀礼として行うもの（中元・歳暮、手土産等）は可能である。但し、華美、過大なものは禁止される。記念行事に伴って贈答として記念品を提供することは可能である。また、取り扱う製品の「販売〇周年記念」等のように、製品に直接関係する記念行事に伴って提供する記念品の価額は、5,000円を超えない額を目安とする。講演会（自社製品を説明するものに限る）において、参加者に贈呈品を提供することは可能であるが、この場合の贈呈品は、参加者1名当たり3,000円以内を目安とする。

試用製品

試用品は、(i)形状見本として、医療担当者が外観的特性について確認することを目的とするもの、(ii)品質、有効性、安全性について評価するために臨床試用することを目的とするもののいずれかの場合以外には提供してはならず、必ず当該使用製品に関する情報提供を伴う必要がある。

提供する量は、形状見本又は臨床試用見本のために必要な最小限度の量とする（公正競争規約に具体的な数量が定められている）。また、反復提供はしてはならず、既に採用している医療機関に対しては提供してはならない。娯楽、会食

接待（商談、会議等を円滑に進行させるために副次的に行うもの）の範囲のものは可能であるが、娯楽や飲食物の提供自体を目的とし、接待の範囲を超えるものは制限される。また、華美、過大な娯楽は制限される。また、社会的儀礼としての親睦や慰労等の娯楽、会食は可能であるが、華美、過大な娯楽となってはならない。

- Advertisements should not encourage relaxed usage of medicines by emphasizing the methods of cosmetic use or consumption as foodstuff, or methods of using medical equipment as cosmetic equipment or health equipment.
- Advertising that significantly lacks integrity or misleads as to the nature of medicines is prohibited.

Advertisements for Medical Devices

If the medical device is intended to be used by healthcare professionals and may cause harm when used by the general public, then it shall not be advertised to the general public.

Applicable regulations are the same as that of medicines (as described above).

Permitted and Prohibited Practices – Other Promotion

Promotion to National Public Servants

The Penal Code prohibits bribing government employees. If a healthcare professional is a government employee (e.g. a doctor at a national hospital), a bribe cannot be given to that medical personnel. A "bribe" is defined as a certain amount of benefit that may satisfy one's need or desire.

Furthermore, pursuant to the National Public Service Act, the National Public Service Officials Ethics Code and relevant regulations prohibit national public servants from receiving benefits from stakeholders. For example, the National Public Service Officials Ethics Code regulates the relationship between stakeholders and national public servant as follows:

- National public servants are not permitted to attend receptions, games, golf, or trips (unless for official business) with stakeholders.
- As an exception, national public servants may be provided with meals in buffet meetings and refreshments at meetings for official business. Also, national public servants may accept promotional samples and commemorative gifts that are widely distributed to the public as gifts.

なお、医薬品については、公正競争規約が改正される見込みである。改正案によれば、(i)講演会等の懇親行事における飲食の提供は2万円以下、MRによる自社製品の説明会に伴う茶菓、弁当は3,000円以下、研究委託に関する会議、講演会の企画に関する世話人会等における飲食の提供は2万円以下、社内研修会の講師に対する飲食の提供は2万円以下、医薬情報活動に伴う飲食の提供は5,000円以下とされている。

寄付

公益目的のために行う寄付は可能である。公益目的とは、営利を目的とせず、広く社会一般の利益を目的とする場合を指す。医療担当者の個人的な研究や院内の通常の業務の範囲内のものは公益目的には該当しない。

以下の行為は、医療機器の取引を不当に誘引する手段であり、禁止されている。

- 医療機関等が自ら支出すべき費用を肩代わりすること（物品の購入、施設の増改築、経営資金の補填その他医療機関等自身の利益のための使用に充てられる場合）
- 医療機関が行う通常の医療業務に対する金品の提供
- 事業者の利益が約束されている場合
- 社会通念を超えて過大となるような金銭の提供、
- 寄付を強制的に割り当てる要請に対し、取引への影響を考慮して応じること。

自社製品に関する講演会

講演会の会場、その他開催方法は、招待旅行または供応と誤解されないようにしなければならない。自社製品の説明という目的にふさわしい開催地、会場、開催時期、スケジュールで行わなければならない。講演会に付随する華美、過大にわたらない接待（同じ会場における立食パーティ）は可能である。

許される出席費用の支払は、次のとおりである。

- 講師等に対しては、社会通念上妥当な範囲の報酬・費用
- 講師以外の出席者に対しては、必要最小限の旅費

Fair Competition Code in Ethical Pharmaceutical Drugs Marketing Industry

The Fair Competition Code in Ethical Pharmaceutical Drugs Marketing Industry prohibits marketers from offering premiums to medical institutions, etc., that unjustifiably induce transactions of medical devices. Primary regulations are described below.

Gifts

Gifts given as social courtesy (mid-year and year-end gifts, calling gifts, etc.) are permitted; however, any lavish, extravagant gifts are prohibited. Marketers may provide commemorative gifts at a memorial event. The monetary value of such gifts given at a memorial event that is directly related to a company's own medical device, e.g., a gift commemorating the anniversary event of the launch of particular medical device, should generally not exceed JPY5,000 to be considered appropriate. Goods distributed to the attendees of lecture meetings (held strictly for the purpose of offering guidance on the use of a particular medical devices) may be permitted. In this context, gifts with a monetary value of JPY3,000 or less are generally considered appropriate.

Drug Samples

Drug samples may be offered free of charge only if they are in accordance with the following purposes:

- Presentation samples to enable healthcare professionals to confirm the outward characteristics of the relevant ethical pharmaceutical drugs.
- Clinical testing samples to enable physicians to confirm and evaluate the quality, efficacy and safety of the drugs.

Drug samples shall always be accompanied by information on the relevant ethical pharmaceutical drug. The quantity offered shall be the necessary minimum in accordance with the purpose of presentation or clinical testing samples. The Fair Competition Code provides specific amounts that constitute "the necessary minimum." Moreover, the samples shall not be recurrently offered or offered to medical institutions that have already adopted the relevant ethical pharmaceutical drugs.

医療機器業公正競争規約

贈答、試用製品、娯楽・会食、寄付、講演会についての規制は2. と同様である。その他、医療機器業公正競争規約では、医療機器特有の以下の規制がある。

貸し出し

医療機関等に対する費用の肩代わりになる医療機器の貸し出しは禁止されている。また、以下の貸し出しは、原則として制限されないが、基準が定められている。

- デモのための貸し出しは1ヶ月以内。同一医療機器の同一診療科に対する貸し出しは1回まで。
- 試用のための貸し出しは6ヶ月以内。同一医療機器の同一診療科に対する貸し出しは1回まで。
- 研究目的の貸し出しは、12ヶ月以内。
- 事故、故障対応の貸し出しは、保証期間終了後又は通常修理に要する期間を超えて貸し出すことはできない。
- 研修のための貸し出しは1ヶ月以内

立会い

立会いとは、医療現場に立ち会って、医療機器に関する情報提供や便益労務の提供を行うことを指すが、医療機器の販売を目的とした立会い及び医療機関等に対する費用の肩代わりになる立会いは禁止されている。他方、自社製品の適正使用の確保のため、添付文書等の記載内容を補足的に説明するための立会い、自社の取り扱う医療機器の安全試用のために行う立会いについては、原則として制限されないが、規約の定める基準を超えて無償で行うことは、不当な取引誘引行為として禁止される。

公共入札

国、地方公共団体、独立行政法人の契約は原則として一般競争入札によらなければならないとされている。したがって、国公立病院（国公立大学付属病院を含む）の製品の調達は入札によって行われることになる。

Entertainments and Meals

Entertainment and meals offered as a form of reception (provided for facilitating communication amongst the attendees of commercial negotiations or meetings) are permitted; entertainment and meals provided solely for leisure pursuits and dining opportunities that are beyond the scope of such as reception (as described above) are prohibited. Furthermore, lavish and extravagant recreational activities and meals are prohibited. Recreational activities such as social gatherings and dining and other meals offered as social courtesy are permitted if not lavish and extravagant.

In regard to ethical pharmaceutical drugs, the Fair Competition Code likely will be amended as follows:

- Meals offered at a lecture meeting or other social event shall not exceed JPY20,000.
- Lunch boxes (bento) and snacks offered at a product explanatory promotion conducted by MR shall not exceed JPY3,000.
- Meals offered at a meeting for organizers to plan a lecture meeting, held in relation to the entrustment of research, etc., shall not exceed JPY20,000.
- Meals offered to a speaker who was invited to an in-house study group shall not exceed JPY20,000.
- Meals that go with a product explanatory activity shall no exceed JPY5,000.

Donations

Donations for the purpose of serving the public interest are generally permitted. Such donations should be made to serve the interests of society as a whole, and should not be made for commercial purposes. Donations made for the purposes of funding a health care provider's individual research or a medical institution's ordinary services are not considered as donations made for the purposes of serving the public interest and are therefore prohibited.

The following are considered as means of unjustifiably inducing transactions, and are prohibited:

- Donations in the form of an agreement to assume expenses to be disbursed by medical institutions (for purposes of purchasing goods, renovating facilities, supplementing administrative funds or otherwise used to serve the interest of the medical institution receiving the donation)

- 入札における談合は禁止されている。入札参加者間で、共通の意思に拠る共同行為、相互拘束があり、競争の実質的制限がある場合は、不当な取引制限となる（独占禁止法）。また、公正な価格を害し、又は不正な利益を目的で談合する場合には、刑法の談合罪も成立する。
- 入札の便宜を受けるために公務員に賄賂を提供する行為は、刑法の贈賄罪に該当する。

違反に対する制裁

薬事法違反

薬事法違反については罰則があり、第66条（誇大広告等の禁止）違反及び第68条（承認前の広告の禁止）違反については2年以下の懲役又は200万円以下の罰金、第67条（特定疾病用の医薬品の広告の制限）違反については、1年以下の懲役又は100万円以下の罰金が課される。

刑法の贈賄罪

贈賄罪については、3年以下の懲役または250万円以下の罰金。談合罪については、2年以下の懲役または250万円以下の罰金

独占禁止法

不当な取引制限については、個人は5年以下の懲役又は500万円以下の罰金、法人に対しては5億円以下の罰金

適正広告基準

適正広告基準は行政指導によるものであり、これに対する罰則はない。

プロモーションコード

医療用医薬品プロモーションコードの違反に対しては、以下の措置がとられる可能性がある。

- コード違反の程度に応じて、「改善勧告」、「警告」または「厳重警告」の措置がとられる。
- 日本製薬工業協会からの除名、会員資格停止などの措置もとられる。

Offering of cash (or other value) in consideration of ordinary medical practices conducted by the medical institution
- Cases where it has been promised that marketers will receive advantageous treatment in return for donations
- Donations that are deemed excessive from standards of social acceptability
- Cases where a marketer was induced to give donations in consideration of possible consequences on future transactions

Lecture Meeting or Seminar About Product

The place, facility and other means of holding such meeting must not represent an invited trip or entertainment. The place, facility, date and schedule shall not depart from the purpose of a lecture meeting held to explain the offerer's products. Reception must neither lavish nor excessive, e.g. a buffet meeting, held in connection with the meeting is permitted.

Permitted payments for the cost of attending the meetings are as follows:

- Fees and expenses may be offered to a speaker if they are deemed appropriate by standards of social acceptability.
- The necessary minimum travel expenses may be offered to a non-speaker.

Fair Competition Code for the Medical Devices Industry

Gifts, samples, entertainment/meals, donations, and lecture meetings are regulated in the same manner as pharmaceuticals, above. In addition, the Fair Competition Code for the Medical Devices Industry provides regulations specifically for medical devices.

Lending

Medical devices shall not be loaned to assume expenses to be disbursed by medical institutions. Described below are the standards (not regulations) on lending medical devices:

- Lending for demonstration shall not exceed one month. The same medical device may be loaned to the same hospital department only once.
- Lending for trial use shall not exceed six months. The same medical device may be loaned to the same hospital department only once.

医療機器業プロモーションコードについては、企業倫理委員会が医機連内部での公表を含めて是正案を決定するとされている。

公正競争規約

医療用医薬品製造販売業公正競争規約、、公正取引協議会は、警告（排除措置を採るべき旨、同種又は類似の違反行為を再び行ってはならない旨等を文書で警告）することができ、警告を受けた事業者がこれに従っていない場合は、100万円の違約金、又は除名処分をし、公正取引委員会に必要な措置を講ずるよう求めることができる。また、公正取引協議会は以上の警告、違約金、除名処分のいずれかを行った場合は、公正取引委員会に報告する。

医療機器業公正競争規約の違反も同様である。

医療従事者及び医療機関との契約

市販後調査（PMS）、研究委託等、医療機関及び医療担当者の契約については、公正競争規約の規制の適用がある。

医療用医薬品製造販売業公正競争規約

- 依頼したPMS、研究委託が名目に過ぎず、実態は不当な取引誘引であれば制限される。
- 症例報告の報酬は、過大にわたらない範囲（通常は1症例あたり1万円）でなければならない。
- 調査、研究の委託に際しては、書面に拠る契約を締結し、委託の趣旨に合った調査、研究成果等の報告書を受領しなければならない。
- 医療機関に勤務する医療担当者個人に対する調査、研究委託については、医療機関が医療担当者にそのような研究を許容していることが必要である。

- Lending for research purpose shall not exceed 12 months.
- Lending in response to accidents and malfunctions shall not exceed the warranty period or the time it that would normally take to fix the device.
- Lending for training shall not exceed one month.

Attendance ("Tachiai")

"Attendance" refers to visiting a medical institution to offer labor benefits and information regarding the medical devices. However, attending with the intent to sell medical devices and assume expenses to be disbursed by medical institutions is not permitted. In principle, attendance is permitted to ensure the safe operation of medical devices or offer supplemental explanations to the content of package inserts, etc. However, the attendance offered for free beyond the provided standard of the Code is prohibited as it falls within the scope of unjustifiably inducing transactions.

Public Procurement and Fraud

In principle, contracts for the state, local governments and incorporated administrative agencies must employ general competitive bidding. Thus, general competitive bidding is employed in national public hospitals (including national university hospitals) to purchase supplies.

- Bid rigging is prohibited. Under the Antimonopoly Act, a concerted action with shared intent among the bidders with mutual restraints and actually restricts competition constitutes unjust restraint on trade. Moreover, the Penal Code crime of offering of bribes applies to bid rigging with the purpose of unjustly gaining profit or affecting fair price.
- An act of offering a bribe to a national public servant in order to acquire inclusion in the bid constitutes the crime of offering of bribes in the Penal Code.

Consequences of Breach

Breach of the Pharmaceutical Affairs Act

A breach of Article 66 (prohibition of misleading advertisements) or Article 68 (prohibition of advertisements prior to approval) of the Act shall be punished by imprisonment with work for not more than two years, or a fine of not more than JPY2,000,000.

上記と同様である。

留意点

広告、プロモーション活動を行うに際しての留意点は以下の点である。

- 広告規制（薬事法、適正広告基準、プロモーションコード、製品情報概要記載要領等）を遵守するための体制を確保する。
- 疾病啓発広告、患者会への情報提供、市民公開講座などによる一般人向け情報提供の内容に注意し、広告規制を遵守する。
- 適応外使用情報の提供範囲について、内部ルールを策定する。
- 汚職防止体制を構築する。その際には、代理店、エージェント等の第三者との契約対応、トレーニング等、サプライチェーン全体での体制構築を行う。
- 医療従事者に対する接待、贈答、会食等に関する社内規定の整備。
- 医療機関、医療従事者等に対する寄付の実施に関する社内体制の整備。
- 医療従事者等とのPMS、研究委託契約の実施に関する社内体制の整備。

A breach of Article 67 (restriction on advertising medicines for specified diseases) Act shall be punished by imprisonment with work for not more than one year, or a fine of not more than JPY1,000,000.

Crime of Offering of Bribes in the Penal Code

The crime of offering of bribes is punishable by imprisonment with work for not more than three years, or a fine of not more than JPY2,500,000. A crime of bid rigging is punishable by imprisonment with work for not more than three years, or a fine of not more than JPY2,500,000.

Antimonopoly Act

An unjust restriction on a transaction shall be punished by imprisonment with work for not more than five years or a fine of not more than JPY5,000,000 for an individual, and a fine of not more than JPY500,000,000 for a company.

Appropriate Advertising Standards

The Appropriate Advertising Standards are administrative guidance, which means that there are no penal provisions.

Promotion Code

Companies that breach the Promotion Code of Ethical Pharmaceutical Drugs may face the following measures:

- "Recommendation for improvement," "warning" or "severe warning" may be given depending on the degree of breach.
- Dismissal or suspension of membership from the Japan Pharmaceutical Manufactures Association.

The Promotion Code in the Medical Devices Industry corporate ethics committee in the Japan Federation of Medical Devices Association will decide on an appropriate correction plan that may include announcing the breach within the association.

Fair Competition Code

For a breach of the Fair Competition Code in the Ethical Pharmaceutical Drugs Marketing Industry, the Fair Trade Counsel of the Fair Competition Code may warn the offender in writing, such as through a cease and desist order, not to repeat the same or similar breach, etc. The marketer who fails to comply with the warning shall be liable to a penalty charge of not more than JPY1,000,000 or dismissal from the Fair Trade Counsel. Furthermore, the Fair Trade Counsel then may ask the Japan Fair Trade Commission to implement necessary remedial measures. If the Counsel conducts any of the measures listed above (warning, penalty charge, or dismissal), then it must file a report with the Japan Fair Trade Commission.

A breach of the Fair Competition Code in the Medical Devices Industry is treated in the same manner as above.

Contracts with Healthcare Professionals and Medical Institutions

Contracts with healthcare professionals and medical institutions in post-marketing surveillance ("PMS"), entrustment of research, etc., are subject to the regulations of the Fair Competition Codes.

Fair Competition Code in the Ethical Pharmaceutical Drugs Marketing Industry

- PMSs or entrustments of research that are mere pretexts and actually correspond to means of unjustifiably inducing transactions of the offerer's pharmaceutical drugs, are restricted under the Code.
- The amount of remuneration for a case report must not exceed the limit beyond which the remuneration corresponds to a means of unjustifiably inducing transactions. Normally, the total amount of remuneration shall not exceed JPY10,000.
- Requests for entrustments of surveillances and research shall basically be agreed with the medical institution in writing, and reports of the results of the requested surveillances and researches must also be received in writing.
- Entrustment of surveillance and research to a specific healthcare professional in a medical institution requires the permission from the medical institution to participate in such researches.

Fair Competition Code in the Medical Devices Industry

Same as pharmaceuticals, above.

Recommendations

The following considerations should be noted in conducting advertising and promotional activities:

- Establish a structure to follow the relevant advertising regulations (the Pharmaceutical Affairs Act, the Appropriate Advertising Standards for Pharmaceutical Affairs Act, Promotion Codes, the Entry Guidance for Outlines of Ethical Pharmaceutical Drugs Information, etc.).
- Pay attention to information offered to the general public in disease education activities, provisions of information to patient groups and open public seminars in order to follow the relevant advertising regulations.
- Formulate internal rules on the scope of providing off-label use information.
- Establish a corruption prevention policy. Such policy must encompass relationships with third parties (such as distributors, agents and consultants), including executing contracts containing adequate anti-bribery clauses as well as provide anti-corruption training.
- Provide internal rules related to offering receptions, gifts, meals, etc., to health care professionals.
- Provide internal rules related to offering donations to medical institutions, health care professionals, etc.
- Provide internal rules related to making PMSs and entrustments of research contracts with health care professionals, etc.

Malaysia

Kherk Ying Chew

Introduction

In Malaysia, the advertising and promotion of medical products is generally regulated by legislation and industry codes.

The main legislation which govern the advertising and promotion of medical products are as follows:

- Medicines (Advertisement and Sale) Act 1956
- Medical Device Act 2012 (yet to be in force)

The industry codes which govern the advertising of medical products are as follows:

- Codes of conduct issued and administered by the Pharmaceutical Association of Malaysia ("PhAMA")
- Code of Conduct for Non Prescription (OTC) Products ("the OTC Code") by PhAMA
- General advertising industry codes

Regulatory Framework

The Medicines (Advertisement and Sale) Act 1956 ("MASA 1956") is the primary legislation governing the advertising of medical products in Malaysia. The newly-introduced Medical Devices Act 2012 ("MDA 2012") seeks to implement a regulatory framework for medical devices which includes the introduction of the requirement to register medical devices as well as regulation of advertisements relating to medical devices.

Advertisements relating to medical products fall under the purview of the Medicine Advertisement Board ("MAB"), an agency of the Pharmaceutical Services Division of the Ministry of Health. A Guideline on Medical Products and Appliances ("Guidelines") issued by the MAB, provides further guidance on the provisions of MASA 1956.

The term "advertisement" is broadly defined to include any notice, circular, report, commentary, pamphlet, label, wrapper or other document, and any announcement made orally or by any means of producing or transmitting light or sound.

Permitted and Prohibited Practices

MASA 1956 imposes the following restrictions on the advertising of medical products:

- Publication of any advertisement referring to a medical product or a medical device must be evaluated and approved by the MAB.
- Advertisements relating to medical products for specified purpose, diagnosis, prevention or treatment of specified diseases or controlled medical products are strictly prohibited.

Both MASA 1956 and the Guidelines set out the types of diseases in which advertisements for medical products relating to such diseases will be prohibited.

Specified Disease

Section 3 of MASA 1956 generally prohibits advertisements for any article calculated to be used as a medicine for the treatment, prevention or diagnosis of the following diseases or conditions:

- Diseases or defects of the kidney
- Diseases or defects of the heart
- Diabetes
- Epilepsy or fits
- Paralysis
- Tuberculosis
- Asthma
- Leprosy
- Cancer
- Deafness
- Drug Addiction
- Hernia or rupture
- Diseases of the eye
- Hypertension
- Mental disorder
- Infertility
- Frigidity
- Impairment of the sexual function or impotency
- Venereal disease
- Nervous debility, or other complaint or infirmity, arising from or relating to sexual intercourse

Specified Purposes

Advertisement of certain pharmaceutical products is prohibited. This includes pharmaceutical products that are used to practice contraception among human beings; improve the condition or functioning of the human kidney or heart; improve the sexual function or sexual performance of human beings;

procure the miscarriage of women; and in relation to disease and conditions specified in the schedule to the Act. Advertisement is relating to skill and service are also prohibited under the Act.

Controlled Medicine or Poison

The Guidelines introduced in 2009 prohibit the advertisement of controlled medicine, poison and products containing poison pursuant to Schedule 1 of the Malaysian Poison Act 1952, unless it is specifically exempted. Although the advertisement of a pharmaceutical product may include prescription drug terms, such advertisements will be prohibited if the substance of the prescription drug is classified as a 'poison' under Schedule 1 of the Malaysian Poison Act 1952. Examples include Botox and Viagra.

Consequences of Breach

For first conviction: a fine not exceeding MYR3,000; imprisonment for any term not exceeding one year; or both.

For subsequent conviction: a fine not exceeding MYR5,000; imprisonment for a term not exceeding two years, or both.

Defenses

MASA 1956 prescribes the following defenses which could be raised by a defendant in any proceedings for any breach of the abovementioned restrictions:

- The advertisement to which the proceedings relate was published in such circumstances that he did not know and had no reason to believe that he was taking part in the publication thereof.
- The said advertisement was published only in a publication of a technical character intended for circulation mainly among persons of the following classes, or one or some of them, that is to say: registered medical practitioners; registered dentists; registered nurses and midwives; registered pharmacists, chemists and wholesalers and retailers of poisons; or persons undergoing training with a view to becoming registered medical practitioners, registered dentists, registered nurses, or registered pharmacists or chemists.

Advertising Guidelines

In the issuance of an approval for any advertisement relating to a medical product, the MAB requires an applicant to ensure that the advertisement which it seeks to publish to the public complies with the Guidelines.

The main objective of the Guidelines are to ensure responsible advertising in promoting the sale of medicines, appliances or remedies which may be purchased by the public without prescription and for which medical claims are made. In this regard, the Guidelines expressly state that the advertisements to the general public ought to achieve the following objectives:

- Help people make rational decisions on the use of medicines, appliances, and remedies determined to be legally available without a prescription
- Take into account people's legitimate desire for information regarding their health
- Not take undue advantage of people's concern for their health

General Requirements

The general regulatory framework on the advertising and promotion of pharmaceutical products as stipulated by the Guidelines can be summarized as follows:

- Advertisements on medical products should contain information that is reliable, accurate, truthful, informative, balanced, up-to-date, capable of substantiation and in good taste.
- Advertisements should not contain any misleading or unverifiable information or omissions which are likely to induce medically unjustifiable use or to give rise to undue risks.
- An advertisement should not contain any statement which either expressly or by implication disparages either the medical profession or the value of professional attention and treatment or another product, and not should not discredit or unfairly attack other products, advertisers or advertisements directly or by implication.

Notwithstanding the above, the Guidelines issued by the MAB also specifically prohibit the following types of advertisements:

- relating to prevention, diagnosis or treatment of the diseases and condition of human beings as specified in the Schedule to The Medicines (Advertisement & Sales) Act 1956
- relating to practicing of contraception among human beings
- on improving of the condition or functioning of the human kidney or heart, or improving the sexual function or sexual performance of human beings
- relating to procuring the miscarriage of women
- which have any visual and/or audio presentation of doctors, dentists, pharmacists, scientists, nurses and other paramedics which give the impression of professional or scientific advice, recommendation or endorsement
- which contain statements or visual presentation which are contrary or offensive to the standard of morality or decency or in any way defamatory or humiliating to any segment of the public
- which are framed to abuse the trust of the customer, induce fear, and play on superstition or exploit the superstitious
- which contain anything that support acts of violence or illegal activities
- which show or refer to dangerous practices or manifest a disregard for safety
- which contain anything that might harm children or young people physically, mentally morally or which exploit their credulity, their lack of experience or their natural sense of loyalty

Professional Codes of Conduct

The codes of conduct regulating advertising and promotion of medical products include:

- Code of Pharmaceutical Marketing Practices for Prescription (Ethical) Products ("PhAMA Code") by PhAMA
- The OTC Code by PhAMA
- Code of Medical Ethics issued by the Malaysian Medical Association
- General advertising codes which include the Code of Advertising Practice ("Advertising Code") and the Communications and Multimedia Content Code ("Content Code")

The PhAMA Code sets out the standards with which its members are required to comply to ensure ethical promotion of pharmaceutical products to healthcare professionals, and that member companies' interactions with healthcare professionals are appropriate and perceived as such.

The OTC Code is separately administered by PhAMA to regulate over-the-counter products used in self-medication to treat ailments which do not require a doctor's prescription. The OTC Code is more focused on the interaction of pharmaceutical companies with the consumers through advertisements.

The Malaysian Advertising Standards Authority and the Communications and Multimedia Content Forum have also issued general industry guidelines in the form of the Advertising Code and the Content Code, respectively. The Advertising Code governs print advertisements while the Content Code governs advertisements via electronic means.

Definition

Under the PhAMA Code, "pharmaceutical product" is defined as any pharmaceutical or biological product (irrespective of whether the product is patented and/or whether it is branded) which is intended to be used by prescription of, or under the supervision of, a healthcare professional, and which is intended for use in the diagnosis, treatment or prevention of disease in humans, or to affect the structure or any function of the human body.

"Healthcare professional" on the other hand, is defined as any member of the medical, dental, pharmacy or nursing professions, or any other person who in the course of his or her professional activities may prescribe, recommend, purchase, supply or administer a pharmaceutical product.

Permitted and Prohibited Practices

The codes of conduct are issued by different regulatory bodies, although the specific guidelines provided therein are similar to one another and to those provided in the Guidelines. In essence, the general principles governing advertising and promoting pharmaceutical products can be summarized as follows:

Content of the Advertisements and Promotional Materials

- Promotional materials for pharmaceutical products should be accurate, fair and objective, and presented in such a way to conform not only to legal requirements but to high ethical standards and good taste.
- Information provided on the promotional materials or on the pharmaceutical products must be capable of being substantiated based on clinical and pharmacological evidence from properly conducted investigations and based on up-to-date evaluation of the product.

- Information provided to medical professionals on the pharmaceutical products should be based on latest references (preferably less than five years).
- No advertisement shall contain exaggerated or all-embracing claims, direct or implied, and superlatives must not be used unless based on substantial scientific evidence and other responsible medical opinion.
- Advertisements for medical products should not refer to any skill or service relating to the treatment of any ailment, disease, injury or condition affecting the human body so as to induce any person to seek the advice of the advertiser.
- Advertisements should not contain any statement or illustration which is likely to induce fear on the part of reader, viewer or listener.
- Advertisement materials disseminated to the public must not include anything which offends good taste or decency, is offensive to public feeling, likely to encourage crime or lead to disorder, or is abusive or threatening in nature.
- Members of the medical, pharmaceutical, dental or related professions should not be depicted in any illustration of a product in such a way to suggest professional advice or recommendation.
- Claims in advertisements must not state categorically that a product has no side effects or toxic hazards, or does not pose risk of addiction.

Methods of Promotion

- Promotion or marketing methods must not incite unfavorable comments or bring discredit upon, or reduce confidence in the pharmaceutical industry.

Prizes, Inducements and Independence of Healthcare Professionals

- Interactions between pharmaceutical companies and healthcare professionals should be focused on information about products, providing scientific and educational information, and supporting medical research and education.
- Pharmaceutical companies are prohibited from organizing any prize competition which is likely to stimulate unnecessarily the use of OTC pharmaceutical products.
- The Code of Medical Ethics expressly states that any collusion between doctors and pharmaceutical chemists for financial gain is reprehensible. The code goes so far as to state that a doctor is prohibited from making arrangement with a chemist for the payment of commission, and from holding, a financial interest in a chemist's shop

in the area of his practice, and from giving professional cards to chemists for further distribution. It is deemed undesirable for messages for a doctor to be received and left at a chemist's shop.

- Similarly, with regard to prescribed medical products, any financial benefit or benefit-in-kind that may be provided or offered to a healthcare professional in exchange for prescribing, recommending, purchasing, supplying or administering products, or for a commitment to continue to do so is strictly prohibited under the industry codes.

Gifts

- Payments in cash or cash equivalents, including gift certificates, gifts for personal benefit such as tickets to sporting or entertainment events and electronic items to healthcare professionals are prohibited, as are stand-alone entertainment or other leisure or social activities.
- Items of medical utility which are of modest value (not exceeding MYR500 or approximately USD156) and are beneficial to the provision of medical services and for patient care are allowed.
- Educational medical material such as journals, textbooks and models not exceeding a limit of MYR1000 (approximately USD312) are allowed. Although items of medical utility are appropriate, these items should not be offered on more than an occasional basis.
- Inexpensive gifts as a cultural courtesy with a monetary limit of MYR100 (approximately USD33) may be given on an infrequent basis to healthcare professionals in acknowledgement of significant national, cultural or religious occasions.
- Promotional aids (whether related to a particular product or of general utility) may be distributed provided it is of small value (not more than MYR100) and relevant to the practice of medicine or pharmacy, or for the benefit of patient care. Promotional aids are items of insignificant and minimal value related to the work of the recipient healthcare professional. Examples of such items are pens, notepads and surgical gloves. Promotional items intended for the personal benefit of the healthcare professional such as music CDs, paintings or food baskets would not be acceptable under the codes.

Sponsorships / Donation

- Sponsorships for an association or organization's social events (such as annual dinner or family day) are generally not allowed.
- Monetary donations to a hospital's social event are not allowed even if no promotional activities are carried out at the event.

- Inappropriate financial benefits to healthcare professionals to influence them to prescribe pharmaceutical products must not be offered.
- Support for charitable events organized by health societies or donations for charitable events where the proceeds benefit patients is allowed.
- Corporate advertisements (but not product promotion) of pharmaceutical companies placed in souvenir programs of medical societies' social events is allowed.
- Sponsorships for healthcare professionals to attend symposiums, congresses or other medical/healthcare or educational programs are permitted, provided that they are not conditional upon an obligation to prescribe and recommend any pharmaceutical product.
- Subject to limited sponsorships for travel, meals, registration fee, accommodation and entertainment, no payments should be made to compensate the healthcare professional for time spent in attending the sponsored event/program or to cover the cost of an accompanying guest or spouse.
- For overseas scientific meetings, sponsorship by pharmaceutical companies should be limited to basic economy travel (if travel time is less than six hours), meals, lodging and registration fee.

"Kind Discounts" to Healthcare Providers

- Kind discounts or gifts may include gift certificates, tickets to sporting events or concerts, travel vouchers or sponsorship for events (e.g., annual dinner).
- Kind discounts provided to healthcare providers who have achieved the sales target set by the pharmaceutical company are strictly prohibited.
- Kind discounts provided to healthcare providers who have agreed to purchase products from the pharmaceutical company are prohibited.

Consequences of Breach

PhAMA Code and the OTC Code

A pharmaceutical company would be bound by the PhAMA Code and the OTC Code if it is a member of PhAMA.

A member's non-compliance with the PhAMA Code and the OTC Code may result in a penalty of up to MYR50,000 (approximately USD15,625). Breach of the PhAMA Code and the OTC Code would also likely result in adverse publicity as names of companies which are the subject of complaints will be published.

The Advertising Code

There are no legal sanctions for breach. The sanctions are principally the withholding of advertising space from advertisers and the withdrawal of trading privileges from advertisers/ advertising agencies. Both sanctions are applied by the media.

There is possibility of adverse publicity if there is a breach. The Advertising Standards Authority Malaysia may publish details of the outcome of any investigation it has undertaken.

The Content Code

The Malaysian Communications and Multimedia Commission ("MCMC") has the power to direct any person to adhere to the Content Code.

Breach of the Content Code may result in various sanctions, including fines of up to MYR50,000 (approximately USD15,625) and other penalties (but not including imprisonment), which may be imposed by the Complaints Bureau.

Any person who fails to adhere to the direction issued by MCMC to comply with the Content Code is subject to a fine of up to MYR200,000 (approximately USD62,500).

Criminal and Civil Liability

Public Procurement Policies and Fraud

The Malaysian government provides a procurement regime ("Government Procurement Policies") which regulates the acquisition of government contracts in relation to works, supplies and services. As public hospitals in Malaysia are established by the federal government, any work, supply and services contract that is entered into by public hospitals is governed by the Government Procurement Policies.

Under the Government Procurement Policies, all individuals, companies or corporate bodies intending to participate in government procurement are required to undergo a registration process. However, if the procurement of supplies and services is of a value of up to MYR50,000 (approximately USD15,625) and is directly through an order issued by the government, the requirement of registration is waived.

The Government Procurement Policies are essentially based on five main principles, namely: public accountability; transparency; value for money; open and fair competition; and fair dealing.

Pharmaceutical companies dealing with public hospitals must adhere to the principles of the Government Procurement Policies. Any bribery or corruption by pharmaceutical companies would be in contravention of these principles.

Penalties

The government could also take disciplinary action and impose penalties on contractors who are in breach of the Government Procurement Polices. Penalties are imposed according to the seriousness of the deviations, ranging from warning, suspension of registration (if any) for a maximum period of five years, to blacklisting of the company from conducting further business with any government ministry, department or agency.

Malaysian Anti-Corruption Commission Act 2009

Malaysia anti-bribery law is provided under the Anti-Corruption Commission Act 2009 ("MACC").

The definition of gratification under the MACC has been defined widely to include:

- money, donation, gift, loan, fee, reward, valuable security, property or interest in property being property of any description whether movable or immovable, or any other similar advantage;
- any office, dignity, employment, contract of employment or services, and any agreement to give employment or render services in any capacity;
- any payment, release, discharge or liquidation of any loan, obligation or other liability, whether in whole or in part; and
- any valuable consideration of any kind, any discount, commission, rebate, bonus, deduction or percentage.

Private Hospitals

It is an offense to corruptly give, promise or offer to any person any gratification as an inducement to or a reward for doing or forbearing to do anything in respect of any matter or transaction, actual or proposed or likely to take place.

The offense of giving or accepting gratification under the MACC extends to acts conducted by an agent which includes any person employed by or acting for another; an officer of a public body or an officer serving in or under any public body; a trustee; an administrator or executor of the estate of a deceased person; a subcontractor; and any person employed by or acting for such trustee, administrator or executor, or subcontractor.

Public Hospitals

It is an offense if any officer of a public body uses his position for any gratification as an inducement or a reward for the officer showing or forbearing to show any favor.

"Public body" under the act is defined to include, without limitation, government, local and statutory authorities, government departments, services or undertakings, and companies or a subsidiary over or in which any of the same has a controlling power of interest.

For public hospitals, "public body" will likely include employees of the hospitals that are able to have a functional influence on purchasing decisions such as head physicians, nursing heads and pharmacists.

Consequences of Breach

Under the MACC, any person who is found guilty of corruptly giving any gratification as an inducement will be subject to imprisonment and a fine. The offender may be imprisoned for a term of not less than 14 days and not more than 20 years. If the gratification is capable of being valued or is of a pecuniary nature, the offender may be liable for a fine of not less than five times the sum or value of the gratification which is the subject matter of the offense, or MYR10,000 (approximately USD3,125), whichever is higher.

Contracts with Healthcare Professionals and Medical Institutions

Contracts entered into between healthcare professionals and medical institutions are governed by the PhAMA codes.

Research Sponsorship and Contract

- Clinical assessments, post-marketing surveillance, and experience programs and post-authorization studies should be conducted with transparency and must not be disguised as promotion.

- Such assessments, programs and studies must be conducted for scientific or educational purposes.
- Material sponsored by a company, relating to pharmaceutical products and their uses, irrespective of whether it is for the purpose of promotion or advertising, should clearly indicate the sponsor's name.
- The name and qualifications of healthcare professionals included in the publications should not be prominent.
- Remuneration paid to healthcare professionals for conducting such research should be reasonable.
- Pharmaceutical companies must ensure that healthcare professionals who have been engaged are suitably qualified so that the results of the research and studies are accurate, fair and objective.

Consulting Contracts

- Reasonable remuneration should be given for services rendered by healthcare professionals. The basis of calculation for their fees should be stipulated in the contract.
- Healthcare professionals who are engaged to provide advice should have sufficient qualifications.

Speakers' Contracts

- Sponsorship of healthcare professionals for such events should be limited to travel, meals, registration fee, accommodation, and also limited entertainment in relation to the event.
- Payment of honoraria to local speakers and presenters is not encouraged. If an honorarium is paid, a guidance amount of no more than MYR1,000 (approximately USD312) per engagement, with up to the maximum amount of MYR2,000 (approximately USD625) per day is permitted.
- A detailed signed contract on the services is required for auditing purposes and to prove that such payment is not an inducement.
- The requirement of a signed contract similarly applies to the engagement of international speakers but pharmaceutical companies should check with the speaker's home country industry code, and apply the provisions accordingly.

Medical Representatives' Agreement

- Medical representatives that the company employs must be adequately trained and possess sufficient medical and technical knowledge to

present information on the company's product in an accurate and responsible manner.
- Such requirements should not only apply to verbal presentations but also printed material that are created by the healthcare professionals.
- The system of remuneration of representatives should not adversely influence the presentation of information on the products nor influence the proper prescription as well as usage of the products by patients consumers.

Recommendations

The following are among the strategies which a medical product company could adopt to minimize the risk of contravening the restrictions which have been imposed on the promotion of medical products in Malaysia:

- Refrain from giving gifts, payments or donating to a healthcare professional for their personal use as a matter of good practice.
- If such gifts, payments or donations are to be given, the same should be given to the medical institution directly and must be in compliance with the industry code applied to the industry.
- Any gifts or benefits given to an individual healthcare professional or an institution should have the effect of benefiting patients.
- Establish board level responsibility for any anti-corruption program.
- Ensure that a senior officer is directly accountable for overseeing the anti-corruption program.
- Design and implement a code of conduct which is in line with the anti-corruption program of the company.
- Implement a transparent gifts and entertainment policy.
- Conduct appropriate training for employees to develop awareness and ensure compliance with the anti-corruption policies of the company.
- Carry out appropriate due diligence on foreign partners, agents, consultants and entities.
- Establish financial controls to minimize risks.
- Implement an anonymous reporting mechanism to encourage reporting of any anti-corruption practices.
- Advertisements of any medical products should be reviewed and approved by the MAB under MASA 1956.
- Ensure that they register their medical devices when MDA 2012 comes into force.
- Avoid giving unilateral benefits that do not generally benefit the patients.

Philippines

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Introduction

Advertising of pharmaceutical products in the Philippines is generally governed by guidelines under the Implementing Rules and Regulations of the Food and Drug Administration Act of 2009 ("FDA IRR"), and regulations issued by the Philippine Food and Drug Administration and the Department of Health. The promotion and advertisement of health products are likewise regulated by Codes of Conduct developed by self-regulating organizations, which are intended to apply to member pharmaceutical companies and other members from the health products industry.

The Regulatory Framework

Pursuant to Republic Act No. 9711 or the Food and Drug Administration Act of 2009 ("FDA Act"), the manufacture, importation, sale, offering for sale, promotion, advertising and sponsorship of any health product in the Philippines is regulated by the Philippine Food and Drug Administration ("FDA"), an office under the Department of Health ("DOH"). The FDA has the power, among others, to prescribe standards, guidelines and regulations with respect to information, advertisements and other marketing instruments and promotion, sponsorship and other marketing activities about health products.

The term "health product" includes food, drugs, cosmetics, devices, biologicals, vaccines, in-vitro diagnostic reagents, and household or urban hazardous substances. The terms "advertisement" and "promotion" are not defined in the FDA Act or in the FDA IRR promulgated in 2011. However, various regulations of the FDA[1] define "advertisement" as any representation by any means whatsoever for the purpose of promoting directly or indirectly the sale or disposal of any health product, and broadly define "promotion" as the practice of giving temporary additional value to a brand, product or service to achieve specific marketing objectives, and includes the distribution of free products or samples.

[1] See, e.g., Administrative Order 65, Series of 1989 and Regulation No. 5, Series of 1987.

Under the FDA IRR, all advertisements, promotions, sponsorship and other marketing activities about a health product must adhere to the standards, guidelines and regulations of the FDA. Advertisements, promotions, sponsorship and other marketing activities on health products refer to those addressed to the general public in any form of media.

Permitted and Prohibited Practices

The FDA IRR provides the following general rules on the advertisement of health products:

- No health product that has not been registered or authorized shall be advertised, promoted or subjected to any marketing activities.
- No claim in the advertisement, promotion and sponsorship, and other marketing activities shall be made other than those contained in the approved label or packaging of the health product, or as duly approved by the FDA.
- No claims, therapeutic, scientific or otherwise, shall be made that has not been duly approved by the FDA.
- All health products that are permitted to be promoted must specifically state the authority or reference number that approved the same promotional, sponsorship or marketing activities.

An approved health product registration is issued a proper authorization by the FDA in the form of a Certificate of Product Registration ("CPR"). An authorization or CPR covering a particular health product shall be *prima facie* evidence of the registrant's marketing authority for said health product. As a general rule, only establishments with a valid License to Operate ("LTO") from the FDA may hold a CPR. Drug manufacturers, traders, distributors, importers, exporters, and wholesalers are required to obtain an LTO from the FDA. An entity applying for an LTO with respect to drug products shall be required to demonstrate its capacity to perform adequately the activities covered by the LTO, and in a manner that satisfactorily assures the safety, efficacy and quality of its drug products.

Regulation of Prescription Drugs

In addition to the requirements under the FDA Act and FDA IRR with respect to the advertisement and promotion of health products, various regulations specifically govern these activities with respect to pharmaceutical products.

Under Administrative Order 65, Series of 1989 ("AO 65"), pharmaceutical products classified by the FDA as a prescription or ethical drug may not be advertised or promoted in any form of mass media, except through medical journals, publications and/or literature solely intended for medical and allied professions. "Prescription or ethical drugs" refer to pharmaceutical products or drug preparations that are to be dispensed only upon written order of a duly licensed physician or dentist for the treatment of a condition or a diagnosed disease.

Furthermore, pursuant to AO 65, all therapeutic claims for drugs, medicines or any pharmaceutical product made in any advertising or promotional materials must be based on adequate scientific pharmacological and clinical evidence, responsible medical opinion or long experience demonstrating their safety, efficacy and therapeutic value. The pharmaceutical company and its medical director shall be responsible and accountable for the content and form of its advertisement and promotional materials.

Under Regulation No. 5, Series of 1987 ("Regulation 5"), giving of sample of a prescription drug directly to the public is strictly prohibited. The distribution of free products or samples during medical missions and within outpatient dispensaries is allowed, provided that the distribution is under the supervision of a physician. Furthermore, under Regulation 5, raffles, gifts, promises of reward or and other forms of inducement to the prescribers of prescription drugs (i.e., duly licensed physicians or dentists), are prohibited.

Promotion of Generic Name

Section 6 (c) of the Generics Act of 1988 ("Generics Act") provides that any organization or company involved in the manufacture, importation, repacking, marketing, and distribution of drugs and medicines shall indicate prominently the generic name of the product. In the case of brand name products, the generic name shall appear prominently and immediately above the brand name in all product labels as well as in advertising and other promotional materials.

Pursuant to the Generics Act, AO 65 provides that all advertising and promotional materials, whether print, visual or auditory, shall feature prominently the generic name of the drug product designated by the FDA. In the case of branded products, the prominence of the generic name shall be insured in all print, visual or auditory materials that feature the brand name. AO 65 provides for specific requirements on how the generic name shall be presented in a label, and in all promotional and advertising materials (i.e., the

generic name shall appear prominently within an outline box, be printed in full and not abbreviated, among others).

In case a product is identified by a brand name together with its generic name, AO 65 also specifically provides how the typeface, font, and color of the generic name and brand name shall be rendered in all promotional and advertising materials, with the end of highlighting the generic name over the brand name of the pharmaceutical product (e.g., the generic name must appear immediately above the brand name, and in a larger point size than the brand name).

The Advertising Board of the Philippines ("AdBoard") recommended a Supplementary Guideline to AO 65, which was acceptable to the FDA. The AdBoard is a governing body composed of representatives of national organizations involved in advertising practice, which have banded together to promote the development of the advertising industry through self-regulation. The Supplementary Guideline includes the following:

- Audiovisual advertisements with a duration of 30 seconds or more shall end with an audio: "[Generic Name] is the generic name for [Brand Name]" together with a product shot showing the generic name. Otherwise, the text of the whole statement shall be shown for at least two seconds.
- Auditory advertisements with a duration of 30 seconds or more shall likewise end with the line: "[Generic Name] is the generic name for [Brand Name]."
- For advertisements with a duration of 15 seconds or less, the generic name must be mentioned or shown at least once within the commercial.

Consequences of Breach

FDA Act and FDA IRR

The printing, broadcasting and dissemination of advertisements, advertising or promotional materials of medical products that do not comply with the guidelines and requirements under the FDA IRR and relevant regulations and issuances of the FDA, may subject the drug establishment to administrative sanctions and penalties. The Licensing, Inspection and Compliance Division of the FDA is tasked with monitoring whether the advertisements and/or promotion of drug products comply with the standards, guidelines, and regulations of the FDA.

The FDA is authorized to receive complaints on violations of FDA rules and regulations. If the FDA finds, based on its own findings or complaints filed, that any of the advertising or promotional material violates the relevant provisions of the FDA IRR, AO 65 or other relevant regulations, it may issue a cease and desist order against the responsible drug establishment to stop the further release, printing, broadcast or dissemination of the advertising or promotional material.

The FDA may also undertake the following punitive and corrective actions in case of repeated and serious violations:

- Seizure and confiscation of products that are subject of violative promotional or advertising materials
- Withdrawal by the FDA of accreditation of the drug establishment's medical director
- Suspension of the LTO of the drug establishment
- Cancellation of the CPR
- Revocation of the LTO of the drug establishment

Additionally, the FDA Act prohibits the advertisement of any health product that is adulterated, unregistered or misbranded (adulterated or misbranded drugs are further discussed below), and imposes the following penalties for the said violation:

- Imprisonment ranging from one year but not more than 10 years
- Fine of not less than PHP50,000 but not more than PHP500,000
- Fine and/or imprisonment, at the discretion of the court.

If the foregoing violation of the FDA Act is committed by a manufacturer, importer or distributor of any health product, the penalty imposable is at least five years imprisonment but not more than 10 years, and a fine of at least PHP500,000 but not more than PHP5,000,000. An additional fine of one percent of the economic value/cost of the violative product or violation, or PHP1,000, whichever is higher, is also imposable for each day of continuing violation.

If the offense is committed by a juridical person, the chairman of the board of directors, the president, general manager, or the partners and/or the persons directly responsible of the erring entity shall suffer the penalties provided by law. If the offense is committed by a foreign national, such violator shall, in addition to the penalties prescribed, be deported without further proceedings after service of sentence.

Generics Act

Any juridical person that violates Section 6 (c) of the Generics Act shall suffer the penalty of a fine of not less than PHP5,000 but not more than PHP10,000, and suspension or revocation of the LTO of such drug establishment or drug outlet at the discretion of the Court, provided that, its officers directly responsible for the violation shall suffer the penalty of fine and suspension or revocation of license to practice profession, if applicable, and by imprisonment of not less than six months but not more than one year, or both fine and imprisonment, at the discretion of the Court. Furthermore, if the guilty party is an alien, he shall be *ipso facto* deported after service of sentence without need of further proceedings.

Any advertising or promotional material found to violate AO 65 will be identified and the medical company responsible shall be notified. The FDA shall issue a cease and desist order stopping the further release, printing, broadcast or dissemination of the violative advertising or promotional material.

AO 65

For repeated or serious violations of the guidelines under AO 65, the FDA may impose any or all of the following sanctions:

- Withdrawal by the FDA of accreditation of the establishment's medical director
- Suspension of the LTO of the drug establishments
- Cancellation of the CPR
- Revocation of the LTO of the drug establishment

Regulation 5

Any person who violates Regulation 5 may be imposed any or all of the following sanctions by the FDA:

- Issuance of a cease and desist order
- Cancellation of the CPR and withdrawal of the product from the market within 45 days from date of cancellation
- Imposition of administrative fines in the amount of PHP5,000.

AdBoard

As a self-regulatory body, the AdBoard relies on the agreement between member-associations to carry out its rulings. Any violation of its standards or guidelines may cause all media – print and broadcast – to refuse to print or broadcast violative advertising material.

Criminal Liability in Relation to Anti-Bribery and Anti-Corruption Laws

As discussed above, criminal liability may arise from violations of the FDA Act. In addition, in relation to health products, including pharmaceutical products, anti-bribery and anti-corruption laws are also potential basis for criminal sanctions.

Philippine anti-bribery and anti-corruption laws consist of the following:

- the Revised Penal Code;
- Republic Act No. 3019 or The Anti-Graft and Corrupt Practices Act ("RA 3019");
- PD No. 46 which penalizes giving of gifts on any occasion ("PD 46"); and
- Republic Act No. 6713 or The Code of Conduct and Ethical Standards for Public Officials and Employees ("RA 6713").

These laws, in many instances, overlap with each other. Notably, while certain gifts/payments may appear to be allowed under certain laws, e.g., exemption for unsolicited gifts or presents of small or insignificant value under RA 3019, the same gifts/payments may technically be covered by the broad language of other laws, e.g., indirect bribery, which penalizes acceptance of any gift given by reason of one's public position.

Philippine anti-bribery and anti-corruption laws are relevant insofar as transactions between pharmaceutical companies and public officials are concerned, e.g., with healthcare professionals in government hospitals, officials of the FDA who are involved in the processing or approval of licenses and/or new drugs, public officials involved in procurement of medical supplies, or officials of the Intellectual Property Office involved in the processing or approval of licenses or permits relating to intellectual property.

Notably, the term "public officer" is broadly defined under Philippine anti-bribery and anti-corruption laws. "Public officers" include "any person who,

by direct provision of law, popular election or appointment by competent authority, shall take part in the performance of public functions in the Government of the Philippine Islands, or shall perform in said Government or in any of its branches public duties as an employee, agent or subordinate official, of any rank or class."[2] They include those employed either on a permanent or temporary basis, whether or not they are in the career or non-career service, including military personnel, and whether or not they receive compensation, regardless of amount.[3]

"Government", on the other hand, includes the national government, local governments, government-owned and government-controlled corporations, and all other instrumentalities or agencies of the Republic of the Philippines and their branches.[4] A "government-owned and controlled corporation" is any agency organized as a stock or non-stock corporation, vested with functions relating to public needs whether governmental or proprietary in nature, and owned by the government directly or indirectly or through its instrumentalities either wholly, or, where applicable as in the case of stock corporations, to the extent of at least 51 percent of its capital stock.[5]

Bribery Under the Revised Penal Code

The Revised Penal Code defines two types of bribery, namely, direct bribery and indirect bribery.

Direct Bribery

Direct bribery is committed by accepting an offer/promise, or receiving a gift/present, in consideration for:

- an act constituting a crime;
- an unjust act (not constituting a crime); or
- refraining from doing something which is the public officer's official duty to do.[6]

[2] Revised Penal Code, Article 203.
[3] See RA 6713, Section 3(b) and RA 3019, Section 2(b).
[4] See RA 3019, Section 2(a).
[5] The Administrative Code of 1987, Section 2 (13).
[6] Revised Penal Code, Article 210.

The elements of direct bribery are:

- the offender is a public officer;
- the offender accepts an offer or a promise, or receives a gift or present by himself or through another;
- the offer or promise must be accepted or gift received by the public officer with a view to committing some crime, or in consideration of the execution of an act which, although not constituting a crime, is unjust, or to refrain from doing something which is his official duty to do; and
- the act is connected with the performance of the public officer's official duties.

In a case officers of the Land Transportation Office ("LT Office") were convicted of having committed direct bribery for collecting "protection money" from a taxi driver, in exchange for refraining from impounding his vehicle for alleged violations of LT Office rules and regulations.[7]

Indirect Bribery

Indirect bribery, on the other hand, is committed by a public officer simply by accepting a gift/present given by reason of his office.[8]

The elements of indirect bribery are:

- the offender is a public officer;
- the offender accepts gifts offered; and
- the gift is given by reason of his public office.

Corruption of Public Officials

The crime committed by a public officer who receives an improper payment or a promise thereof may either be direct bribery or indirect bribery. The private person who gives the gift or promise may also be held liable for the crime of "corruption of public officials.[9]"

[7] *Balderama vs. People of the Philippines* (G.R. Nos. 147578-85 & 147598-605, 28 January 2009)
[8] Revised Penal Code, Article 211.
[9] Revised Penal Code, Article 212.

Special Anti-Corruption Laws

PD 46 (Giving of Gifts on any Occasion)

PD 46 punishes the act of giving, or offering to give, to a public official or employee, a gift, present or other valuable thing on any occasion, including Christmas, when such gift, present or other valuable thing is given by reason of the public official/employee's position, regardless of whether or not the same is for past favor or the giver hopes or expects to receive a favor or better treatment in the future from the public official or employee concerned in the discharge of his official functions. Included within the prohibition is the throwing of parties or entertainment in honor of the public official or employee or of his immediate relatives.

Republic Act No. 6713 (Code of Conduct and Ethical Standards for Public Officials and Employees)

RA 6713 prohibits public officials and employees from soliciting or accepting, directly or indirectly, any gift, gratuity, favor, entertainment, loan or anything of monetary value from any person in the course of their official duties or in connection with any operation being regulated by, or any transaction which may be affected by the functions of their office.

RA 6713 provides that "gift" shall not include an unsolicited gift of nominal or insignificant value not given in anticipation of, or in exchange for, a favor from a public official or employee. The phrase "receiving any gift" includes the act of accepting directly or indirectly, a gift from a person other than a family member or relative, even on the occasion of a family celebration or national festivity like Christmas, if the value of the gift is neither nominal nor insignificant, or if the gift is given in anticipation of, or in exchange for, a favor.

Private individuals who participate in conspiracy as co-principals, accomplices or accessories, with public officials or employees are subject to the same penal liabilities as the public officials or employees, and shall be tried jointly with them.

Note, however, that this exception for "unsolicited gifts" under RA 6713, is not recognized in other relevant Philippine laws, e.g., PD 46 discussed above, or the Revised Penal Code.

RA 3019 (Anti-Graft and Corrupt Practices Act)

RA 3019 prohibits a public officer from:

- knowingly inducing or causing a public official to commit an act constituting a violation of official rules and regulations / offense in connection with official duties;
- directly or indirectly receiving a gift, present, share, percentage or benefit, for himself or another, in connection with a contract or transaction between the government and any other party;
- directly or indirectly receiving a gift, present or any other pecuniary or material benefit, for himself or another, from any person for whom a government permit or license will be or is obtained;
- accepting, or having a member of his family accept, employment in a private enterprise which has pending official business with him, during the pendency of his employment or within one year after his termination;
- in the discharge of his official functions, causing undue injury / giving unwarranted benefit, advantage or preference to any party through manifest partiality / evident bad faith / gross or inexcusable negligence;
- neglecting or refusing, after due demand/request, without sufficient justification, to act within a reasonable time on any matter pending before him for the purpose of obtaining benefit, or favoring his or another party's interest;
- entering into any contract or transaction manifestly and grossly disadvantageous to the government, whether or not the public officer profited or will profit;
- directly or indirectly having financial or pecuniary interest in any business, contract or transaction in which he intervenes or takes part in his official capacity;
- directly or indirectly becoming interested for personal gain, or having material interest in, any transaction or act requiring his approval as part of a board or group, regardless of his vote;
- knowingly approving or granting any license, permit, privilege or benefit in favor of unqualified persons, or dummies of the same; and
- divulging valuable and confidential official information acquired by him or his office, to unauthorized persons.

A private individual hired by a government agency on a contractual basis for a particular project and for a specific period is considered a public officer for the duration of his contract.

By way of exception, unsolicited gifts or presents of small or insignificant value offered or given as a mere ordinary token of gratitude or friendship according to local customs or usage are not covered by RA 3019. RA 3019 defines the phrase "receiving any gift" as "includ(ing) the act of accepting directly or indirectly a gift from a person other than a member of the public officer's immediate family, in behalf of himself or of any member of his family or relative within the fourth civil degree, either by consanguinity or affinity, even on the occasion of a family celebration or national festivity like Christmas, if the value of the gift is under the circumstances manifestly excessive." As mentioned above, however, this exception is not recognized in other laws such as PD 46 or the Revised Penal Code.

The private person who gives the gift, present, share, percentage or benefit shall, together with the offending public officer, be punished with imprisonment and be permanently or temporarily disqualified from transacting business in any form with the Government.

The following case-summaries illustrate how the Supreme Court has resolved issues relating to violations of RA 3019.

- In one case, the Supreme Court held that a court sheriff's act of demanding and collecting money from a complainant and his clients to defray the expenses of the implementation of certain writs issued by the court, was in violation of RA 3019.[10]
- In another case decided by the Supreme Court, a municipal mayor was convicted of violating RA 3019 for refusing to release full payment to a private contractor, unless the mayor received her "kickback."[11]
- A mayor who approved the acquisition of a dump truck without a public bidding, when a similar truck could have been bought at a much lower price, was found to have violated RA 3019.[12]
- A private contractor was convicted of violating RA 3019 when he, in conspiracy with other municipal officers and employees, caused the approval and release of funds for the construction of a municipal building and public market, where such funds were higher than the actual contract price.[13]

[10] *Pasok vs. Diaz* (A.M. No. P-07-2300, 29 November 2011)
[11] *Cadiao-Palacios vs. People* (G.R. No. 168544, 31 March 2009)
[12] *Ong vs. People* (G.R. No. 176546, 25 September 2009)
[13] *Santillano vs. People of the Philippines* (G.R. No. 175045, 3 March 2010)

- A private supplier was convicted of violating RA 3019 when she conspired with police officers to have funds released and paid to her purportedly for the purchase of combat, clothing and individual equipment of police personnel when no delivery of such equipment were ever effected.[14]

Administrative Issuances

Department of Health Order No. 2007-0043

The DOH prohibits its officials and employees from soliciting directly or indirectly any gift and/or benefit for themselves or for others, regardless of the cost, unless otherwise approved by the Department of Social Welfare and Development; where this may influence, or may reasonably be seen to influence or to have influenced past, present, or future performance of their functions; or if the gift or benefit is from:

- a tobacco or milk company and organizations/interests and related industries;
- a bidder, supplier, contractor or entity and their agents with contracts with the DOH;
- those applying for DOH authorization;
- parties transacting business with any DOH office/bureau/center/hospital; or
- an individual, counsel, witness, or their agent undergoing investigation conducted by, or involved in a case before the DOH or any government agency or court.

Donations of food, medical supplies, medicines and medical devices from any donor may be allowed, provided that such donations are:

- covered by appropriate Memorandum of Agreement/Understanding, certificate of donation or acknowledgement receipt; and
- given to DOH hospitals for indigent patients or distributed during DOH public health campaigns or DOH health emergency response activities.

DOH officials and employees may receive plaques, awards, certificates or other tokens of gratitude and/or benefits as appropriate to the occasion to

[14] *Luspo vs. People of the Philippines* (G.R. Nos. 188487, 188541, and 188556, 14 February 2011)

which he/she is invited as a guest speaker or lecturer. Transportation and accommodation provided to enable the DOH official/employee to be a speaker or lecturer during the occasion may also be accepted. DOH officials and employees may also receive performance-based cash rewards, scholarship grants and similar benefits granted by appropriate government agencies, non-profit private institutions, and national or international non-profit organizations.

Note on Commercial Bribery

In the Philippines, there is no law which penalizes bribery between private individuals in the course of their commercial transactions. An essential element of bribery or any acts penalized under Philippine anti-bribery and anti-corruption laws is the involvement of public officers, who solicit, accept or are offered, gifts or anything of value from any person, or perform any of the prohibited acts discussed above.

Sanctions

Any public officer or private person convicted of any of the offenses above may be punished with imprisonment or a fine or both, and disqualified to hold public office, by the court's discretion. In addition, the offending public officer or private person shall be civilly liable for damages. The government office to which the public officer belongs may also impose disciplinary sanctions, including suspension or removal from office.

Public Procurement and Fraud

Public Procurement

Republic Act No. 9184 or The Government Procurement Reform Act ("RA 9184") and the Revised Implementing Rules and Regulations of RA 9184 apply to the procurement of infrastructure projects, goods and consulting services regardless of source of funds, whether local or foreign, by all branches and instrumentalities of the Philippine government, its departments, offices and agencies, including government-owned and/or -controlled corporations and local government units. As such, RA 9184 applies to the procurement of government entities of drugs and other pharmaceutical products and services from both local and foreign pharmaceutical corporations.

RA 9184 is anchored on the following principles: transparency; competitiveness; streamlined procurement process; accountability; and public

monitoring. Guided by these principles, the procurement of goods and services begins with a pre-procurement conference where specifications of the goods and services to be procured are discussed followed by an invitation to bid, a pre-bid conference, submission of bidding documents, evaluation and announcement of the lowest calculated bid/highest rated bid, or a failure in the bidding process. In the interest of transparency, participants are also required to submit a disclosure of relations, wherein all bids shall be accompanied by a sworn affidavit of the bidder that it is not related to the head of the procuring entity, members of the Bids and Awards Committee ("BAC"), the technical working group, the BAC Secretariat, the head of the Project Management Office or the end-user unit, and the project consultants, by consanguinity or affinity up to the third civil degree. Existence of a relationship with the aforementioned persons within the third civil degree and failure to disclose the same, shall be a ground for the automatic disqualification of the bid.

As a general rule, all procurement shall be done through competitive bidding subject to a number of exceptions, including: limited source bidding which is allowed for highly specialized goods and services (e.g., sophisticated defense equipment); direct contracting which is allowed for a proprietary source because of the existence of patents, copyrights and trade secrets; repeat order which is allowed in replenishing goods from a previous winning bidder; shopping which is allowed for readily available off-the-shelf goods or ordinary/regular equipment to be procured directly from suppliers of known qualifications; and negotiated biddings which are allowed when there are two failed biddings or emergency situations, among others. Because medical products and services are generally patented or subject to intellectual property rights, it is not uncommon for the procurement of these products and services to be accomplished through limited source bidding or direct contracting.

Fraud

As mentioned above, fraud and other corrupt practices occurring in the bidding process carry penal, civil and administrative sanctions.

In addition to the penal sanctions under the various anti-bribery laws discussed above, RA 9184 penalizes the: opening of any sealed bid prior to the appointed time for the public opening of bids or other documents; delaying, without justifiable cause, the screening for eligibility, opening of bids, evaluation and post evaluation of bids, and awarding of contracts beyond the prescribed periods of bids or other documents; unduly influencing or exerting undue pressure on any member of the BAC or any officer or

employee of the procuring entity to take a particular bidder; splitting of contracts which exceed procedural purchase limits and competitive bidding; and when the head of the agency abuses the exercise of his power to reject any and all bids with manifest preference to any bidder who is closely related to him. When any of the foregoing acts is done in collusion with private individuals, the private individuals shall likewise be liable for the offense.

In addition, RA 9184 also penalizes the commission by private individuals of the following acts: when two or more bidders agree and submit different bids as if they were bona fide bidders, when they knew that one or more of them was so much higher than the other that it could not be honestly accepted and that the contract will surely be awarded to the pre-arranged lowest bid; when a bidder maliciously submits different bids through two or more persons, corporations, partnerships or any other business entity in which he has interest to create the appearance of competition that does not in fact exist so as to be adjudged as the winning bidder; when two or more bidders enter into an agreement which call upon one to refrain from bidding for procurement contracts, or which call for withdrawal of bids already submitted, or which are otherwise intended to secure as undue advantage to any one of them; and when a bidder, by himself or in connivance with others, employ schemes which tend to restrain the natural rivalry of the parties or operates to stifle or suppress competition and thus produce a result disadvantageous to the public.

The penalties under RA 9184 for the foregoing offenses range from six years to 15 years of imprisonment. In addition, a conviction under RA 9184 or RA 3019 shall carry with it civil liability, which may either consist of restitution for the damage done or the forfeiture in favor of the government of any unwarranted benefit derived from the act or acts in question or both, at the discretion of the courts. Lastly, the offender may also be subject to administrative sanctions which include suspension or disqualification from participating in government procurement processes.

Professional Codes of Conduct

Code of Ethics of the Philippine Medical Association

As discussed above, while existing anti-bribery and anti-corruption laws target dealings with government officials and public officers, there are codes of conduct for members of the health and pharmaceutical industries which regulate activities and arrangements among such members.

The Code of Ethics of the Philippine Medical Association ("PMA") ("PMA Code of Ethics") sets forth certain standards governing physicians and their

dealings and relationships with patients, colleagues and other allied professionals, as well as other members of the health products industry. Among its general principles, the PMA Code of Ethics posits that the promotion and advancement of the health of patients should be given the highest priority over the benefits of the physicians and members of such health product industries.[15] The PMA Code of Ethics also provides for certain duties and what are considered as acceptable and ethical behavior of physicians when dealing with promotional, marketing and other related or similar activities involving the health products industry.

Grants and Subsidies

The PMA Code of Ethics recognizes that physicians may accept gifts from a health product company provided the same is of reasonable value, primarily entails benefits to patient care, or relates to the physicians' work.[16] It is also considered ethical for physicians to request donations for a charitable purpose from pharmaceutical companies for as long as this does not redound to the physician's personal benefit.[17] Furthermore, physicians may accept reasonable subsidies from health and other industries to support their participation in Continuing Medical Education ("CME").[18]

CME conferences and professional meetings may be organized by a medical society in cooperation with sponsoring entities.[19] However, during the course of CME activities sponsored by a pharmaceutical company, only generic names of products must be used.[20] The sponsoring entity may promote or indicate their branded products only after the lectures.[21] When commercial exhibits are part of the overall program, information on the product displayed during such exhibits should be limited to relevant information about the product.[22]

Funds from commercial sources may be accepted if the same is intended for the benefit of a medical association or society.[23] With respect to grants of scholarships for physicians or to medical students by pharmaceutical

[15] PMA Code of Ethics, Article 1, Section 7.
[16] *Id* at Article VI, Section 3.
[17] *Id* at Article VI, Section 4.
[18] *Id* at Article IV, Section 12.
[19] *Id* at Article IV, Section 10.
[20] *Id* at Article IV, Section 15.
[21] *Ibid.*
[22] *Id* at Article IV, Section 16.
[23] *Id* at Article IV, Section 11.

companies, these are permissible for as long as the selection of scholars are made by the organizers or the academic institutions concerned.[24]

Marketing Activities

The PMA Code of Ethics devotes a section on the relationship between physicians and the health products industry, as well as marketing activities involving physicians.

As a rule, physicians are not allowed to commercially endorse any medical or health product.[25] They are also prohibited from deriving any form of material gain from product samples.[26] To this end, Republic Act No. 5921 or the Pharmacy Law expressly prohibits the sale of any sample of any drug, device or medicine which are intended to be given for free to the physician and other qualified person by a manufacturer or distributor of such product.

Pharmaceutical companies may, however, request physicians to participate in post-marketing or similar activities, where physicians are asked to try new products on patients, provided that the patients are properly informed and have given their informed consent.[27] Physicians are encouraged to report or share the result of such activities to duly constituted authorities.[28]

PHAP Code of Pharmaceutical Marketing Practices

The Pharmaceutical and Healthcare Association of the Philippines ("PHAP") is a non-stock non-profit organization with members consisting of companies engaged in research and development, manufacturing, retail and distribution of pharmaceutical products and medical devices.[29] Among PHAP's objectives are the promotion of extensive research and development to discover innovative and breakthrough medicines for all Filipinos, as well as to make medicines more accessible to patients.[30] To become a PHAP member, an establishment must adhere to the International Federation of Pharmaceutical Manufacturers & Associations ("IFPMA") Code of Pharmaceutical Marketing Practices, the PHAP Code of Pharmaceutical

[24] *Id* at Article IV, Section 14.
[25] *Id* at Article III, Section 5.
[26] *Id* at Article VI, Section 1.
[27] *Id* at Article VI, Section 2.
[28] *Ibid.*
[29] *See* http://phapcares.org.ph/index.php?option=com_content&view=article&id=12&Itemid=3
[30] *See* http://www.phap.org.ph/sub.php?id=1&sid=4

Marketing Practices and its Implementing Guidelines ("PHAP Code"), and the Code of Advertising to the Public for Over-the-Counter Medicines.[31]

The PHAP Code sets standards for the promotion of pharmaceutical products to ensure that medical decisions are made in the best interests of patients, and that all interactions with healthcare professionals, medical institutions and patient organizations are ethical, professional, and appropriate at all times. It covers not only member companies of PHAP as described above, but also local subsidiaries of the IFPMA member companies.

Under the PHAP Code, a "healthcare professional" refers to any member of the medical, dental, pharmacy or nursing professions or any other person who in the course of his or her professional activities may prescribe, recommend, purchase, supply or administer a pharmaceutical product.[32] The terms "promotion and advertisement" mean any activity undertaken, organized or sponsored by a member company which is directed at healthcare professionals to promote the prescription, recommendation, supply, administration or consumption of its pharmaceutical product(s) through any media, including the internet.[33]

Independence of Healthcare Professionals

Underlying most provisions of the PHAP Code is the importance of upholding the independence of healthcare professionals. Hence, the PHAP Code prescribes that no financial benefit or benefit-in-kind (including grants, scholarships, subsidies, support, consulting contracts or educational or practice-related items) may be provided or offered to a healthcare professional in exchange for prescribing, recommending, purchasing, supplying or administering products, or for a commitment to continue to do so.[34] Nothing may be offered or provided in a manner or on conditions that would inappropriately influence a healthcare professional's prescribing practices.[35]

In this regard, gifts of any kind for the personal benefit of healthcare professionals are not allowed, irrespective of value, kind or occasion, except for the following:

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[31] *Supra* note 29.
[32] PHAP Code, Article 1.1
[33] *Ibid.*
[34] *Id* at Article 13.0.
[35] *Ibid.*

- Equipment, tools, devices, computers and educational materials (e.g., ECG machines, stethoscopes, x-ray machines/films, scanners, and other diagnostic equipment) may be donated or loaned to medical training institutions and hospitals, but not to individuals.
- Items of medical utility may be offered for free provided that such items are of modest value and are beneficial to the provision of the medical services and for patient care.
- During Christmas, gifts of moderate value may be given to healthcare professionals even if these gifts are unrelated to the practice of medicine, as long as the retail price is not more than PHP1,500.00.[36]

Balanced and Accurate Product Information

The PHAP Code also highlights the responsibility of pharmaceutical companies, their employees and medical/technical advisers to ensure that the contents of all promotional and medical claims, including those contained in materials to be used by medical representatives, are balanced, accurate, correct and fully supported by the product information, literature or "data on file" or appropriate industry source, where these do not conflict with the product information.[37] A full disclosure of product information must accompany all promotional materials for at least twelve 12 months from the date a product is launched.[38]

In line with the foregoing principles, the PHAP Code regulates marketing, promotional and other similar activities of member companies:

Promotional Giveaways and Product Samples

Promotional giveaway items, such as pens, notepads, t-shirts and mugs, where no promotional claims are made need not be accompanied with product information. However, these items should not be of such value (i.e., valued at less than PHP1,000.00), which would bring discredit upon the industry or the recipient. Items of higher cost may be donated to institutions (such as medical societies, professional organizations and hospital

[36] *Id* at Article 13.1.
[37] *Id* at Article 2.1.
[38] *Id* at Article 3.1.

departments) but not to individuals.[39] If promotional claims are made, these items must be accompanied by a document containing product information.[40]

Free samples of pharmaceutical products may be supplied to healthcare professionals, and only with their consent, in order to enhance patient care or to gain clinical experience.[41] However, the PHAP also prohibits the sale or misuse of samples by medical representatives and employees.[42]

Competitions and Raffles

The PHAP allows member companies to hold competitions, provided the following criteria are met: raffles and competitions are permitted only during official conventions organized by the PMA or its affiliates, and should not conflict with any of the official convention activities; competitions must be based on medical knowledge or on the acquisition of it and hence, the prizes must be proportionate to the complexity of the contest; the prizes must be relevant and specific to the practice of medicine which may include stethoscopes and other medical equipment; individual prizes offered are to be of low monetary value (i.e., less than PHP1,000.00) or be items of educational material; and entry into a competition must not depend on prescribing, ordering or recommending a product, and no such condition shall be made or implied.[43]

Exhibit Booths

The main objective of congresses and symposia is medical education. Hence, exhibit booths must be directed only to healthcare professionals.[44] Product samples may be given to healthcare professionals attending such congresses or symposia, but these samples must always be accompanied by product information.[45] Contests, raffles, and other similar activities conducted in the booths are allowed, provided prizes are limited to stethoscopes, medical books, medical journals and other tokens.[46] Video presentations must also be scientific or related to the products promoted.

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[39] *Id* at Article 4.5.4.
[40] *Id* at Article 4.5.5.
[41] *Id* at Article 9.1.
[42] *Ibid.*
[43] *Id* at Article 6.0.
[44] *Id* at Article 10.1
[45] *Id* at Article 10.3
[46] *Id* at Article 10.4

- Conventions, symposia, scientific programs and post-graduate courses

Participation in and sponsorship of continuing medical education and other medical activities organized by various medical specialty societies or by pharmaceutical companies, whether expenses are paid for by the local pharmaceutical company or its affiliate or headquarters, and whether held locally or outside the country, are also regulated. No company may organize or sponsor an event for healthcare professionals (including sponsoring individuals to attend such events) that takes place outside of their home country unless it is appropriate and justified to do so from a logistical or security point of view.[47] International scientific congresses and symposia that derive participants from many countries are therefore justified and permitted. Travel should be by economy class.[48] The scientific agenda must be the primary basis for the company's sponsorship of or participation in the event, and any support to individual doctors should not be conditional upon any obligation to prescribe or promote any medicinal product.[49]

With respect to sponsorship of CMEs, pharmaceutical companies are strongly encouraged to observe reasonable restraint in expenditures related to CME.[50] While PHAP members may sponsor healthcare professionals to attend such CME events, invitations should be extended only to healthcare professionals in the professional's area of activity/interest.[51]

- Sponsorships

Pharmaceutical companies sponsoring doctors to overseas company meetings (Central America, USA, Australia, Japan and Europe) may sponsor only up to a maximum of seven doctors per event.[52] At a level above this, the rationale of an overseas meeting versus an in-country meeting is highly questionable. Pharmaceutical companies may sponsor no more than 12 healthcare professionals to regional company scientific meetings.[53] Regional

[47] *Id* at Article 11.1
[48] *Ibid.*
[49] *Id* at Article 11.2.
[50] *Id* at Article 11.5.
[51] *Ibid.*
[52] *Id* at Article 11.9.1.
[53] *Ibid.*

events are described as those held in ASEAN countries, Hong Kong, Taiwan, China and Korea.[54]

Local company-sponsored continuing medical education events must be held in business accommodation locations, and not in primarily resort locations.[55] Under no circumstance is a pharmaceutical company allowed to pay expenses for spouses or other family members.[56] The only exception is if the spouse is medically qualified and practices in a therapeutic area relevant to the scientific meeting or society. Support of raffles with high-value items (i.e., over PHP1,000.00) is considered to be inappropriate.[57]

Member companies should not specifically support sports events, such as golf tournaments, or charity or fund-raising activities such as movie premieres.[58] Sponsorship of events, such as fellowship night, if the event is clearly part of a scientific meeting, is acceptable as long as such sponsorship is on a modest scale.[59]

Sanctions

Sanctions against a subject company may be applied where breaches of the PHAP Code have been established. Sanctions may take the form of one or more of the following:

- the requirement that the subject company take immediate action to discontinue or modify any practice that is determined to constitute a breach of the Code;
- retraction statements, including corrective letters and advertising, to be issued by the subject company;
- the imposition of a fine on the subject company ranging from PHP20,000.00 to PHP300,000.00.[60]

[54] *Id* at Article 11.9.2.
[55] *Id* at Article 11.9.3.
[56] *Ibid.*
[57] *Ibid.*
[58] *Id* at Article 12.1.
[59] *Id* at Article 12.2.
[60] *Id* at Article 17.

Contracts with Healthcare Professionals and Medical Institutions

Research Activities

Under the PMA Code of Ethics, sponsored research activities should be ethically defensible, socially responsible and scientifically valid.[61] Any remuneration paid for such research activities should be reasonable and should not constitute an enticement.[62]

Speaking / Consultant Engagements

The PMA Code of the Ethics also provides that speakers or consultants of conferences or meetings are allowed to accept from health industries honoraria and reimbursement for reasonable transportation, lodging and meal expenses.[63]

Sponsorship of Clinical Trials

Under the PHAP Code, sponsorship of clinical trial investigator's meetings and presentations is allowed, provided the scientific agenda is the primary basis for the company's sponsorship and any support to individual doctors is not conditional upon any obligation to prescribe or promote any medicinal product. Honoraria not to exceed USD100 per day may be given to each sponsored healthcare professional in connection with the conduct of such clinical trial investigation. The limits imposed under the PHAP Code with respect to sponsorship of activities (as discussed above) shall also apply.[64] Furthermore, under the PMA Code of Ethics, such research trials conducted by physicians for an industry should be done in accordance with the national or institutional guidelines for the protection of human subjects.

Recommendations

With respect to advertising and promotional activities targeted towards consumers and the general public, pharmaceutical companies must ensure that all materials used for any form of promotion or sale activities, whenever permitted under the law, must consistently contain accurate, balanced and complete relevant product information. For this purpose, it is recommended

[61] PMA Code of Ethics, Article VI, Section 5.
[62] *Ibid.*
[63] PMA Code of Ethics, Article IV, Section 13.
[64] PHAP Code, Article 14.2.

that such promotional materials be cleared with the company's medical director at all times. In addition to obtaining the approvals required under the relevant laws and regulations, consultations and pre-clearances with the relevant agencies, such as the FDA or the Adboard, may also be undertaken by pharmaceutical companies to ensure compliance with the minimum advertising requirements and standards set by the relevant regulating agency.

Pharmaceutical companies dealing with or intending to enter into transactions with public officials must strictly comply with Philippine anti-bribery and anti-corruption laws. In this regard, pharmaceutical companies may want to avoid giving any gift, gratuity, favor, entertainment, loan or anything of monetary value, to any public official. Pharmaceutical companies intending to provide products or services to government entities must also strictly comply with public procurement laws.

Pharmaceutical companies intending to engage in promotional and marketing activities in the Philippines are encouraged to exercise restraint in expenditures with respect to dealings with independent healthcare professionals. Activities targeted towards healthcare professionals must always be evaluated with a view to ensuring that these professionals' independence is not compromised and public health and welfare are given foremost consideration. To this end, pharmaceutical companies are encouraged to comply with the limits set forth in the PHAP Code on what would be considered as reasonable expenditure when its comes to sponsoring healthcare events and in providing benefits to healthcare professionals. Industry practice may also be considered, but in case of doubt, pharmaceutical companies are encouraged to err on the side of restraint.

Singapore

Andy Leck, Ren Jun Lim

Introduction

In Singapore, various legislations, guidelines and industry codes of conduct govern the promotion of medicinal products and medical devices. It is important to first identify the types of promotional activities involved, for example sponsorship of meetings and symposia, hospitality and entertainment, gifts and donations. Certain considerations should also be taken into account in relation to public procurement and contracts with healthcare professionals and institutions.

These will be examined below.

The Regulatory Framework

Advertising of medicinal products is governed by the Medicines Act ("MA") and the Medicines (Medical Advertisements) Regulations ("MAR"), whereas advertising of medical devices is governed by the Health Products Act ("HPA") and the Health Products (Medical Devices) Regulations 2010 ("MDR").

A "medicinal product" is defined under the MA as: any substance or article (not being an instrument, apparatus or appliance) which is manufactured, sold, supplied, imported or exported for use wholly or mainly in either or both of the following ways:

- use by being administered to one or more human beings or animals for a medicinal purpose;
- use as an ingredient in the preparation of a substance or article which is to be administered to one or more human beings or animals for a medicinal purpose."

A "medicinal purpose" means "any one or more of the following purposes:

- treating or preventing disease;
- diagnosing disease or ascertaining the existence, degree or extent of a physiological condition;
- contraception;
- inducing anaesthesia;

- otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating, reducing or postponing, or increasing or accelerating, the operation of that function or in any other way.

On the other hand, a "medical device" is defined under the HPA as: any instrument, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article that is intended by its manufacturer to be used, whether alone or in combination, for humans for one or more of the specific purposes of:

- diagnosis, prevention, monitoring, treatment or alleviation of any disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
- investigation, replacement, modification or support of the anatomy or of a physiological process;
- supporting or sustaining life;
- control of conception;
- disinfection of medical devices; or
- providing information for medical or diagnostic purposes by means of an in vitro examination of specimens derived from the human body, and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means.

The term "advertisement" is given a very broad meaning under both the MA and the HPA.

The MA essentially regulates "medical advertisements," which are "advertisement[s] relating or likely to cause any person to believe that it relates to any medicinal product… used or represented to be used for a medicinal purpose." An "advertisement" includes "every form of advertising, whether in a publication, or by display of any notice or signboard, or by means of any catalogue, price list, letter (whether circular or addressed to a particular person) or other documents, or by words inscribed on any article, or by the exhibition of a photograph or cinematograph film, or by way of sound recording, sound broadcasting or television, or in any other way." An "advertisement" also includes "words forming part of a sound recording or embodied in a sound-track associated with a cinematograph film" and "words broadcast by way of sound broadcasting or television or transmitted to subscribers to a diffusion service." Although an "advertisement" does not

include “spoken words,” the MA separately regulates “representations,” which include any statements or undertakings consisting of spoken words.

Similarly, the HPA defines “advertisement” to mean: the publication, dissemination or conveyance of any information for the purpose of promoting, whether directly or indirectly, the sale or use of [a medical device] by any means or in any form, including the following:

- publication in a newspaper, magazine, journal or other periodical,
- display of posters or notices;
- circulars, handbills, brochures, pamphlets, books or other documents;
- letters addressed to individuals or bodies corporate or incorporate;
- photographs or cinematograph films;
- sound broadcasting, television, the internet or other media;
- public demonstration of the use of the health product; and
- offer of trials of the health product to members of the public.

From this broad definition, it appears that the HPA also covers oral advertisements.

The key difference between the MA and the HPA regimes is that permits are required for “medical advertisements” (defined above under the MA) and “sales promotion” of medicinal products (but none are required for medical devices).

Under the MAR, a “sales promotion” means “any sales campaign (including door to door sales), exhibition, competition or any other activity for the purpose of introducing, publicizing or promoting the sale or use of any medicinal product.” Permit fees range from SGD100 (about USD80) to SGD300 (about USD240). Breach of this permit requirement is an offense punishable with a fine not exceeding SGD5,000 (about USD4,000) or imprisonment not exceeding 12 months, or both. Furthermore, if the offense is committed by a corporate body and is proved to have been committed with the consent, connivance or neglect of any director, manager, secretary or any other similar officer, the officer may be punished accordingly.

According to the MAR, the following types of medical advertisements do not require a permit:

- Reference advertisements - product information pertaining to the sale and correct use of a medicinal product, published by a person or

company with no commercial interest in the product, for dissemination to practitioners and pharmacists
- Trade advertisements - documents for the purpose of a sale by way of wholesale dealing which does not contain any recommendations on product use

Apart from the MA and HPA (which specifically apply to medicinal products and medical devices), the following general consumer / trade legislations may also apply:

- The Consumer Protection (Trade Descriptions and Safety Requirements) Act ("CPTDA")
- The Consumer Protection (Fair Trading) Act ("CPFTA")

The CPFTA only applies to consumer transactions, and aims to protect consumers against unfair practices. The CPTDA may apply to business and consumer transactions, and generally regulates descriptions of goods supplied in the course of trade. Unlike the MA and the HPA, both the CPTDA and the CPFTA do not substantively define "advertisement." Nonetheless (as shown below), their regulated practices are very broadly defined to potentially capture any form of advertisement, written or otherwise.

From a compliance angle, the principal anti-bribery legislation is the Prevention of Corruption Act ("PCA"). The PCA may potentially apply to the promotion of medicinal products and medical devices.

Permitted and Prohibited Practices

Generally, the abovementioned legislations do not spell out what forms of advertising/marketing practices are permissible. Rather, they only state what acts are prohibited. Nonetheless, as elaborated below, applicable industry codes may be helpful to determine the permissible ambits of advertising/marketing behavior (such as gifts, seminars, hospitality, entertainment and donations/sponsorships).

This section will address the prohibited practices under the MA / MAR, HPA/MDR, CPTDA, the CPFTA and the PCA, as well as the consequences of breach.

The MA / MAR

Any person who issues or causes another person to issue a false or misleading advertisement relating to medicinal products of any description

shall be guilty of an offense. Also, any person who makes a false or misleading representation relating to a medicinal product in connection with the sale of that product shall be guilty of an offense.

An advertisement/representation is taken to be false or misleading if:

- it falsely describes the medicinal products to which it relates; or
- it is likely to mislead as to the nature or quality of medicinal products of that description or as to their uses or effects.

Except in an advertisement which is distributed only to / intended for circulation among practitioners, pharmacists and nurses, no person shall publish or cause to be published:

- any medical advertisement which directly or indirectly claims, indicates or suggests that the article advertised will prevent, alleviate or cure any of the 19 diseases or conditions specified in the First Schedule (such as cancer, diabetes, tuberculosis and infertility); or
- any advertisement referring to any skill or service relating to the treatment of any disease affecting the human body.

The MA also addresses the issue of "off-label" advertisements. Any person who issues or causes another person to issue an advertisement relating to medicinal products of that description which consists/includes "unauthorised recommendations" shall be guilty of an offense. The term "unauthorised recommendations" is defined as "recommendations whereby medicinal products of a description to which the licence in question is applicable are recommended to be used for purposes other than those specified in the licence" (i.e., recommendations of off-label uses/purposes).

For each of the above MA offenses, the punishment is a fine not exceeding SGD5,000 (about USD4,000) or imprisonment not exceeding two years, or both.

Under the MAR, no person shall, in conducting any sales promotion, offer any gift or prize to promote the sale of any medicinal product. Furthermore, no person shall alter or amend any medical advertisement for which a permit has been granted unless prior approval has been obtained from the Health Sciences Authority of Singapore ("HSA"). Breach of any of these requirements is an offense punishable by a fine not exceeding SGD5,000 (about USD4,000) or imprisonment up to 12 months, or both.

If any MA or MAR offense is committed by a corporate body and is proved to have been committed with the consent, connivance or neglect of any director, manager, secretary or any other similar officer, the officer may be punished accordingly.

The HPA / MDR

Under the HPA, any person who advertises any medical device or causes any medical device to be advertised in a false and misleading way shall be guilty of an offense. An advertisement shall be taken to be false or misleading if:

- it falsely describes the medical device or gives any false information concerning the medical device; or
- it is likely to create an erroneous impression regarding the formulation, composition, design specification, quality, safety, efficacy or uses of the medical device.

The HPA also addresses the issue of "off-label" advertisements. No person shall advertise any registered medical device or cause any registered medical device to be advertised in such a way as to represent the registered medical device as being usable for any purpose other than that for which it has been registered.

Under the MDR, comparative advertisements (which differentiate the medical device from any other competing or similar medical device) must be substantiated by facts or evidence. Otherwise, it will be an offense. In this regard, it appears that comparative advertisements may only be written and not oral, since the substantiation must be indicated on the face of the advertisement.

The MDR also sets out the following prohibitions, any breach of which will be an offense:

- If the medical device is intended for direct delivery to the general public or for direct use by the general public, the advertisement shall not contain any statement about the intended use and efficacy of the medical device unless such statement has been verified by objective evidence and such objective evidence has been furnished to the HSA at the time the application to register the medical device was made.
- An advertisement shall not contain any statement which expressly or implicitly suggests that the use of the medical device is promoted or endorsed by the HSA.

- No person shall advertise any registered "professional use only" medical device, unless the advertisement is distributed only to, or is contained in a publication intended for circulation mainly among, qualified practitioners.
- An advertisement shall not expressly or implicitly claim, indicate or suggest that the medical device will prevent, alleviate or cure any of the 19 diseases or conditions specified in the Second Schedule (such as cancer, diabetes, tuberculosis and infertility).

For each of the above HPA and MDR offenses, the punishment is a fine not exceeding SGD20,000 (about USD16,000) or imprisonment not exceeding 12 months, or both. The fine may be doubled to SGD40,000 (about USD32,000) if the offense is committed by a corporate body. Furthermore, if the offense is committed by a corporate body and is proved to have been committed with the consent, connivance or neglect of any director, manager, secretary or any other similar officer, the officer may be punished accordingly.

The CPTDA

Any person who in the course of a trade or business applies a false trade description to any goods, or supplies any goods to which a false trade description is applied, shall be guilty of an offense.

The definition of "goods" includes "all kinds of movable property" and will likely capture medicinal products and medical devices.

A "trade description" is defined broadly and includes any physical characteristics (such as volume, capacity, weight, method of manufacture, composition, fitness for purpose, strength, performance, behavior and accuracy), results of testing, approval by any person / conformity with an approved type, manufacturer / producer / processor details and any other history. It includes an oral statement.

A "false trade description" is a trade description which is false or likely to mislead in a material respect as regards the goods which it is applied. It includes a false indication that any goods comply with a standard specified by any person, recognized by any person or implied by the approval of any person.

Breach of the CPTDA is punishable by a fine not exceeding SGD10,000 (about USD8,000) or imprisonment of up to two years, or both. If the offense is committed by a corporate body and is proved to have been committed with

the consent, connivance or neglect of any director, manager, secretary or any other similar officer, the officer may be punished accordingly.

The CPFTA

The CPFTA prohibits any "unfair practice" which includes:

- doing/omitting to do anything (which arguably includes an oral statement) which as a result a consumer might reasonably be deceived or misled;
- making false claims;
- taking advantage of a consumer if the supplier knows or ought to reasonably know that the consumer is not in a position to protect its interests or is not reasonably able to understand the character, nature, language or effect of the transaction; or
- doing anything specified as a "specific unfair practice" in the Second Schedule, which includes representing that goods have approval, components, qualities, uses or benefits that they do not have.

Any affected consumer may sue the supplier, and claim for variation of the contract, orders for repair or replacement of parts for goods, restitution of money or property, damages or an order for specific performance. Separately, the Consumer Association of Singapore which is the relevant regulatory body in charge of consumer protection, may seek a court declaration that the supplier has or is about to be engaged in an unfair practice and/or an injunction against the supplier.

From September 2012 onwards, the CPFTA will include provisions relating to "lemon laws" to provide consumers with an alternative simplified regime for obtaining redress for goods which do not conform to contract at the time of delivery. These provisions give consumers four additional remedies, as follows:

- Repair
- Replacement
- Reduction in price
- Rescission

The PCA

If any "gratification" is corruptly received/given (or agreed to be received/given) for the doing or preventing the doing of anything in relation to any transaction (actual or proposed), the giver and/or recipient shall be

guilty of an offense, even if he acted on behalf of another. The punishment is a fine not exceeding SGD100,000 (about USD80,000) or imprisonment up to five years, or both.

Significantly, the PCA may be enforced against corporate entities.

The definition of "gratification" is broad. It includes:

- money or any gift, loan, fee, reward, commission, valuable security or other property or interest in property of any description, whether movable or immovable;
- any office, employment or contract;
- any payment, release, discharge or liquidation of any loan, obligation, or other liability whatsoever, whether in whole or in part;
- any other service, favor or advantage of any description whatsoever; and
- any offer, undertaking or promise of any gratification within the four items above.

In determining whether any gratification has been given/received "corruptly," the courts adopt a two-stage test:

- whether the transaction is corrupt according to the reasonable man; and
- whether the accused had a corrupt purpose in mind.

In applying this test, the courts usually embark on a multi-factorial consideration of the relevant circumstances of the case (collectively, the "PCA Corrupt Test Factors"), such as:

- whether justice was perverted;
- whether the transaction took place in secrecy;
- whether there was a pre-existing relationship between the parties;
- the relative cost of the gratification *vis-à-vis* the receiver;
- the relative cost of the gratification *vis-à-vis* the transaction;
- the timing of the gratification;
- the degree of personal relationship between the giver and receiver; and
- whether any rules or regulations were breached and the purpose of such rules.

Professional Codes of Conduct

In addition to the above legislative provisions, there are various industry guidelines and codes of practice which deal with advertisements and marketing practices relating to medicinal products and/or medical devices. These industry guidelines and codes of practice do not have the force of law. The pertinent ones include the following:

- A Guide On Advertisements And Sales Promotion Of Medicinal Products issued by the HSA ("Medicinal Products Advertisement Guide") -- offers guidance on how the HSA applies the MA and the MAR.
- Guidance On Medical Devices Advertisements And Sales Promotion issued by the HSA ("Medical Devices Advertisements Guide") -- offers guidance on how the HSA applies the HPA and the MDR.
- The Singapore Code of Advertising Practice ("SCAP") -- a set of guidelines regulating advertising activities in Singapore. It is administered by the Advertising Standards Authority of Singapore ("ASAS").
- The Singapore Association of Pharmaceutical Industries Code of Marketing Practice ("SAPI Code") -- an industry code which addresses marketing practices vis-à-vis pharmaceutical, medicinal and biological products only, and not medical devices, between SAPI members and healthcare professionals.
- The Singapore Medical Council's Ethical Code And Ethical Guidelines ("SMC Code") -- sets out what the SMC regards as minimum standards of registered medical practitioners discharging their professional duties, including conduct in respect of financial interests, sponsorships and gifts. The SMC usually relies on the SMC Code for guidance in disciplinary proceedings against errant registered medical practitioners.

Medicinal Products Advertisement Guide

The following sales promotion activities are expressly allowed:

- Giving discounts
- Banding of different pack sizes of the same medicinal product or medicinal product within the same range, with or without a discount
- Distribution of samples of vitamin and mineral products, medicated plasters, antiseptic preparations, medicated soaps (subject to approval)

The following sales promotion activities are expressly prohibited (apart from those prohibited under the MAR):

- Use of the word "free" or "complimentary"
- Use of money-back guarantee
- Offer of medicine free-of-charge with the purchase of a non-medicinal product
- Distribution of samples of medicinal products to the general public.

The following types of advertisements relating to a medicinal product do not require a permit from the HSA (apart from those spelt out in the MAR):

- Package inserts accompanying the product
- Announcements and warnings on imitation of medicinal products with no intent to advertise the product
- Announcements on the name and address of a new distributor
- Display cards on product shelves printed with only the name of the medicinal product and the price (not the special or discounted price)
- Packaging with a protruding display flap, containing a single unit of medicinal product
- Promotional advertisements for dissemination to healthcare professionals only; it should be stated clearly on the materials that they are for healthcare professionals only and not for general circulation.

The following types of sales promotion activities do not require a permit from the HSA:

- Distribution of samples or bonus offers to drug stores, pharmacies, wholesalers and clinics, provided that there is no sales promotion to the general public
- Storewide sales promotion that is not specific to any product by named basis.

The Medicinal Products Advertisement Guide also sets out various general principles (collectively, the "Medical Advertisement Guide General Principles") in relation to medical advertisements and sales promotion. The pertinent ones include the following:

- Advertisements should truthfully state the nature, quality and properties of the medicinal product. They should not mislead in any way by ambiguity, exaggeration, omission or otherwise.

- All claims must be substantiated. The literature should be of established sources.
- Recommendations relating to the use of medicinal products should be accurately stated in moderate terms and should be relevant to their properties.
- Advertisements should not contain comparisons with other medicinal products or related products unless scientifically proven.
- Advertisements should not misuse research results or make unnecessary quotations from technical and scientific publications.
- Advertisements should not suggest trial use of medicinal products.
- Advertisements should not give the impression of advice or support from healthcare professionals.
- Testimonials from non-professionals are generally prohibited unless they can be substantiated.
- The names and logos of the HSA and any of its professional groups cannot be used.
- There should not be any words, phrases or illustrations which claim or imply the cure of any ailment, illness or disease other than the relief of its symptoms.
- There should not be direct or indirect suggestion that a medicinal product can prevent, retard or reverse the physiological changes and degenerative conditions brought about by or associated with ageing.
- Advertisements should not discourage the public from seeking professional medical advice.
- Advertisements must comply with the SCAP.

The following terms and claims are not allowed in advertising:

- Superlatives, such as, “miraculously,” “100% safe” or “no side effects”
- Exaggerated claims, such as, “guaranteed,” “instant cure” or “complete cures”
- Misleading claims, such as, “anti-ageing”.

The above guidelines are helpful in assessing whether advertising claims are false and misleading under the MA.

Medical Devices Advertisement Guide

Like the Medicinal Products Advertisement Guide, the Medical Devices Advertisement Guide contains various general principles in relation to advertisements of medical devices. These principles largely mirror the Medical Advertisement Guide General Principles, and are helpful in

assessing whether advertising claims are false and misleading under the HPA.

SCAP

The basic premise of the SCAP is that all advertisements should be legal, decent, honest and truthful. In this regard, its general and specific principles applicable to medicinal products and medical devices are similar to the Medical Advertisement Guide General Principles.

The ASAS may ask an advertiser or an advertising agency to amend or withdraw any advertisement in breach of the SCAP.

SAPI Code

The SAPI Code is an industry code which addresses marketing practices *vis-à-vis* pharmaceutical, medicinal and biological products only, and not medical devices, between SAPI members and healthcare professionals. Marketing practices include:

- sponsorship of meetings and symposia;
- hospitality and entertainment provided at sponsored meetings and symposia;
- gifts and promotional items; and
- donations and grants.

The SAPI Code does not have the force of law. Nonetheless, as highlighted above, one of the PCA Corrupt Test Factors (in ascertaining whether a gratification has been given/received "corruptly") is whether any rules or regulations were breached and the purpose of such rules.

Therefore, the SAPI Code may be relevant insofar as compliance with it will help show that the promotional/marketing activity in question was not conducted "corruptly" under the PCA. For this reason, it may be helpful to comply with the SAPI Code even for the medical device industry. However, it bears noting that such compliance (whether for the medicinal product or medical device industries) is not a safe harbor defense. The SAPI Code is merely a useful guideline.

The following sections will touch on the key ambits of various marketing activities set out in the SAPI Code.

Sponsorship of Meetings / Symposia

Under the SAPI Code, when a pharmaceutical / medical device company sponsors a symposium, congress or other medical / healthcare or educational program for both local and overseas meetings the following should be observed:

- The sponsorship must be able to withstand public and professional scrutiny and conform to the professional standards of ethics and good trust.
- The company's sponsorship by the company should be clearly stated in advance, at the meeting and in any proceedings. Printed, audio-visual or computer-based material arising from such meetings should accurately reflect this.
- Sponsorship of healthcare professionals should be limited to travel, meals, accommodation and registration fees, with travel and accommodation provided for overseas meeting only.
- No payment should be made to compensate healthcare professionals for time spent attending the event.
- Any support provided to individual healthcare professionals must not be conditional upon any obligation to prescribe, recommend or promote any medicinal product / medical device.
- Payments of reasonable honoraria and reimbursement of out-of-pocket expenses, including travel and accommodation, may be provided to healthcare professionals who are providing genuine services as speakers or presenters on the basis of a written contract with the company at the event.
- Invitations to events should not be extended to spouses unless they themselves are practicing members of the medical or allied profession.
- All companies should only provide economy class tickets for air travel of less than six hours. This should apply to all faculty members, such as speakers, members of advisory boards as well as attendees.
- Companies should not pay any cost for persons accompanying invited members of the medical and allied professions.
- When the event is to be held in an overseas location, the majority of the attendees should be from the country in which the event is held.
- A minimum of 75 percent of time should be spent on core activities of the event and a maximum of 25 percent of time may be devoted to recreational activities, such as cultural dance and sight-seeing tour of modest or nominal fees.
- Any activities that have an element of chance should not be part of the event.

Hospitality / Entertainment Provided at Sponsored Meetings / Symposia

The key principle is that scientific objectives should be the principal focus in arranging such events, and entertainment/hospitality is inconsistent with such objectives. In this regard, the SAPI Code sets out the following:

- Entertainment/hospitality should be kept to a modest level and be able to withstand professional and public scrutiny.
- Meetings should be held in an appropriate venue that is conducive to the scientific or educational objectives of the event. Companies should avoid using renowned or extravagant venues. The choice of venue must be able to successfully withstand public and professional scrutiny and conform to professional and community standards of ethics and good taste. Venues associated with activities such as gambling, gaming and entertainment are deemed inappropriate.
- Hospitality should be limited to refreshments and/or meals incidental to the main purpose of the event and should only be provided to participants, and should not extend beyond members of the healthcare professions.
- Providing hospitality in relation to food and drinks as per social / cultural norms in a local setting to members of the medical and allied professions should be limited to less than SGD100 (about USD80) per person (excluding taxes). However, this should be accompanied with dissemination of scientific or educational information.
- No stand-alone entertainment or other leisure or social activities should be provided or paid for by companies. However, entertainment of modest nature which is secondary to refreshments and/or meals is allowed during the event.

Gifts / Promotional Items

The general rule is that inappropriate financial or material benefits should not be offered to healthcare professionals to influence them in the prescribing of pharmaceutical products. In this regard, the SAPI Code states the following:

- No gifts or financial inducement shall be offered or given to members of the medical and allied professions for purpose of sales promotion. This is consistent with the MAR.
- Payments in cash or cash equivalents (such as gift certificate) must not be offered to healthcare professionals either directly or indirectly.

- Promotional items of insignificant value of no more than SGD20 (about USD16) provided free of charge are permissible as long as they are related to the healthcare professional's work and/or entail a benefit to patients. Gifts as a token of appreciation for services rendered by healthcare professionals should be limited to SGD50 (about USD40) or less.
- Inexpensive food items and drinks as per social/cultural norm may be distributed to healthcare professionals during the course of day-to-day promotional activities only and should be limited to less than or equal to SGD20 (about USD16) per healthcare professional.
- Congratulatory flowers limited to promotions, conferment of awards or clinic/hospital opening should be limited to SGD150 (about USD120) per occasion.
- Congratulatory messages in any form of media on behalf of a healthcare professional or a hospital/clinic are strictly prohibited.
- Exceptional gifts such as cakes, cookies and mandarin oranges during various festive seasons should be symbolic and modest, with a value of up to SGD50 (about USD40). Each healthcare professional should only be offered a maximum of two such gifts per year.
- Items of medical utility may be offered or given free of charge provided such items are of modest value and are beneficial to the provision of medical services and for patient care. The value of such items should be limited to les than or equal to SGD200 (about USD160).

Donations / Grants

Companies may provide donations by request, strictly for charitable purposes and charitable organizations. In addition, companies can provide grants towards financial support strictly for educational programs, (including but not limited to request to accredited educational programs, non-accredited educational programs, fellowships, advocacy organizations, societies, medical conferences, congresses or independent meetings) if they are:

- unsolicited;
- for an institution or organization, not an individual healthcare practitioner;
- unrelated to the prescribing, purchasing, registration of any products;
- substantiated by written documentation of the program details; and
- able to withstand public scrutiny.

Interaction Between SAPI Code and PCA - Tips

The following tips may be helpful in respect of the interaction between the SAPI Code and the PCA:

- The PCA prohibits any gratification that is corruptly given/received "for the doing or preventing the doing of anything in relation to any transaction." It would therefore be prudent to avoid providing any sponsorships, hospitality, entertainment and gifts / promotional items "for the doing or preventing the doing of anything in relation to any transaction" (actual or proposed).
- In cases of promotional / marketing activities that have been addressed by the SAPI Code, medicinal product / medical device companies (whether SAPI members or not) should comply with these ambits. This will help militate against liability under the PCA.
- There are naturally several types of promotional/marketing activities that are not addressed by the SAPI Code. These include entertainment / hospitality per se (not provided for sponsored congresses/symposia), gifts for personal occasions like birthdays, and travel arrangements (not provided for sponsored congresses/symposia). In this regard, the PCA is deliberately drafted broadly and does not identify any specific safe harbors in relation to various forms of gratification. A common sense approach should therefore be adopted in light of all the circumstances, including close adherence to the PCA Corrupt Test Factors.

By way of illustration:

- If a local hospital is organizing a tender for medical devices, then any approach for a friendly round of golf by the company's business development personnel to healthcare professionals working at the hospital (especially those in a position to potentially influence the award of the bid) around the time of evaluation of the bids would be open to question, and is not recommended. Conversely, if the company's local chief executive officer organizes and pays for a party where one or more of the guests are from the hospital but happen to be mutual friends of the person for whom the party is being held, this may be less of a concern.
- If an expensive birthday gift is given to a healthcare professional (who is in a position to influence the award of tenders) close to the time of evaluation of a tender bid, this may be subject to closer scrutiny than an inexpensive birthday gift where there is no pending award.

- Insofar as it makes "business sense" for travel to other countries (e.g., to visit corporate headquarters in the US to talk about products and opportunities face-to-face) as opposed to it being an excuse for travel to an exotic holiday destination, then payment for travel may be acceptable. The costs should nonetheless be reasonable, and proper receipts should be procured and kept. Where possible, payment should be made direct to the service providers rather than made in cash (or by way of *per diem*) to the traveler.

SMC Code

While the SMC Code only applies to registered medical practitioners in Singapore (and therefore will not subject the relevant medicinal product / medical device company to sanctions from the SMC), it may be useful for medicinal product / medical device companies to comply with its guidelines governing financial relationships with these companies.

The reasons are two-fold. Firstly, compliance may help show that such relationships are not entered into corruptly for the purposes of the PCA. Secondly, the risk of doctors being censured is reduced. This consequently mitigates the risk of the company being exposed to negative publicity.

Financial / Commercial Interests

Under the SMC Code, a doctor must refrain from improperly prescribing drugs or devices in which he has a financial interest, and sharing fees or obtaining commissions from referrals of patients.

Additionally, a doctor shall not exert undue influence upon a patient in relation to transactions in which he has an interest.

If a doctor has a financial interest in an organization or service to which he intends to refer patients for admission, treatment or, investigation, or for the purchase of any drugs, medicine or service in the course of treatment, he shall always disclose his interest to the patient before making a referral.

A doctor shall not let financial considerations imposed by his own practice, investments or financial arrangements influence the objectivity of his clinical judgement in the treatment of his patients.

Sponsored Educational Events and Research

A doctor may be invited to participate in medical events, conferences, talks, publications or educational websites sponsored by companies marketing

pharmaceutical products /medical devices. The doctor should ensure that his participation is not seen as an endorsement of such products, neither is it meant to persuade patients or members of the public to use the products.

Apart from identification and establishment of credentials, no details of services provided by the doctor or service details shall appear in any way in relation to such participation.

A doctor who is sponsored by a company to participate in an educational event or who reports research sponsored by a company must declare all such potential conflicts of interest to the audience.

Gifts / Hospitality

A doctor shall not ask for gifts, hospitality or other inducements that may affect or be seen to affect his judgement in making decisions about patients' treatment. A doctor can receive small, insubstantial gifts which cannot be regarded as inducement.

Public Procurement

The PCA sets out various presumptions of liability as well as offenses in relation to gratification provided to or received by government officials / employees / public bodies. In this regard, there is a presumption that a gratification is given or received corruptly if the giver or recipient is in the employment of the government, any department of the government, or a "public body" ("PCA Presumption"), unless the contrary is proved on a balance of probabilities. This presumption is not conclusive that an offense has been committed, and may be rebutted by the accused.

If the gratification is offered by a person who intends to tender for a contract with the Singapore government or a "public body" to any person who has made a tender for a contract with the Singapore government or a "public body" as an inducement or reward to withdraw that tender, the offeror and/or person who solicits or accepts the business courtesy as such inducement shall be guilty of an offense. The punishment is a fine not exceeding SGD100,000 (about USD80,000) or imprisonment for a term not exceeding seven years, or both.

If the gratification is offered to a member of a "public body" as an inducement or reward for the member to procure or prevent the passing of a vote for the grant of a contract in favor of the person offering the gratification, the offeror and/or the member of a "public body" who solicits

or accepts the courtesy as such inducement shall be guilty of an offense. The punishment is a fine not exceeding SGD100,000 (about USD80,000) or imprisonment for a term not exceeding seven years, or both.

"Public body" is defined to mean "any corporation, board, council, commissioners, or other body which has power to act under and for the purposes of any written law relating to public health or to undertakings or public utility or otherwise to administer money levied or raised by rates or charges in pursuance of any written law."

Apart from the PCA, the Penal Code (the principal criminal legislation in Singapore) also deals with public procurement corruption, as follows:

- If the gratification is given so that the recipient may corruptly influence a "public servant," the recipient shall be guilty of an offense. The punishment is a fine or imprisonment not exceeding three years.
- If the gratification is given so that the recipient may exercise personal influence with a "public servant," the recipient shall be guilty of an offense. The punishment is a fine or imprisonment not exceeding one year.
- If the gratification is given to a "public servant" as a motive or reward for doing or forbearing to do any official act, or for showing or forbearing to show, in the exercise of his official functions, favor or disfavor to any person, or for rendering or attempting to render any service or disservice with any person, with the government, or with any member of Parliament or the Cabinet, or with any public servant, the public servant shall commit an offense. The punishment is a fine or imprisonment not exceeding three years.

"Public servant" is defined broadly, and captures any government official.

Public vs. Private Hospitals / Healthcare Professionals - a Misnomer in Singapore

In light of the above, especially the PCA Presumption, a key issue for medicinal products and medical device companies is whether public/government hospitals and their healthcare professionals are "public bodies," government employees, employees of "public bodies" and/or "public servants."

The terms "public / government hospitals" and "public / government healthcare professionals" appear to be misnomers in Singapore. There is no distinction drawn between private hospitals and non-private hospitals (which

should be correctly termed as "restructured hospitals" in Singapore, ultimately owned by the Ministry of Finance but which operate quite independently from the civil service) under the Private Hospitals and Medical Clinics Act ("PHMCA"), which regulates the licensing of private and non-private hospitals alike.

It is not clear (at least from relevant legislation) whether "restructured hospitals" and healthcare professionals employed by "restructured hospitals" are public bodies and government / public body employees / public servants for the purpose of Singapore's anti-corruption laws.

By reference to the Parliamentary Debates in respect of the PHMCA, it appears that the government's view is that these hospitals and healthcare professionals should not be regarded as public bodies and employees of the government, any government department or a public body.

Nonetheless, given that "restructured hospitals" are still owned by the Ministry of Finance, US authorities may have a different view as to whether such hospitals and healthcare professionals are regarded as foreign government bodies and officials for the purposes of the US Foreign Corrupt Practices Act.

Contracts with Healthcare Professionals and Medical Institutions

Medicinal product and medical device companies will invariably enter into various contracts with healthcare professionals and medical institutions. These contracts include research contracts, consultancy contracts and speakership contracts. The following points may be helpful:

- Understand that there could be corruption issues wherever such agreements are executed. The PCA Corrupt Test Factors, the SAPI Code and the SMC Code should be complied with.
- The scope of performance and consideration should be defined precisely in the contracts.
- Any consideration must be reasonable and defensible according to market rate.
- Suitable anti-corruption clauses should be included. The contracting party should warrant and confirm that the execution and performance of the contract does not violate any applicable anti-corruption laws, regulations or codes of conduct, as well as any internal compliance policies.

- If contracts are entered into with the healthcare professionals directly, they should warrant and confirm that the execution and performance of the contract does not breach their employment agreements. Furthermore, they should also warrant and confirm that written consent has been sought from their employer. For prudence, request for a copy of such written consent.

Recommendations

The promotion and advertisement of medicinal products and medical devices are snared with various legal risks. In some cases, severe criminal punishment may be meted out. To mitigate these risks, the following points are recommended:

- Check whether permits are required for medical advertisements /sales promotion of medicinal products.
- Check whether the claims in medicinal product / medical device advertisements pass regulatory muster.
- Conduct regular training for the business / marketing team on permissible sales promotion / advertisement claims.
- Create a corporate compliance policy that is in line with the PCA Corrupt Test Factors, the SAPI Code and the SMC Code and ensure that all employees are bound by this policy.
- Conduct regular training for the business / marketing team on permissible marketing activities from an anti-corruption viewpoint.
- Ensure that contracts with healthcare professionals and medical institutions are appropriately drafted (as highlighted in the previous section).

臺灣

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序言

在臺灣，藥物（藥物包括用於人類之藥品及醫療器材）的廣告與行銷係同時由國家立法與專業實務守則所規範。相關的主管機關在中央層級主要包括行政院衛生署食品藥物管理局（以下稱「食品藥物管理局」）及公平交易委員會（以下稱「公平會」）；在地方層級則爲各縣市政府之衛生局。藥物廣告申請案係由食品藥物管理局進行審查，違規藥物廣告則由各縣市政府之衛生局監督並進行裁罰。不實廣告或是因藥物廣告或行銷引起的不公平競爭則由公平會管轄。

法令架構

藥物廣告

藥物廣告在臺灣主要受「藥事法」（2012年最新修正）所規範。藥事法所稱「藥物廣告」係指「利用傳播方法，宣傳醫療效能，以達招徠銷售爲目的之行爲」。藥事法亦規定，採訪、報導或宣傳，其內容暗示或影射醫療效能者，視爲藥物廣告。

依藥事法規定，藥商刊播藥物廣告時，應於刊播前將所有文字、圖畫或言詞，申請食品藥物管理局或直轄市衛生主管機關核准。僅持有該藥物之許可證之藥商能夠從事藥物廣告。藥物廣告，經主管機關核准者，其有效期間爲一年。期滿仍需繼續廣告者，得申請原核准之衛生主管機關核定展延之；每次展延之期間，不得超過一年。

除藥事法之外，藥物廣告亦受到「消費者保護法」（以下稱「消保法」，2005年最新修正）及「公平交易法」（以下稱「公平法」，2011年最新修正）一般規定所規範。消保法要求企業經營者

應確保廣告內容之真實，其對消費者所負之義務不得低於廣告之內容。

虛僞不實或引人錯誤的廣告則爲公平法所禁止。依據公平法，事業不得在商品或其廣告上，或以其他使公眾得知之方法，對於商品之價格、數量、品質、內容、製造方法、製造日期、有效期限、使用方法、用途、

Taiwan

Grace Shao, Belle Chiou

Introduction

In Taiwan, advertising / promoting of medical products, including drugs and medical devices for human use, is simultaneously governed by state legislation and professional codes of practice. The regulators, at the national government level, primarily include the Taiwan Food and Drug Administration ("TFDA") and the Fair Trade Commission ("FTC"); and at the local government level, the Department of Health of city or country government ("Local DOH"). Medical product advertising applications are reviewed by the TFDA, and illegal advertising is monitored and sanctioned by the Local DOH. False or misleading advertising and unfair competition due to promoting of medical products are supervised and sanctioned by the FTC.

Regulatory Framework

Advertising of Medical Products

Advertising of medical products in Taiwan is primarily governed by the Pharmaceutical Affairs Law ("PAL"), last amended in 2012. Under the PAL, "advertising of medical products" refers to the act of advertising the medical efficacy of medical products by means of communication aiming to solicit and promote the sale of advertised products. Interviews, news reports or propaganda containing information implying or suggesting medical efficacy of a product for human use are also regarded as advertisements of medical products.

The PAL provides that a prior approval for medical product advertising from the TFDA or municipal competent health authority is required. All text, images and phrases of product advertisements must be reviewed and approved by the regulator before the advertisements become public. Marketing approval is required to advertise medical products. The approval for advertising is valid for one year, extendable for another year if the advertiser submits an extension application.

原產地、製造者、製造地、加工者、加工地等，爲虛僞不實或引人錯誤之表示或表徵。

反不公平競爭

除藥物廣告外，藥事法並未對藥物行銷活動多作規定。藥商對醫護人員之藥物行銷活動，主要受到反不公平競爭及反賄賂之相關立法所規範。

違規藥物廣告，例如：違法之比較廣告，可能構成公平法之不公平競爭。依據公平法，事業不得爲競爭之目的，而陳述或散布足以損害他人營業信譽之不實情事。

不當的行銷活動，例如基於行銷藥物之目的，對醫護人員或醫療機構提供不適當的餽贈、娛樂、招待、贊助，及其他利益等，亦有可能構成不公平競爭。依據公平法，事業（含藥品及醫療器材廠商）不得以脅迫、利誘或其他不正當方法，使競爭者之交易相對人與自己交易，而有限制競爭或妨礙公平競爭之虞之行爲。此外，事業亦不得爲其他足以影響交易秩序之欺罔或顯失公平之行爲。

公平會則另以「公平交易委員會對於贈品贈獎促銷額度案件之處理原則」（以下稱「贈品處理原則」，2012年最新修正）規定事業提供促銷贈品贈獎價值之上限。依贈品處理原則，事業銷售商品或服務附送贈品，贈品價值不得超過新臺幣50元或商品或服務價值之二分之一（視何者較高）；同時，其全年贈獎總額之上限，爲新臺幣1億元，或銷售金額的五分之一（視何者較高，但不

得高於臺幣4億元）。此外，其最大獎項之金額，不得超過行政院勞工委員會公布之每月基本工資的120倍。

反賄賂

貪污治罪條例（2011年最新修正）禁止任何人（例如藥商之代表）對公務員（含公立醫療機構之具有法定職務權限之醫護人員）行求、期約或交付賄賂或其他不正利益。行賄者及受賄者將受到該條例之刑事制裁。

刑法背信罪則禁止私人事業或機構的員工（例如任職於私立醫療機構之醫護人員）收受賄賂或其他不正利益而爲違背其任務之行爲。藥商若對

In addition to PAL, the general provisions of the Consumer Protection Law ("CPL"), last amended in 2005 and the Fair Trade Law ("FTL"), last amended in 2011; the anti-trust law of Taiwan must also be taken into account when advertising medical products. The CPL generally requires that advertisers must ensure the accuracy of the contents of their advertisements and are obligated to uphold the promises made to the consumers in such advertisements.

The FTL prohibits false or misleading advertisements. Under the FTL, no enterprise may make or use false or misleading representations or symbols as to price, quantity, quality, content, production process, production date, validity period, method of use, purpose of use, place of origin, manufacturer, place of manufacturing, processor, or place of processing of goods or in advertisements, or in any other way making known to the public.

Anti-Unfair Competition

Other than advertisements, the PAL does not say much on promotion of medical products. Product promotional activities targeting healthcare professionals are mainly governed by anti-unfair competition legislation and anti-bribery legislation.

Illegal advertising of medical products, for example, comparative advertising, may constitute unfair competition under the FTL. According to the FTL, no enterprise may, for the purpose of competition, make or disseminate any false statement that may damage the business reputation of another.

Unethical promotional activities, such as offering improper gifts, entertainments, hospitality, sponsorship, and other interests to healthcare professionals/institutions for the purpose of promotion of medical products, may also raise concerns of unfair competition. Pursuant to the FTL, no enterprise, including pharmaceutical and medical device companies, may cause the trading counterparts of its competitors to do business with itself by coercion, inducement with interest, or other improper means, which is likely to lessen competition or to impede fair competition. The FTL also prohibits any enterprise from deceptive or obviously unfair conduct that may affect trading order.

To strengthen the FTL, the FTC promulgated "Guidelines on Cases Concerning Promotion by Means of Gifts and Prizes" ("Gift Guidelines"), last amended in 2012 which set out the limitations on the value of gifts or prizes offered by an enterprise. Under the Guidelines, the value of gifts

藥商若對私立醫療機構之醫護人員行賄，則可能被認定是刑法（2011年最新修正）背信罪之共犯而受到處罰。

政府採購

政府採購法（2011最新修正）之宗旨在建立公平、公開之政府採購程序，並處罰違反政府採購法之行爲。該法亦適用於公立醫療機構之採購程序。因此，公立醫療機構採購藥物，須依政府採購法之投開標程序爲之。

許可及禁止之廣告

許可之藥物廣告媒體

藥事法允許藥商得於電視、廣播、報紙、雜誌、海報、網站或電子郵件等媒體上進行藥物廣告。但處方藥物之廣告以登載於學術性醫療刊物或僅醫護人員得瀏覽之網站爲限。

對消費者或病人之廣告

法令並無明文禁止藥商直接針對消費者或病人進行藥物廣告。但處方藥物之廣告以登載於學術性醫療刊物或僅醫護人員得瀏覽之網站爲限。

禁止之藥物廣告方式

藥物廣告，不得以下列方式爲之：

- 假借他人名義爲宣傳者。
- 利用書刊資料保證其效能或性能。
- 藉採訪或報導爲宣傳。
- 以其他不正當方式爲宣傳。

禁止之藥物廣告訴求

法令禁止以下之廣告訴求：

- 標榜或暗示性方面之效能者。
- 提供獎勵，而有助長濫用藥物之虞者。

which are given with products or services offered by a company may not exceed the higher of either TWD50 or half the value of such product/service. The total value of prizes given by a company within one year may not exceed the higher of either TWD100 million or one-fifth of the annual sales amount of that enterprise, subject to a maximum value of TWD400 million. Furthermore, the value of the highest prize may not exceed 120 times the statutory monthly minimum wage.

Bribery

The Anti-Corruption Law ("ACL"), last amended in 2011 prohibits any person (e.g., representatives of a pharmaceutical or medical device company) from bribing or unjustly enriching public officials (e.g., public hospital's healthcare professionals who have legal authority in accordance with law). The provider and taker of bribes will face criminal liability if he/she is found guilty of bribery under the Anti-Corruption Law.

The Criminal Code prohibits private parties' employees (e.g., healthcare professionals employed by private hospitals) from illegally receiving bribes or other improper benefits in breach of their work duties. A briber is deemed an accomplice of the person being bribed and may be subject to criminal penalty.

Public Procurement

The Government Procurement Act ("GPA"), last amended in 2011 aims to establish a fair and open government procurement system and punishes some offenses which encroach the fairness of government procurement. This Act is also applicable to the procurement process of public hospitals. Therefore, medical products purchased by public hospitals are subject to the tendering rules under the GPA.

Permitted and Prohibited Practices - Advertisements

Types of Media Permitted for Medical Product Advertising

An advertiser may advertise its medical products on TV, radio, newspapers, websites or by email, posters, etc. However, prescription-only medical products can only be advertised in scholarly medical publications or on websites to which only healthcare professionals have access.

- 於廣告使用虛僞之資訊。
- 誇張藥物效能及安全性者。

藥商名稱廣告

就藥商名稱進行廣告，並不構成藥事法上之「藥物廣告」。因此無庸經過事先核准。

藥物名稱廣告

就藥物名稱進行廣告，縱未提及「醫療效能」，仍可能被主管機關認定爲藥事法上之「藥物廣告」，而須經事先核准。

藥商網站上之自家藥物資訊

藥商於自家網站介紹產品並不受藥事法藥物廣告之規定所規範。但該介紹之產品資訊僅限於食品藥物管理局所核准之完整仿單內容，並應加貼藥物外盒及實體外觀之圖片。

病人資訊講習

部分藥商認爲，病人資訊講習如係爲病人或醫師等特定人而非爲公眾舉辦，並不構成藥事法上之「藥物廣告」。惟根據食品藥物管理局之見解，此等資訊講習如爲行銷目的而宣傳產品，則該資訊講習亦可能被認定爲「藥物廣告」，而應先經主管機關核准。

提供科學數據或文獻

藥商提供給醫護人員有關藥物之科學數據或文獻通常不會被視爲藥物廣告。然而，如果所提供科學數據或文獻有暗示或影射特定藥物之醫療效能，或甚至包含藥商之名稱，則該數據或文獻資料可能被視爲藥事法之藥物廣告而受主管機關所監督。

藥物價格廣告

藥物價格廣告係法令所允許。惟若該廣告宣傳價格優惠（例如：折扣）而有鼓勵濫用藥物之虞時，主管機關可能不予核准該廣告申請。

Advertising to End-Consumers / Patients

Advertising non-prescription medical products to consumers is permitted. Conversely, advertising prescription-only medical products to consumers is not permitted. As mentioned, advertisements of such products can be published in academic medical journals or on websites to which only healthcare professionals may have access.

Prohibited Forms of Medical Product Advertising

Medical product companies are prohibited from running advertising campaigns that use:

- a third-party name in the advisement without his/her consent
- information published in books or journals to guarantee the effects and functions of the products
- interviews or reports to promote the products
- other inappropriate methods

Prohibited Advertising Claims

Medical product advertisements may not:

- Mention or suggest sexual function
- Offer incentives which may encourage misuse of medical products
- Fabricate the information used in the advertisement
- Exaggerate the medical effectiveness or safety of the product.

Advertising of Company Name

Advertising the name of a pharmaceutical or medical device company without mentioning any product information does not amount to "medical product advertising" under the PAL. Prior regulatory approval is therefore not required.

Off-Label Use Advertising

Advertising of medical products can only refer to the indications which have been approved by the TFDA in the marketing approval of the advertised product. Advertising of off-label use is a violation of PAL.

仿單標示外使用廣告

藥物廣告僅得提及食品藥物管理局於查驗登記時核准之適應症。仿單標示外使用之廣告，係違反藥事法之規定。

比較廣告

雖然法令並未明文禁止藥商使用比較廣告，但實務上，主管機關並不會核准比較性的藥物廣告，因爲如果主管機關核准比較廣告，容易被認爲在保證某一產品優於另一產品。

薦證廣告

薦證廣告是法令所允許的。薦證者可以是知名公眾人物、醫藥專業人士、或消費者。薦證廣告內容須忠實反映薦證者之意見。薦證者明知或可得而知其所從事之薦證有引人錯誤之虞，而仍爲薦證者，與廣告主負連帶損害賠償責任。

以贈品或贈獎促銷

對消費者以贈品或贈獎促銷藥物，有鼓勵濫用藥物之虞，故實務上並不允許。藥商可對醫護人員提供贈品或贈獎以促銷藥物，惟須遵守前揭公平會「贈品處理原則」之規定。

違反法令之效果

違規藥物廣告之法律責任

□藥事法

違反藥事法有關藥物廣告之規定，可能受到下列種類之處罰：

- 新臺幣2,500萬元以下罰鍰。
- 主管機關登報公告廣告主負責人姓名、藥物名稱及所犯情節。
- 廢止該藥物許可證。
- 廣告主在傳播媒體上聲明致歉。
- 原品名在2年內不得申請使用。
- 消費者保護法

Advertising of Product Name

Conversely, advertising the name of a medical product is likely to be regarded by regulators as "medical product advertising" under the PAL and prior regulatory approval for advertising may be required, even though no "medical effectiveness of the pharmaceutical product" is claimed in the advertisement.

Product Information Company's Website

Regulatory approval is not required for the "product information" disclosed on the website of the holder of marketing approval of medical products.

According to the TFDA's regulations, such "product information" must include, and is limited to, the name and photos or package of the product, and the entire contents of user instruction of the product which have been approved by the TFDA.

Advertising of Price

Advertising the price of a medical product is permitted in Taiwan. However, if there are any incentives advertised, e.g., discounts, which are likely to encourage abuse of medical products, the regulatory approval for such advertising will not be granted.

Promotion by Means of Gifts or Prizes

Promoting medical products by offering gifts or prizes to consumers is likely to encourage abuse of the medical products and therefore is not permitted in practice. Subject to the aforesaid Gifts Guidelines, a pharmaceutical or medical device company may offer gifts or prizes for healthcare professionals who purchase their products.

Comparative Advertising

Comparative advertising is not expressly prohibited under Taiwan law. However, for comparative advertising cannot for approval from the regulator.

The TFDA believes that if comparative advertising is approved, it may be seen as guaranteeing to consumers that one product is better than the other.

Testimonial Advertisement

Testimonial advertisement for medical products is permitted in Taiwan. An endorser can be a celebrity, a medical professional, or a consumer. The

藥商若違反消保法有關「企業經營者應確保廣告內容之真實及對消費者所負之義務不得低於廣告之內容」之規定，使消費者受有損害者，該藥商應對消費者負損害賠償責任。刊登或報導廣告之

媒體經營者明知或可得而知廣告內容與事實不符者，就消費者因信賴該廣告所受之損害與企業經營者負連帶責任。

□公平交易法

若主管機關認定一藥物廣告有公平交易法所稱虛僞不實或引人錯誤之表示，廣告主最高將被處以新臺幣2,500萬元之罰鍰。廣告代理業、廣告媒體業或廣告薦證者，若明知或可得而知廣告有引人錯誤之虞，應與廣告主負連帶損害賠償責任。

不公平競爭

違規藥物廣告（例如不實廣告）如被主管機關認定其內容貶損競爭廠商之營業信譽者，行爲人將被處以2年以下有期徒刑、拘役或科或併科新臺幣5,000萬元以下罰金。

倫理守則

醫師與廠商間關係守則

衛生署於2006年公告「醫師與廠商間關係守則」，規範醫師參加廠商主辦或贊助之醫學會議、醫師接受廠商餽贈、醫師或醫療機構執行廠商贊助之研究、及醫師擔任廠商顧問或爲廠商提供諮詢時等應遵守事項。

餽贈

醫師接受廠商餽贈，應遵守下列事項：

- 不得違反法律或全國性醫學會、公會之政策。
- 符合當地慣例且非昂貴之禮物。
- 不可收受金錢或等同現金之禮券或有價證券。
- 不得因餽贈而約定或暗示「將」使用特定醫藥產品或轉介病人至特定處所。

contents of the advertisement must truly reflect the endorser's comments on the advertised products. The endorser will be jointly and severally liable with the advertiser if he/she knows or should have known that his/her endorsement is likely to mislead the public.

Supply of Scientific Data and Literature

Normally, the supply of scientific data and literature relating to medical products to healthcare professionals by the pharmaceutical or medical device company is not considered advertising. However, if the scientific data and literature imply or suggest the effect of a specific medical product, or even include the name of the medical product suppler, they may be treated as product advertising under the PAL and will thus be subject to supervision by the regulators.

Patient Information Sessions

Some players in the industry believe that information session for patients or doctors does not constitute "medical product advertising" under the PAL if the information session is provided for specific persons only, and not the public. But according to the TFDA, the information session is also likely determined as "medical product advertising," which requires prior approval from the regulator, if the products are promoted there with a purpose to generate sales of the products.

Consequences of Breach

Liabilities for Illegal Advertising of Medical Products

Liability Under the Pharmaceutical Affairs Law

The liabilities for infringement of the advertising legislation under the PAL mainly include the following:

- A fine of up to TWD25 million
- Publication of the violation, the name of the advertiser's responsible person, and the name of advertised product in the newspaper by the regulator
- Revocation of the marketing approval of the advertised product
- Publication of an apology in the media by the advertiser
- Suspension of use of the name of the advertised product for two years

贊助

醫師參加廠商主辦或贊助之醫學會議，應遵守下列事項：

- 會議應以提昇醫療品質、促進病人權益及專業資訊之交流爲其主要目的，其學術討論時間應達總時間三分之二以上。
- 醫師接受贊助，以本人之註冊費、旅費及膳食費爲限。但擔任演講人或主持人時，得收受適當之演講費或主持費。
- 會議主辦單位應公開贊助廠商名稱，主辦單位、演講者、主持人與贊助廠商間之關係，應主動告知與會者。
- 醫師於會議中發表之資料應符合科學實證原則，不受贊助廠商之影響，並應平衡論述替代診療方式。
- 主辦單位或醫師應拒絕廠商對會議內容、發表方式、講員之選定等，爲不當之干預。

醫師或醫療機構執行廠商贊助之研究，應遵守下列事項：

- 研究及成果發表，應符合法律、倫理及赫爾辛基宣言之規範，並嚴守臨床專業判斷。
- 主持研究之報酬，應以其所投注研究之時間與心力，不以研究之結論衡酌。
- 研究成果發表時，應一併公布直接或間接贊助者的名稱。
- 從事研究前，應與廠商充分溝通；廠商不得限制研究成果之發表。

顧問及諮詢

醫師擔任廠商顧問或爲廠商提供諮詢時，應遵守下列事項：

- 任何專業判斷，不得因擔任廠商顧問或爲廠商提供諮詢而受到影響。
- 對病人之義務，不得因擔任廠商顧問或爲廠商提供諮詢而有所怠忽。
- 演講、發表文章或報告時，應公開與廠商之從屬或其他關係。

Liability Under the Consumer Protection Law

If a pharmaceutical or medical device company violates the advertiser's responsibility for the accuracy of the contents of its advertisements for a medical product under the CPL and therefore causes damage to the consumer(s), it will be liable for the damage the consumer(s) suffered. In addition, the advertising medium will be jointly and severally liable with the advertiser if it knows or should have known that the contents of advertisements are inconsistent with the facts.

Liability Under the Fair Trade Law

If an advertisement for a medical product is determined by the regulator as false or misleading advertisement under the FTL, the advertiser will be imposed a fine of up to TWD25 million. The advertising agency, the advertising medium and/or the endorser will be jointly and severally liable with the advertiser if they know or should have known the advertisement is likely to mislead the public.

Unfair Competition

If illegal advertising of medical products, for example, false or misleading advertisements, is determined by the regulator to have damaged the business reputation of the competitor, the infringer will be punished by imprisonment for up to two years and/or a fine of up to TWD$50 million.

Professional Codes of Conduct

Guidelines Governing the Relationships Between Physicians and Vendors

The Department of Health of the Executive Yuan promulgated in 2006 the Guidelines Governing the Relationships between Physicians and Vendors ("DOH Guidelines") which set forth the principles for physicians "on" accepting gifts, participating in professional meetings and conducting research sponsored by the vendors (e.g., pharmaceutical or medical device companies), and for the physicians' provision of consulting services to vendors.

公務員廉政倫理規範

國立醫療機構之醫護人員亦受行政院訂定發布之「公務員廉政倫理規範」（2010年最新修正）所規範。

餽贈

公務員不得要求、期約或收受與其職務有利害關係者餽贈財物。但有下列情形之一，且係偶發而無影響特定權利義務之虞時，得受贈之：

- 屬公務禮儀。
- 長官之獎勵、救助或慰問。
- 受贈之財物市價在新臺幣500元以下；或對本機關（構）內多數人爲餽贈，其市價總額在新臺幣1,000元以下。
- 因訂婚、結婚、生育、喬遷、就職、陞遷異動、退休、辭職、離職及本人、配偶或直系親屬之傷病、死亡受贈之財物，其市價不超過正常社交禮俗標準。

所謂「正常社交禮俗標準」係指一般人社交往來，市價不超過新臺幣3,000元者。但同一年度來自同一來源受贈財物以新臺幣10,000元爲限。

下列情形推定爲公務員之受贈財物：

- 以公務員配偶、直系血親、同財共居家屬之名義收受者。
- 藉由第三人收受後轉交公務員本人或上述家屬者。
- 款待
- 公務員不得參加與其職務有利害關係者之飲宴應酬。但有下列情形之一者，不在此限：
  (1) 因公務禮儀確有必要參加。
  (2) 因民俗節慶公開舉辦之活動且邀請一般人參加。
  (3) 屬長官對屬員之獎勵、慰勞。
  (4) 因訂婚、結婚、生育、喬遷、就職、陞遷異動、 退休、辭職、離職等所舉辦之活動，而未超過正常社交禮俗標準。
- 公務員受邀之飲宴應酬，雖與其無職務上利害關係，而與其身分、職務顯不相宜者，仍應避免。
- 公務員於視察、調查、出差或參加會議等活動時，不得在茶點及執行公務確有必要之簡便食宿、交通以外接受相關機關（構）飲宴或其他應酬活動。

Gifts

When receiving a gift from a vendor, a physician must follow the rules below:

- Do not violate any laws or any policies established by a national medical society or association.
- Conform with local practice and accept only inexpensive gifts.
- Do not accept money, gift vouchers equivalent to cash, or securities.
- Do not agree or imply use of any specific medical product, or refer any patient to any specific facility based on the gift received.

Sponsorship

With respect to physicians' participation in professional meetings sponsored by the vendors, the DOH guidelines provide certain standards, as follows:

- Professional meetings should be for the purpose of promoting quality healthcare, benefiting patients and exchanging useful and up-to-date information about the medical profession. Academic discussion time must comprise at least two-thirds of the total time of the meeting.
- Physicians are allowed to accept only certain grants covering expenses for travel and meals, and registration fees. They may also accept remuneration if they have been invited to deliver lectures or act as moderators in professional meetings.
- Organizers of professional meetings must announce the names of sponsors and duly inform participants about the relationship between the sponsor and organizer, lecturers or moderator.
- Physicians must present their works or materials at professional meetings in accordance with scientific practice without being affected or having to be pressured by vendors, and provide a balanced opinion on alternative treatments.
- Organizers should reject vendors' uncalled-for intervention in the content of professional meetings, manner of publication and the choice of lecturers.

On research sponsored by vendors, the DOH Guidelines also set forth certain standards, as follows:

- The performance of any research work and the publication of the results of such research should be in compliance with applicable laws, ethical rules and the Declaration of Helsinki, and adhere to professional judgment.

□演講、座談、研習及評審（選）

- 公務員出席演講、座談、研習及評審（選）等活動，支領鐘點費每小時不得超過新臺幣5,000元。公務員參加上述活動，另有支領稿費者，每千字不得超過新臺幣2,000元。
- 公務員參加上述活動，如屬與其職務有利害關係者籌辦或邀請，應先簽報其長官核准及知會政風機構登錄後始得前往。

IRPMA市場行銷規範

中華民國開發性製藥研究協會 (「IRPMA」)訂定藥品市場行銷規範(「行銷規範」，2011年最新修正)，提供IRPMA會員公司(「會員公司」)對醫護人員進行藥品行銷的道德標準，及與醫護人員互動的依據。

行銷規範中，「醫護人員」係指所有醫學、牙醫、藥劑或護理等專業人員，其專業職責包含開立處方、推薦、採購、供應藥品或給藥等項目；「會員公司」指所有IRPMA團體會員、個人會員及其代理商、經銷商。

不須處方之自我醫療OTC藥品行銷活動、價格或其他藥品供應之交易條件、醫護人員確實提供給會員公司的顧問或其他服務、臨床試驗之執行及由會員公司提供之非行銷性資訊，並不在行銷規範所欲規範之列。

總則

- 互動基礎：會員公司與醫護人員之關係須以病患福利與促進醫療爲基礎。互動關係須著重於提供醫護人員產品訊息、科學和教育資訊，並支持醫學研究與教育。
- 醫護人員之獨立性：不得對醫護人員以財務或任何形式的利益（包括獎助金、獎學金、補助、贊助、顧問契約或提供教育或醫療相關用品）換取對方開立處方、推薦、採購、供應藥品、給藥、或任何促銷產品的相關義務。亦不得以任何方式影響醫護人員開立處方。
- 適當的用途：藥品行銷必須提供客觀、不誇大的產品資訊，以鼓勵適當的藥品使用。
- 當地法規：會員公司須遵守所有相關的法律、當地的法規和產業規範等。會員公司有義務在進行行銷活動前，事先查詢當地的規定。

- The remuneration for conducting the research should be based on the time and effort a physician has spent but not the conclusion of the research.
- The name of the sponsor must be announced when the research results are published.
- The vendor must not impose improper restrictions on the publication of research results.

Consulting Services

When acting as the consultant of a supplier or providing advice to a vendor, a physician must not:

- Give any professional determination compromised by the fact that he/she acts as the consultant of a vendor or provides advice to a vendor.
- Be negligent of his or her obligations to a patient due to his or her acting as the consultant of a vendor or providing advice to a vendor.
- Disclose his or her affiliation or other relationship with the vendor when making a speech, or publishing an article or report.

Code of Conduct for Government Officials

The Code of Conduct for Public Officials promulgated by the Executive Yuan (last amended in 2010) applies to healthcare professionals employed by state-owned hospitals.

Gifts

The Code of Conduct for Public Officials provides that a public official may not demand, solicit or accept gifts from persons who are in a conflict of interest with his or her official duties. However, where any of the following applies, and where it is an occasional event unlikely to affect specific rights and obligations, the gift may be accepted if:

- It is part of official etiquette.
- It is a reward, assistance or condolence gift from a supervisor.
- The market value of the gift is under TWD500; or where it is a gift to the majority of the authority (institution), total market value is under TWD1,000.

- 透明的行銷：行銷活動不可矯飾僞裝。會員公司不能以臨床試驗、上市後監視、體驗計畫、授權後研究等包裝藥品行銷活動。此類研究、計畫和評估之執行必須以科學或教育爲主要目的。不論是否具有行銷性質，任何由公司贊助的有關藥品及其用途的資訊，均須明確註明贊助廠商。

與醫護人員的互動

活動

- 科學及教育目的：由廠商舉辦或贊助醫護人員之專題研討會、學術討論會及各項行銷、科學或專業會議（統稱「活動」），均須以告知醫護人員產品訊息或提供科學或教育資訊爲主要目的。
- 國外活動：除非基於安全和合理考量，廠商不得主辦或贊助國外活動（包括贊助個人參加國外活動）。邀請各國人士參加的國際科學討論會議和專題研討會則不在此限。
- 活動中之行銷資訊：於國際科學討論會和專題研討會現場發送或於展示攤位提供的產品行銷資訊，可包括尚未於會議所在國登記上市或以不同條件登記的藥品資訊；惟須符合以下規定：
  (1) 此會議必須確實爲國際科學會議， 非主辦國之講者及與會者須佔顯著比率。
  (2) 尚未於主辦國登記上市之藥品行銷資料（不含促銷用品）須列出該藥品目前已核准上市的國家，並說明該產品目前在該國仍不可取得。
  (3) 含處方訊息之行銷資料，若與主辦國核准之處方訊息（適應症、警告語等）不一致時，須特別註明此訊息與該國登記條件不同。
  (4) 說明文件須列出該藥品已登記的國家， 並指出在主辦國內尚無法取得。

贊助

會員公司可贊助醫護人員參與各項活動，但須遵守下列原則：

- 該活動須符合行銷規範有關款待之規定。
- 對醫護人員的贊助僅限於旅費、食宿及註冊報名費用。

- Gift is received for an engagement, marriage, birth, relocation, employment, promotion or reassignment, retirement, resignation, termination of employment, or sickness, injury or death of the individual, his or her spouse or a direct relative, provided that the market value of such gift does not exceed the usual standard of social etiquette.

The aforesaid "usual standard for social etiquette" means that the market value of the social interactions does not exceed TWD3,000, and gifts or hospitality received from the same source within one year do not exceed TWD10,000.

Note that the following are deemed to be gifts to a public official:

- Gifts received in the name of the public official's spouse, direct blood relative, or cohabiting relative
- Gifts received by a third party, and then redirected to the public official or the public official's spouse, direct blood relative, or cohabiting relative

Hospitality

Public officials may not attend entertainment and hospitality events hosted by persons in a conflict of interest with such official. Nevertheless, the following exceptions apply:

- It is necessary to attend such event due to official etiquette.
- It is a public event hosted for folk customs or festival reasons, and the general public is invited.
- It is a reward or encouragement given by a supervisor to a subordinate.
- It is an event hosted for an engagement, marriage, birth, relocation, employment, promotion or re-assignment, retirement, resignation or termination of employment, provided that the value of entertainment and hospitality does not exceed the usual standard of social etiquette.

Public officials should avoid attending entertainment and hospitality events that are clearly disproportionate with their status and duties, notwithstanding the host has no conflict of interest with their duties.

A public official must not appear in inappropriate locations, except as required for official duties and having been approved by the supervisor, or for other legitimate reasons. Public officials must not have improper contact with persons whose duties may pose a conflict of interest.

- 不得補償醫護人員因參加會議所費時間的損失。
- 不得以贊助行爲交換醫護人員開立處方或推薦、促銷藥品的義務。
- 廠商不得支付與受邀醫護人員同行者的任何費用。

主講人與演講者酬勞

可給付應邀演講的醫護人員適當酬勞和相關之旅行、食宿墊付費用；惟雙方須簽訂書面契約。

款待

- 適當的地點：所有的活動均須在適當的地點舉辦，以配合其科學與教育目的。廠商應該避免選擇有名或豪奢的場地。
- 款待的限制：款待應侷限於附加於活動本身的點心或餐點，並符合下列規定：
  (1) 僅提供與會者，不包括同行人士
  (2) 款待須爲當地可接受的程度
- 一般而言，醫護人員接受的款待不應超過其願意自費負擔的水平。
- 娛樂：會員公司不得提供單獨的娛興節目或社交活動來招待醫護人員。用餐時的簡單娛樂是可接受的，但其重要性不得超過餐點本身。

贈品與醫療物品

- 金錢：不得提供醫護人員金錢或其他金錢形式的贈品（如：禮券）。
- 個人餽贈：不得餽贈個人用品（如音樂CD、DVD、運動比賽或表演門票、電子產品等）。
- 行銷贈品：廠商可提供醫護人員或相關行政人員促銷贈品或幫助提示產品的物品，但須爲價格低廉且與醫療行爲相關的小物品。
- 醫療用品：廠商可提供對醫療服務或病患有益的低價醫療用品。
- 習俗性餽贈：依各國習俗，廠商可在重要節慶致送醫護人員禮品，此贈品內容可與醫療無關，但是送禮次數不可頻繁，價格不可昂貴，且必須符合當地法律規定。

While conducting an inspection, investigation, a business trip or attending a meeting, the public official may not accept dining or other hospitality from relevant authorities (institutions) other than snacks and/or plain and convenient food, accommodation and transportation required for carrying out official duties.

Speeches, Conferences, Seminars and Adjudications

The pay for a public official to attend speeches, conferences, seminars and adjudications must not exceed TWD5,000 per hour. Where a writer's fee is paid for attending an above event, the fee must not exceed TWD2,000 per 1,000 words.

Where an above event is organized by a person with a conflict of interest with the public official's duties, the public official must first apply for approval from his or her supervisor and register with the relevant ethics department before attending.

IRPMA Code of Marketing Practices

The ROC International Research-Based Pharmaceutical Manufacturers Association ("IRPMA") promulgated the IRPMA Code of Marketing Practices ("IRPMA Code"), last amended in 2011 which sets forth standards for the ethical promotion of pharmaceutical products to healthcare professionals, and for member companies' interactions with them.

Under the IRPMA Code, a "healthcare professional" means "any member of the medical, dental, pharmacy or nursing professions or any other person who in the course of his or her professional activities may prescribe, recommend, purchase, supply, or administer a pharmaceutical product." Member companies of IRPMA include drug and medical product manufacturers as well as their distributors and agents.

The IRPMA Code does not seek to regulate the promotion of non-prescription pharmaceutical products, pricing or other trade terms for the supply of pharmaceutical products, the engagement of a healthcare professional to provide genuine consultancy or other genuine services to a member company, the conduct of clinical trials, or the provision of non-promotional information by member companies.

樣品

- 樣品：在符合當地法規情形下，廠商可免費提供醫護人員藥品樣品，以增進病患照護。樣品不得轉售或移作他用。
- 監控與責任：廠商須有適當的樣品監控系統，包括監控業務人員持有的樣品。廠商不得收集臨床資訊，亦不應提供醫護人員任何酬勞。

行政、民事及刑事責任

公平交易法

藥商之行銷活動（例如提供不當餽贈等利益予醫護人員以促銷特定藥物）若被主管機關認定爲公平法上之「不公平競爭」者，公平會最重可處新臺幣2,500萬元罰鍰，並命藥商限期停止、改正其行爲或採取必要更正措施；若藥商逾期仍不停止或更正者，主管機關可對藥商連續處以罰鍰；連續或再度違反者，法院可處行爲人2年以下有期徒刑、拘役或科或併科新臺幣5,000萬元以下罰金。

貪污治罪條例

違反貪污治罪條例之刑事責任包括：

- 對於觸犯違背職務行賄罪之行爲人，法院最重可處7年有期徒刑，得併科新臺幣300萬元以下罰金。對於觸犯違背職務受賄罪之公務員，法院得處無期徒刑或10年以上有期徒刑，並得併科新臺幣1億元以下罰金。
- 對於觸犯不違背職務行賄罪之行爲人，法院最重可處3年有期徒刑、拘役或科或併科新臺幣50萬元以下罰金。對於觸犯不違背職務受賄之罪公務員，法院得處7年以上有期徒刑，並得併科新臺幣6,000萬元以下罰金。

背信罪

私立醫療機構之醫護人員若收受藥商之賄賂或其他不正利益，而爲違背其任務之行爲，有可能構成刑法上之背信罪。而行賄之人則可能成爲背信罪之共犯。背信罪可處5年以下有期徒刑、拘役或科或併科新臺幣3,000元以下罰金。

The IRPMA Code provides the following principles:

- Basis of Interaction: Member companies' relationships with healthcare professionals are intended to benefit patients and to enhance the practice of medicine. Interactions should be focused on informing healthcare professionals about products, providing scientific and educational information, and supporting medical research and education.
- Independence of Healthcare Professionals: No financial benefit or benefit-in-kind (including grants, scholarships, subsidies, support, consulting contracts or educational or practice-related items) may be provided or offered to a healthcare professional in exchange for prescribing, recommending, purchasing, supplying or administering products or for a commitment to continue to do so. Nothing may be offered or provided in a manner or on conditions that would have an inappropriate influence on a healthcare professional's prescribing practices.
- Appropriate Use: Promotion should encourage the appropriate use of pharmaceutical products by presenting them objectively and without exaggerating their properties.
- Local Regulations: In all cases, all relevant laws, local regulations and industry codes must be observed and companies have a responsibility to check local requirements, in advance of preparing promotional materials or events in any specific country.
- Transparency of Promotion: Promotion should not be disguised. Clinical assessments, post-marketing surveillance, and experience programs and post-authorization studies must not be disguised promotion. Such assessments, programs and studies must be conducted with a primarily scientific or educational purpose. Materials relating to pharmaceutical products and their uses, whether promotional in nature or not, which are sponsored by a company should clearly indicate by whom it has been sponsored.

Events

Scientific and Educational Objectives: The purpose and focus of all symposia, congresses and other promotional, scientific or professional meetings ("Event") for healthcare professionals organized or sponsored by a company should be to inform healthcare professionals about products, and/or to provide scientific or educational information.

政府採購法下之違法態樣

公立醫院對藥物之採購應遵守政府採購法之規定。下列行爲可能被認定爲違反政府採購法：

- 於採購程序中與相關公務員有不當往來，或對之施以不當之影響。
- 妨害採購的秘密性。
- 使用不法強制方式，使廠商不爲投標、違反其本意投標，或使得標廠商放棄得標、得標後轉包或分包。
- 以詐術或其他非法之方法，使廠商無法投標或開標發生不正確結果。
- 意圖影響決標價格或獲取不當利益，而以契約、協議或其他方式之合意，使廠商不爲投標或不爲價格之競爭。

關於違反政府採購法之處罰，有期徒刑最重可處7年，罰金最高可科新臺幣6,000萬元。

藥商與醫護人員及醫療機構間之契約

法令並未特別針對藥商與醫療機構間之契約作規範。

依據IRPMA行銷規範，藥商得聘請醫護人員演講，惟該演講須爲真實且雙方簽訂書面契約。至於其他服務，行銷規範並未規定，惟前述規定可以得適用之。

建議

藥物之廣告及行銷涉及許多方面之法律風險，包括：行政裁罰、民事責任及刑事處罰。藥商應謹慎爲之，以降低其法律風險。本文建議藥商宜注意以下各點：

- 餽贈、娛樂、款待、捐獻或贊助，在某些情形下，有可能被認定爲賄賂。
- 對公立醫療機構之採購評選委員，不宜提供餽贈等利益，否則可能被認定爲貪污治罪條例之行賄行爲。

Events Involving Foreign Travel: No company may organize or sponsor an event for healthcare professionals that takes place outside of their home country unless it is appropriate and justified to do so from a logistical or security point of view. International scientific congresses and symposia that involve participants from many countries are therefore justified and permitted.

Promotional Information at Events: Promotional information which appears on exhibition stands or is distributed to participants at international scientific congresses and symposia may refer to pharmaceutical products which are not registered in the country where the event takes place, or which are registered under different conditions, provided that the following conditions are observed:

- The meeting should be a truly international, scientific event with a significant proportion of the speakers and attendees from countries other than the country where the event takes place.
- Promotional materials (excluding promotional aids) for a pharmaceutical product not registered in the country of the event should be accompanied by a suitable statement indicating the countries in which the product is registered and make clear that such product is not available locally.
- Promotional materials which refer to the prescribing information (indications, warnings, etc.) authorized in a country or countries other than that in which the event takes place but where the product is also registered, should be accompanied by an explanatory statement indicating that registration conditions differ internationally.
- An explanatory statement should identify the countries in which the product is registered and make it clear that it is not available locally.

Sponsorship

Member companies may sponsor healthcare professionals to attend events provided such sponsorship is in accordance with the following requirements:

- The event complies with the hospitality requirements of the IRPMA Code.
- Sponsorship of healthcare professionals is limited to the payment of travel, meals, accommodation and registration fees.
- No payments are made to compensate healthcare professionals for time spent in attending the event.

- 行賄者及受賄者皆受貪污治罪條例之處罰。藉由第三人轉交賄賂，亦構成行賄及受賄。
- 藥商贊助之研討會之目的必須是學術性或專業性的。研討會舉辦之場地，應確保是基於知識傳播之適當及便利性，而非基於休閒便利性。除非有充足之正當理由，如果大多數之參與者係來自臺灣，則藥商不應選擇在海外舉辦該研討會。
- 違規藥物廣告不僅是對廣告相關立法之違反，亦可能構成公平法上之不公平競爭。因此，藥商應避免使用任何可能置競爭者於不公平地位之廣告手段。

- Any sponsorship provided to individual healthcare professionals must not be conditional upon an obligation to prescribe, recommend or promote any pharmaceutical product.
- Companies should not pay any costs associated with individuals accompanying invited healthcare professionals.

Payments for Speakers and Presenters

Payments of reasonable fees and reimbursement of out-of-pocket expenses, including travel and accommodation, may be provided to healthcare professionals who are providing genuine services as speakers or presenters on the basis of a written contract with the company at the event.

Hospitality

Appropriate Venue: All events should be held in an appropriate venue that is conducive to the scientific or educational objectives and purpose of the event or meeting. Companies should avoid using renowned or extravagant venues.

Limits of Hospitality: Hospitality should be limited to refreshments and/or meals incidental to the main purpose of the event and should only be provided: to participants of the event and not their guests; and if it is moderate and reasonable as judged by local standards.

As a general rule, the hospitality provided should not exceed what healthcare professional recipients would normally be prepared to pay for themselves.

Entertainment: No stand-alone entertainment or other leisure or social activities should be provided or paid for by member companies. At events, entertainment of a modest nature which is secondary to refreshments and/or meals is allowed.

Gifts and Items of Medical Utility

Cash: Payments in cash or cash equivalents (such as gift certificates) must not be offered to healthcare professionals.

Personal Gifts: Gifts for the personal benefit of healthcare professionals (including, but not limited to, music CDs, DVDs, sporting or entertainment tickets, electronic items) must not be provided or offered.

Promotional Aids: Promotional or souvenir items may be provided or offered to healthcare professionals and appropriate administrative staff, provided the gift is of minimal value and relevant to the practice of the healthcare professional.

Items of Medical Utility: Items of medical utility may be offered or provided free of charge, provided that such items are of modest value and are beneficial to the provision of medical services and for patient care.

Cultural Courtesy Gifts: In some countries, if allowed under local law and in accordance with local practice, an inexpensive gift not related to the practice of medicine may be given on an infrequent basis to healthcare professionals in acknowledgment of significant national, cultural or religious holidays.

Samples

Permitted Samples: In accordance with local laws and regulations, free samples of a pharmaceutical product may be supplied to healthcare professionals in order to enhance patient care. Samples should not be resold or otherwise misused.

Control and Accountability: Companies should have adequate systems of control and accountability for samples provided to healthcare professionals, including how to look after such samples while they are in possession of medical representatives. Companies should not collect clinical data and should not make any payment to physicians.

Administrative, Criminal and Civil Liability

Liabilities for Unfair Competition

If the promotional activities conducted by a pharmaceutical or medical device company, such as offering improper gifts to healthcare professionals for the purpose of promoting a specific medical product, are determined by the regulator or court as “unfair competition” under the FTL, the violator will be imposed a fine of up to TWD25 million and must rectify the violation within a specific time limit. If the violation is continued after the time limit, the violator may be imposed an additional fine continuously and may, in extreme cases, be punished with imprisonment of up to two years and/or a fine of up to TWD50 million.

Liabilities for Violation of the Anti-Corruption Law

The liabilities applicable to violation of the ACL include the following:

- The provider of bribes for a public official's action breaching official duties will face imprisonment of up to seven years and a fine of up to TWD3 million. The public official receiving such bribes is subject to imprisonment for life or at least 10 years and/or a fine of up to TWD100 million.
- The provider of bribes for a civil servant's action not breaching official duties will face imprisonment of up to three years and/or a fine of up to TWD500,000. The public official receiving such bribes is subject to imprisonment for at least seven years and/or a fine of up to TWD60 million.

Liabilities for Breach of Fiduciary Duty Under the Criminal Code

As mentioned, the provider of bribes to private parties' employees is deemed an accomplice of the person being bribed and may be subject to the same penalty, which is imprisonment of up to five years and/or a fine of up to TWD30,000.

Public Procurement and Fraud

Medical products purchased by public hospitals are subject to the tendering rules under the GPA. In the process of bidding for the government tenders, the following acts will likely be deemed as violation of the GPA:

- Inappropriate contact with or improper influence on government officials during tender opening and tender evaluation period
- Breach of procurement confidentiality
- Use of forceful means to cause a bidder not to tender or to tender contrary to its true intention, or cause the winning bidder to forego or to assign or subcontract an award
- Use of fraudulent or other illegal means to make a bidder unable to tender or cause the opening of tenders to have an inaccurate result
- Cause the bidder not to tender or not to proceed with price competition through contract, agreement or other meeting of the minds with the intent to adversely affect the price of award or benefits

Punishment for breach of the GPA includes imprisonment of up to seven years and a fine of up to TWD60 million.

Contracts with Healthcare Professionals and Medical Institutions

There are no express laws or regulations that specifically govern contracts with healthcare professionals and medical institutions.

According to the IRPMA Code, medical product companies may engage healthcare professionals for speaking arrangements if the speeches are genuine, and written contracts for the speeches are in place. As to other services, the IRPMA Code is silent, but the aforesaid provisions likely remain applicable.

Recommendations

Advertising/promotion of medical products involves legal risks including administrative sanctions, civil liabilities, and criminal penalties. Medical product companies must act very prudently in order to lower their legal risks. We recommend that medical companies pay very close attention to the following items:

- Offering gifts, entertainment or hospitality, and donation or provision of sponsorship may be deemed as a form of bribery under certain circumstances.
- Any benefit provided to the procurement evaluation committee members of public hospitals must be avoided or it may be deemed as a bribe under the ACL.
- Providers and takers of bribes may both be punished by the Anti-Corruption Law or the Criminal Code. Bribery via a third party is also considered as bribery.
- The purpose of the symposium sponsored by the medical product company must be academic or professional. The choice of the venue of symposium may not be on the basis of leisure or entertainment. If most attendants are from Taiwan, an overseas venue for a symposium should be avoided unless there is a strong and sufficient reason.
- Illegal advertising of medical products is not only a violation of advertising legislation, but also probably causes concerns of unfair competition under the FTL. Therefore, the advertiser must avoid using any advertising method which may put its competitors in an unfair position.

ประเทศไทย

พีระพรรณ ตั้งสุวรรณ, ประวีณ จันทนาโกเมษ, พริม อุทิตานนท์

บทนำ

การโฆษณาและกิจกรรมส่งเสริมการขายสำหรับผลิตภัณฑ์ทางการแพทย์ในหลายๆ
กรณีต้องได้รับอนุมัติจากสำนักงานคณะกรรมการอาหารและยา) อย (.
ข้อกำหนดในการได้รับอนุมัติมีความแตกต่างตามประเภทของผลิตภัณฑ์โดยขึ้นอยู่กับว่า
ผลิตภัณฑ์ดังกล่าวจัดอยู่ในกลุ่มผลิตภัณฑ์ใด
ระดับความอันตรายของผลิตภัณฑ์หากผลิตภัณฑ์ดังกล่าวถูกนำไปใช้อย่างไม่เหมาะสม
หรืออาจขึ้นอยู่กับว่าผลิตภัณฑ์ดังกล่าวต้องใช้โดยแพทย์สั่งหรือคนไข้สามารถเลือกใช้ได้เอง

อย่างไรก็ตาม
ผลิตภัณฑ์เหล่านี้มีข้อกำหนดพื้นฐานบางประการที่เกี่ยวข้องกับการโฆษณาและกิจกรรมส่งเสริมกา
รขายที่เหมือนกัน กล่าวคือ การโฆษณาต้องไม่มีข้อมูลที่เป็นเท็จหรือเกินความจริง
นอกจากนี้โฆษณาดังกล่าวต้องไม่มีข้อความที่ก้าวร้าวเกินควรหรือเป็นไปตามความเห็นส่วนตัวโดย
สิ้นเชิง หรือเป็นข้อมูลที่ไม่อาจพิสูจน์ได้

แม้กฎหมายที่เกี่ยวข้องไม่มีการห้ามการโฆษณาเปรียบเทียบเปรียบเปรย
แต่โดยทั่วไปแล้วกฎระเบียบของอย.ก็ไม่ส่งเสริมโฆษณาลักษณะดังกล่าว

ในส่วนที่เกี่ยวข้องกับขั้นตอนการขออนุมัติ คำขอทุกประเภทจะต้องมีหลักฐาน
ข้อมูลและเอกสารเชิงวิทยาศาสตร์และ/หรือทางวิชาการสนับสนุนประกอบด้วย

แม้ว่าอย. กำลังพยายามปรับปรุงขั้นตอนการดำเนินการและทรัพยากรอื่นๆ
ผู้ประกอบการในประเทศไทยยังคงหวังว่าเวลาในการดำเนินการต่างๆ
และปริมาณของเอกสารที่ต้องใช้จะลดลง กล่าวโดยทั่วไปคือ ขั้นตอนควรจะง่ายขึ้น
และควรจะสามารถทำให้แล้วเสร็จโดยเร็วโดยไม่จำเป็นต้องใช้ระยะเวลาเกินควร

กฎหมายควบคุมการโฆษณาเวชภัณฑ์

โครงสร้างทางกฎหมาย

- เครื่องตรวจวัดระดับหรือปริมาณแอลกอฮอลล์ในร่างกาย

Thailand

Peerapan Tungsuwan, Praween Chantanakomes, Prim Uditananda

Introduction

Advertisements and, in many cases, promotional activities for various medical products require an approval from the Food and Drug Administration ("FDA"). The approval requirements are different from one product to another depending on what category such products are classified in; how dangerous the products may be if the products are taken or used improperly, or whether the products must be prescribed by physicians or can be used directly by patients.

However, there are some basic requirements relating to advertisements and promotional activities that are common to all these products. In this respect, such advertisements must not contain false or exaggerated information. Moreover, the advertisements cannot contain overly aggressive or purely discretionary terms, or information which cannot be proven.

It should be noted that while comparative advertisements are not totally prohibited under the relevant laws, such types of advertisements are generally discouraged by the FDA's guidelines.

As far as the process of obtaining an approval is concerned, all applications are required to be accompanied by supporting evidence, as well as scientific and/or academic information and documentation.

As the FDA seeks to improve its processes and other resources, it may be the wish of the medical product industry in Thailand that the relevant processes take them less time and require less documents. Generally speaking, the overall process should be simpler and should be completed more quickly.

Regulatory Framework

Medical Devices

In Thailand, medical devices are governed by the Medical Device Act, B.E. 2551 (A.D. 2008) ("Medical Device Act"). The Medical Device Control Division of the FDA enforces the provisions of the Medical Device Act.

- เต้านมเทียมซิลิโคนใช้ฝังในร่างกาย

กลุ่มที่ 3 เครื่องมือแพทย์ที่ไม่เข้าข่ายในกลุ่มที่ 1 หรือกลุ่มที่ 2

อย่างไรก็ตาม การแบ่งกลุ่มเครื่องมือแพทย์ข้างต้นอาจมีการเปลี่ยนแปลงได้เนื่องจากในขณะนี้ อย. กำลังอยู่ในขั้นตอนการประเมินเครื่องมือแพทย์แต่ละชนิดใหม่
ตามหลักเกณฑ์ประเมินความเสี่ยงภายใต้ ASEAN Harmonization Scheme

นอกจากนี้ยังมีข้อกำหนดเฉพาะที่ออกตามความใน พรบ. เครื่องมือแพทย์
ที่อาจกำหนดข้อบังคับบางประการซึ่งรวมถึงแต่ไม่จำกัดเพียงข้อบังคับเกี่ยวกับฉลากและการโฆษณาเครื่องมือแพทย์ เช่น ประกาศอย. เรื่อง กำหนดหลักเกณฑ์
วิธีการและเงื่อนไขการโฆษณาเครื่องมือแพทย์ พ.ศ. 2553 (“ประกาศโฆษณา”)

นอกเหนือจากประกาศโฆษณาแล้ว
ยังมีกฎหมายและ/หรือระเบียบข้อบังคับอื่นที่เกี่ยวข้องกับการโฆษณาและการส่งเสริมการขายเครื่องมือแพทย์ซึ่งอาจไม่ได้ระบุไว้ใน พรบ. เครื่องมือแพทย์ อันได้แก่กฎหมายดังต่อไปนี้

- พระราชบัญญัติคุ้มครองผู้บริโภค พ.ศ. 2522
- พระราชบัญญัติขายตรงและตลาดแบบตรง พ.ศ. 2545
- พระราชบัญญัติสถานพยาบาล พ.ศ. 2541
- พระราชบัญญัติวิชาชีพเวชกรรม พ.ศ. 2525
  (หรือกฎหมายในลักษณะเดียวกันซึ่งกำกับดูแลผู้ประกอบวิชาชีพทางการแพทย์และสาธารณสุขอื่นๆ)

<u>ยา</u>

ยาอยู่ภายใต้บังคับของพระราชบัญญัติยา พ.ศ. 2510 (“พรบ. ยา”) โดยมีกองสำนักยาของอย. เป็นหน่วยงานที่บังคับใช้บทบัญญัติของพรบ. ยา

ภายใต้บังคับของ พรบ. ยานั้นได้มีการแบ่งยาออกเป็นประเภทต่างๆ ดังต่อไปนี้

กลุ่มที่ 1:	ยาควบคุมพิเศษ
กลุ่มที่ 2:	ยาอันตราย
กลุ่มที่ 3:	ยาแผนปัจจุบัน
กลุ่มที่ 4:	ยาแผนปัจจุบันเฉพาะยาบรรจุเสร็จที่ไม่ใช่ยาอันตรายหรือยาควบคุมพิเศษ

Under the Medical Device Act, medical devices are divided into three categories.

Category 1: Medical devices that require the manufacturer or importer to obtain a license prior to being able to manufacture or import the product, which presently consist of seven products, as follows:

- Condoms
- Rubber gloves for physical examination
- Rubber gloves for surgical operations
- HIV infection tester kits for diagnostic purposes
- Contact lenses

Category 2: Medical devices that require the manufacturer or importer to provide the specifications of the product prior to being able to manufacture or import the product, which presently consist of four products, as follows:

- HIV infection tester kits for non-diagnostic purposes
- Equipment or products used in physical therapy
- Alcohol tester kits
- Implanted silicon breast prostheses

Category 3: Medical devices which do not fall under Categories 1 and 2.

Notwithstanding the above, kindly note that the above classification of medical devices may be subject to change as the FDA is in the process of re-evaluating each type of medical device in accordance with the risk assessment factors under the ASEAN Harmonization Scheme.

There are also specific regulations, issued under the ambit of the Medical Device Act which may outline certain regulatory requirements, including, but not limited to, the labeling and advertising requirements for medical devices, such as, the Notification on Guidelines, Procedures and Restrictions of Medical Device Advertising, B.E. 2553 (A.D. 2010) ("Notification").

In addition to the above, there may also be other relevant laws and/or regulations relating to advertisements and promotional activities for medical devices which may not be outlined under the Medical Device Act, as follows:

- Consumer Protection Act, B.E. 2522 (A.D. 1979)

กลุ่มที่ 5: ยาสำหรับสัตว์
กลุ่มที่ 6: ยาสามัญประจำบ้าน
กลุ่มที่ 7: ยาแผนโบราณ

นอกจากนี้ยังมีระเบียบข้อบังคับบางประการที่ออกตามความของพรบ. ยา
ที่อาจกำหนดข้อบังคับบางประการ
ซึ่งรวมถึงแต่ไม่จำกัดเพียงข้อกำหนดเรื่องฉลากและการโฆษณายา เช่น ประกาศกระทรวงต่างๆ
ที่เกี่ยวกับยาบางกลุ่มเป็นต้น และ อย.
ยังได้ออกแนวทางปฏิบัติภายในซึ่งอาจนำมาใช้เพื่อพิจารณาการโฆษณายา กล่าวคือ
คู่มือการโฆษณาขายยา พ.ศ. 2551 ("คู่มือ")

นอกจากที่ระบุไว้ข้างต้นแล้ว
และเช่นเดียวกันกับประเด็นเรื่องโฆษณาเครื่องมือแพทย์ซึ่งระบุไว้ข้างต้น
ยังอาจมีกฎหมายและ/หรือระเบียบข้อบังคับที่เกี่ยวข้องอื่นๆ
ซึ่งเกี่ยวกับกิจกรรมด้านการโฆษณาและการส่งเสริมการขายยาซึ่งอาจไม่ได้ระบุไว้ในพรบ. ยา
อันได้แก่กฎหมายดังต่อไปนี้

- พระราชบัญญัติคุ้มครองผู้บริโภค พ.ศ. 2522
- พระราชบัญญัติขายตรงและตลาดแบบตรง พ.ศ. 2545
- พระราชบัญญัติสถานพยาบาล พ.ศ. 2541
- พระราชบัญญัติวิชาชีพเวชกรรม พ.ศ. 2525
  (หรือกฎหมายในลักษณะเดียวกันซึ่งกำกับดูแลผู้ประกอบวิชาชีพทางการแพทย์และสาธารณสุขอื่นๆ)

การกระทำที่อนุญาตให้ทำได้และการกระทำที่ต้องห้าม

การโฆษณาเครื่องมือแพทย์

ภายใต้บังคับ พรบ. เครื่องมือแพทย์ คำว่า "การโฆษณา" หมายถึงการกระทำไม่ว่าโดยวิธีใดๆ
ให้ประชาชนเห็น ได้ยินหรือทราบข้อความเพื่อประโยชน์ในทางการค้า
และให้หมายรวมถึงการส่งเสริมการขายด้วย ทั้งนี้ "การส่งเสริมการขาย" หมายถึงการให้ข้อมูล
การชักชวน หรือการกระทำโดยวิธีใดๆ เพื่อชักนำให้เกิดการขาย

- Direct Sales and Direct Marketing Act, B.E. 2545 (A.D. 2002)
- Medical Facility Act, B.E. 2541 (A.D. 1998)
- Medical Professional Act, B.E. 2525 (A.D. 1982) (or other similar laws which govern other healthcare professionals)

Drugs

Drugs are governed by the Drug Act, B.E. 2510 (A.D. 1967) ("Drug Act"). The Drug Bureau of the FDA enforces the provisions of the Drug Act.

Under the Drug Act, drugs are divided into the following categories;

Category 1:	Specially-controlled drugs
Category 2:	Dangerous drugs
Category 3:	Modern drugs
Category 4:	Modern-packaged drugs other than those categorized as dangerous or specially-controlled drugs
Category 5:	Veterinary drugs
Category 6:	Household drugs
Category 7:	Traditional drugs

There are also specific regulations issued within the ambit of the Drug Act which may outline certain regulatory requirements, including, but not limited to, the labeling and advertising requirements for drugs, such as the various ministerial notifications relating to a specific drug category. Additionally, the FDA has also issued its internal guidelines which may be used to consider drug advertisements, namely, the Guidelines on Dug Advertising, B.E. 2551 (A.D. 2008) ("Guidelines").

In addition to the above and similar to the issue of medical device advertisements which are outlined above, there may also be other relevant laws and/or regulations relating to advertisements and promotional activities of drugs which may not be outlined under the Drug Act, as follows:

- Consumer Protection Act, B.E. 2522 (A.D. 1979)
- Direct Sales and Direct Marketing Act, B.E. 2545 (A.D. 2002)
- Medical Facility Act , B.E. 2541 (A.D. 1998)
- Medical Professional Act, B.E. 2525 (A.D. 1982) (or other similar laws which govern other healthcare professionals)

ผู้ที่มีความประสงค์จะโฆษณาเครื่องมือแพทย์จะต้องได้รับใบอนุญาตจาก อย.
ก่อนที่จะสามารถใช้โฆษณานั้นได้ การโฆษณาเครื่องมือแพทย์ที่อยู่ในกลุ่มที่ 1
และเครื่องมือแพทย์บางชนิดที่อยู่ในกลุ่มที่ 2
สามารถกระทำได้เฉพาะต่อผู้ประกอบวิชาชีพทางการแพทย์และสาธารณสุขเท่านั้น ทั้งนี้ คำว่า
"ผู้ประกอบวิชาชีพทางการแพทย์และสาธารณสุข" หมายถึงผู้ประกอบวิชาชีพเวชกรรม
ผู้ประกอบวิชาชีพทันตกรรม ผู้ประกอบวิชาชีพสัตวแพทย์ศาสตร์ชั้นหนึ่ง
ผู้ประกอบวิชาชีพกายภาพบำบัด ผู้ประกอบวิชาชีพเทคนิคการแพทย์
หรือผู้ประกอบวิชาชีพทางการแพทย์และสาธารณสุขอื่นๆ
ตามที่ระบุในประกาศกระทรวงที่เกี่ยวข้อง

เครื่องมือแพทย์ประเภทอื่นสามารถโฆษณากับผู้ใช้หรือผู้ป่วยได้

ภายใต้พรบ. เครื่องมือแพทย์ การโฆษณาเครื่องมือแพทย์จะต้องไม่มีลักษณะต่อไปนี้

- ไม่แสดงคุณประโยชน์ คุณภาพ ปริมาณ มาตรฐาน
  ส่วนประกอบหรือแหล่งกำเนิดของเครื่องมือแพทย์อันเป็นเท็จหรือเกินความจริง
- ไม่แสดงการรับรองหรือยกย่องคุณประโยชน์ของเครื่องมือแพทย์ โดยบุคคลหนึ่งบุคคลใด
- ไม่จัดให้มีรางวัลด้วยการเสี่ยงโชคโดยวิธีใดๆ
- ไม่แสดงคุณประโยชน์ว่าสามารถป้องกัน บำบัด บรรเทา
  รักษาโรคหรืออาการของโรคที่ห้ามโฆษณาตามที่ประกาศกระทรวงที่เกี่ยวข้องกำหนด
- ไม่แสดงข้อความที่ก่อให้เกิดความเข้าใจผิดในสาระสำคัญของเครื่อ งมือแพทย์

นอกจากนี้ประกาศโฆษณายังระบุข้อบังคับอื่นเกี่ยวกับการโฆษณาเครื่องมือแพทย์อีกด้วย
ยกตัวอย่างเช่น ห้ามโฆษณาเครื่องมือแพทย์ประเภทต่อไปนี้

- เครื่องมือแพทย์ปลอม
- เครื่องมือแพทย์ผิดมาตรฐาน
- เครื่องมือแพทย์เสื่อมคุณภาพ
- เครื่องมือแพทย์ที่ไม่ปลอดภัยในการใช้
- เครื่องมือแพทย์ที่ผลิตหรือนำเข้าไม่ตรงตามที่ได้รับอนุญาตหรือได้แจ้งรายการละเอียด
- เครื่องมือแพทย์ที่ใบอนุญาตหรือใบรับแจ้งรายการละเอียดซึ่งออกให้สำหรับเครื่องมือแพท
  ย์นั้นถูกเพิกถอน

Permitted and Prohibited Practices

Advertising of Medical Devices

Under the Medical Device Act, "advertising" means any form of action taken in order for the public to see, hear or know of any statement, for commercial purposes, including for sales promotional purposes. "Sales promotion" means the provision of information, persuasion, or any actions taken in order to promote sales.

Persons wishing to advertise medical devices must first obtain a license from the FDA. Medical devices which fall under Category 1 and some medical devices under Category 2 can only be advertised to healthcare professionals. The term "healthcare professional" means medical and public health practitioners of pharmacy, dentistry, first-class veterinary sciences, physical therapy, medical technology, or other medical and public health practices as prescribed in the relevant ministerial notification.

Other types of medical devices can be advertised to end consumers or patients.

Under the Medical Device Act, advertisment of any medical device must not:

- show the properties, qualities, volumes, standards, components or origin of the medical device which are false or exaggerated;
- show a guarantee of, or praise for, the properties of the medical device by any particular person;
- provide a reward by means of gambling in any form;
- show properties which indicate the capabilities to prevent, heal, relieve or remedy a disease or symptom which is forbidden to be advertised as stipulated in the relevant ministerial notification; and
- show any wording which causes a material misunderstanding in relation to the medical device.

Moreover, the Notification also outlines more specific requirements in relation to the advertising of medical devices. For example, the advertising of the following types of medical devices is prohibited:

- Fake medical devices
- Substandard medical devices
- Deteriorated medical devices
- Medical devices that are unsafe to use

นอกจากนี้ประกาศโฆษณายังห้ามบุคคลทำการโฆษณาเปรียบเทียบ
เว้นแต่เป็นการเปรียบเทียบระหว่างผลิตภัณฑ์ของผู้โฆษณาเอง
หรือเป็นการเปรียบเทียบในเชิงวิชาการ แต่ทั้งนี้ห้ามระบุชื่อทางการค้าของบุคคลอื่น

การใช้เอกสารอ้างอิงด้านวิชาการ ผลการศึกษาวิจัย สถิติ การรับรองจากสถาบันใดๆ
และการยืนยันข้อเท็จจริงอันใดอันหนึ่งเพื่อสนับสนุนการโฆษณาจะต้องเป็นไปตามหลักสากล
ทั้งนี้เอกสารอ้างอิงด้านวิชาการจะต้องเป็นที่ยอมรับและเชื่อถือได้ในลักษณะต่อไปนี้

- การอ้างอิงเพื่อพิสูจน์หรือสนับสนุนข้อความที่ใช้ในการโฆษณาจะต้องเป็นไปตามหลักวิชาการ และเอกสารอ้างอิงดังกล่าวจะต้องระบุผู้ทำวิจัยและผู้สนับสนุนเงินทุน (หากมี)
- เอกสารอ้างอิงด้านวิชาการได้แก่
- เอกสารทางวิชาการ เช่น บทความ ผลการวิจัย ผลการทดลอง
  ผลการตรวจสอบคุณภาพของเครื่องมือแพทย์ที่ตีพิมพ์ในวารสารซึ่งเป็นที่ยอมรับและเชื่อถือได้ หรือ
- หนังสือรับรองที่ออกโดยหน่วยงานของรัฐที่มีหน้าที่กำกับดูแลหรือสถาบันเอกชนที่รัฐรับรอง

<u>การโฆษณายา</u>

ภายใต้บังคับพรบ. ยา ผู้ผลิตยา
ผู้นำเข้ายาหรือผู้ขายยาจะต้องปฏิบัติตามข้อบังคับเกี่ยวกับฉลากและเอกสารกำกับยา
นอกจากนี้พรบ. ยา ยังกำหนดให้ผู้ที่มีความประสงค์จะโฆษณายาทางวิทยุกระจายเสียง
เครื่องขยายเสียง วิทยุโทรทัศน์ ทางฉายภาพหรือภาพยนต์ หรือสื่อสิ่งพิมพ์ ต้องส่งสื่อโฆษณาให้
อย. พิจารณาอนุมัติและต้องได้รับใบอนุญาตจาก อย.

ก่อนจะสามารถใช้และเผยแพร่โฆษณาดังกล่าวต่อประชาชนทั่วไป รวมทั้งต้องปฏิบัติตามเงื่อนไขที่
อย. กำหนดด้วย

ในบรรดาข้อกำหนดต่างๆ บทบัญญัติที่เคร่งครัดที่สุดของพรบ. ยากำหนดว่าการโฆษณายาจะต้อง

- ไม่โอ้อวดสรรพคุณยาหรือวัตถุอันเป็นส่วนประกอบของยาว่าสามารถบำบัด บรรเทา
  รักษาหรือป้องกันโรคหรือความเจ็บป่วยได้อย่างศักดิ์สิทธิ์หรือหายขาด
  หรือใช้ถ้อยคำอื่นใดที่มีความหมายทำนองเดียวกัน

- Medical devices which are not produced or imported in accordance with the issued license or notified specification
- Medical devices whereby the licenses or specification certificates which have been issued in relation to such medical devices have been revoked

Furthermore, the Notification also prohibits persons from carrying out comparative advertising, except where the comparisons are made between the advertiser's own products or comparisons are based on an academic perspective, provided that the trade names of the other persons are not specified.

The use of academic references, study results, statistics, certification from any institution and any confirmation to support the advertising must follow international principles. Academic references must be well-accepted and be reliable in the following manner:

- A citation to prove or support details used in the advertising must follow academic principles and such references must state the authors and sponsors (if available).
- References are:
    - academic documents, such as articles, research papers, test results, and medical device quality inspections that are issued in well-accepted and reliable journals; or
    - certificates which are issued by government authorities or government certified private institutions.

Advertising of Drugs

Under the Drug Act, the manufacturers, importers or sellers of drugs are required to follow the requirements regarding labels and packaging inserts.

Additionally, the Drug Act requires any person wishing to advertise drugs through audio, visual or printed media to first submit the advertising materials for the FDA's review and approval, obtain a license from the FDA prior to being able to use and release the advertisement to the general public, and follow the conditions set by the FDA.

- ไม่แสดงสรรพคุณยาอันเป็นเท็จหรือเกินความจริง
- ไม่ทำให้เข้าใจว่ายามีวัตถุใดเป็นตัวยาหรือเป็นส่วนประกอบของยา ซึ่งความจริงไม่มีวัตถุหรือส่วนประกอบนั้นในยา หรือมีแต่ไม่เท่าที่มีอยู่จริง

นอกจากนี้ห้ามมิให้โฆษณายาโดยไม่สุภาพ หรือโดยการร้องรำทำเพลง
หรือแสดงความทุกข์ทรมานของผู้ป่วย
ข้อห้ามเกี่ยวกับการโฆษณายายังครอบคลุมไปถึงการโฆษณาโดยวิธีแถมพกหรือออกสลากรางวัล

ในทางปฏิบัติ อย.
อาจมีข้อบังคับบางประการเกี่ยวกับการโฆษณายาบางประเภทซึ่งอาจไม่ได้ระบุไว้ในพรบ. ยา

<u>กิจกรรมส่งเสริมการขายที่ทำกับผู้ประกอบวิชาชีพทางการแพทย์และสาธารณสุข</u>

กิจกรรมส่งเสริมการขายที่กระทำต่อผู้ประกอบวิชาชีพทางการแพทย์และสาธารณสุขซึ่งถือเป็น
"เจ้าพนักงาน" จะต้องพิจารณาด้วยความระมัดระวัง
ทั้งนี้กิจกรรมส่งเสริมการขายดังกล่าวอาจรวมถึงแต่ไม่จำกัดเพียงการให้ของกำนัล
การจัดหาความบันเทิง หรือการเลี้ยงรับรองในลักษณะอื่น
การสนับสนุนให้ผู้ประกอบวิชาชีพทางการแพทย์และสาธารณสุขเข้าร่วมงานภายในประเทศหรือที่
ต่างประเทศ เช่น การประชุมทางการแพทย์ การประชุมสัมมนา
หรือการเดินทางไปเยี่ยมชมถึงสถานที่ (การสนับสนุนดังกล่าวอาจครอบคลุมไปถึงค่าที่พัก
ค่าเดินทาง ค่าอาหารและค่าลงทะเบียน) และด้วยเหตุผลที่ระบุมาข้างต้น
จึงพึงต้องพิจารณาเรื่องต่อไปนี้

ความผิดฐานให้สินบน

ภายใต้บังคับมาตรา 144 แห่งประมวลกฎหมายอาญาของประเทศไทย
บุคคลอาจมีความผิดฐานให้สินบนหากบุคคลนั้นให้ ขอให้
หรือรับว่าจะให้ทรัพย์สินหรือประโยชน์อื่นใดแก่เจ้าพนักงานเพื่อจูงใจเจ้าพนักงานให้กระทำการ
หรือไม่กระทำการ หรือประวิงการกระทำอันมิชอบด้วยหน้าที่ของเจ้าพนักงานผู้นั้น

ด้วยเหตุผลที่กล่าวข้างต้น
ความผิดที่ถือเป็นการให้สินบนจะต้องประกอบด้วยเจตนาทุจริตและมีการให้ประโยชน์เพื่อให้เจ้าพ

Among other stipulations, the strongest section of the Drug Act requires that drug advertisements must not:

- boast that a drug or its ingredients are capable of miraculous cures or total treatment; nor state that a drug can relieve, cure or prevent diseases or illnesses; nor use other words with a similar meaning;
- exaggerate or falsely declare the properties of the drug; and
- create an understanding that the drug contains any medicinal substance or ingredient it does not actually contain, or, if it contains a particular medicinal substance or ingredient, create an understanding that it is in a quantity other than that which it actually contains.

Moreover, drug advertisements cannot be impolite, contain singing or dancing, or show the suffering or distress of patients. The prohibition relating to advertising drugs also extends to advertising via the provision of gifts or lucky draws.

In practice, the FDA may have specific requirements for the advertisement of certain types of drugs which may not be outlined under the Drug Act.

Promotion Activities Conducted with Healthcare Professionals

Promotion activities which are undertaken with healthcare professionals who are deemed to be "officials" should be considered with care. Such promotion activities may include, but should not be limited to, the provision of gifts, entertainment, other forms of hospitality, and sponsorship of the healthcare professional to attend local or overseas events such as medical congresses, symposiums or onsite visits. (Such sponsorship may cover accommodation, travel, meal and registration expenses.) In light of the foregoing, the following matters may be considered:

Bribery Offenses

Under Section 144 of Thailand's Penal Code, a person may be guilty of a bribery offense if he or she gives, offers or agrees to give property or any other benefit to an official in order to induce the official to do or refrain from doing any act, or to delay the performance of any act, which is contrary to the official's functions or duties.

Based on the above, an offense constituting bribery requires the existence of dishonest intent, and benefits are given to make the official perform or not perform his or her duty on a *quid pro quo* basis.

นักงานกระทำการหรือไม่กระทำการในหน้าที่ในลักษณะเป็นการแลกเปลี่ยนผลประโยชน์ต่อกันแลกัน

มาตรา 144
ไม่ได้กำหนดข้อยกเว้นเกี่ยวกับเงินค่าอำนวยความสะดวกและไม่มีข้อยกเว้นอย่างชัดแจ้งเกี่ยวกับค่าใช้จ่ายทางธุรกิจที่ให้โดยสุจริตใจ แต่แม้จะไม่มีข้อยกเว้นดังกล่าวก็ตาม
การให้เงินแก่เจ้าหน้าที่ของรัฐจะฝ่าฝืนมาตรา 144
เฉพาะถ้าการให้เงินดังกล่าวมีเจตนาทุจริตเพื่อจูงใจเจ้าหน้าที่ของรัฐ (ตามที่ระบุข้างต้น)

ทั้งนี้ไม่ได้มีการจำกัดความคำว่า "เจ้าพนักงาน" ไว้ในประมวลกฎหมายอาญา อย่างไรก็ตาม
ตามคำวินิจฉัยของศาลฎีกา คำว่า "เจ้าพนักงาน"
หมายถึงบุคคลใดก็ตามผู้ที่ปฏิบัติหน้าที่ทางราชการ ได้รับค่าตอบแทนจากงบประมาณแผ่นดิน
และได้รับการแต่งตั้งตามกฎหมาย
แพทย์ที่ทำงานในโรงพยาบาลของรัฐอาจถูกถือเป็นเจ้าหน้าที่ของรัฐตามประมวลกฎหมายอาญา
นอกจากนี้
ผู้ที่ไม่ได้เป็นเจ้าหน้าที่ของรัฐก็อาจถือเป็นเจ้าหน้าที่ของรัฐตามประมวลกฎหมายอาญาด้วยหากได้รับการแต่งตั้งให้ดำรงตำแหน่งในคณะกรรมการหรือคณะอนุกรรมการของทางราชการซึ่งมีอำนาจบางประการที่กฎหมายให้ไว้

การรับทรัพย์สินหรือประโยชน์โดยเจ้าพนักงาน

นอกจากกรณีข้างต้นแล้ว
พระราชบัญญัติประกอบรัฐธรรมนูญว่าด้วยการป้องกันและปราบปรามการทุจริต พ.ศ. 2542
และประกาศที่เกี่ยวข้องระบุว่าห้ามเจ้าหน้าที่ของรัฐรับทรัพย์สินหรือประโยชน์อื่นใดจากบุคคลใด ๆ นอกเหนือจากทรัพย์สินหรือประโยชน์อันควรได้ตามกฎหมาย
กฎหรือข้อบังคับซึ่งออกโดยอาศัยอำนาจตามบทบัญญัติแห่งกฎหมาย
เว้นแต่การรับทรัพย์สินหรือประโยชน์อื่นใดโดยธรรมจรรยา

"ธรรมจรรยา" หมายความว่า
เจ้าพนักงานอาจรับทรัพย์สินหรือประโยชน์อื่นใดจากญาติหรือจากบุคคลอื่นที่ให้กันในโอกาสต่าง ๆ โดยปกติตามขนบธรรมเนียม ประเพณีหรือวัฒนธรรม
หรือให้กันตามมารยาทที่ปฏิบัติกันในสังคม อย่างไรก็ตาม

Section 144 does not provide any exceptions with regards to facilitation payments, nor are there any express exceptions in relation to *bona fide* business expenses. Nevertheless, despite the lack of the foregoing exceptions, payments made to government officials will only violate Section 144 if the payments are made with the dishonest intent to influence the government official (as discussed above).

The term "official" is not defined anywhere in the Penal Code. However, according to Supreme Court rulings, an "official" is any person who performs governmental duties, who receives a salary from the central governmental budget, and is appointed in accordance with the law. It should be noted that doctors or physicians working in state or government hospitals would be deemed to be government officials under the Penal Code. Moreover, non-government officials may also be deemed to be government officials under the Penal Code if they are appointed to certain positions on government boards or committees which have certain authorities given to them by the law.

Receipt of Properties or Benefits by Officials

In addition to the above, under the Act Supplementing the Constitution Relating to the Prevention and Suppression of Corruption, B.E. 2542 (A.D. 1999) and its subordinate notification, no official may receive property or any other benefits from any person, other than legitimate property or benefits derived under the law, rules, or regulations issued by virtue of the provisions of law, with the exception of the receipt of property or any other benefits on an "ethical basis."

"Ethical basis" means that an official may receive property or any other benefits from any relative or from any person on a traditional, customary or cultural occasion, or on an occasion in which societal practice requires the giving of such items. Regardless, no official may receive any property or other benefits on a single occasion, from a person who is not related to the official, with a value in excess of THB3,000 (approximately USD100). The receipt of an asset or other benefit that is given to others as a matter of general practice is acceptable.

ห้ามเจ้าพนักงานรับทรัพย์สินหรือประโยชน์ใดจากบุคคลซึ่งมิใช่ญาติที่มีมูลค่าในการรับแต่ละโอกา
สเกิน 3,000 บาท (ประมาณ 100 เหรียญสหรัฐ)
แต่การรับทรัพย์สินหรือประโยชน์อื่นที่การให้นั้นเป็นการให้ในลักษณะให้กับบุคคลทั่วไปนั้นทำไ
ด้

ผลสืบเนื่องจากการไม่ปฏิบัติตาม

แนวทางปฏิบัติทางวิชาชีพ

เครื่องมือแพทย์

สมาคมอุตสาหกรรมเทคโนโลยีเครื่องมือแพทย์ไทยได้ออกจรรยาบรรณด้านการขายและการตลาด
("THAIMED Code") ให้สมาชิกของสมาคมฯ นำไปใช้ตามความสมัครใจ

เรื่องที่ระบุไว้ใน THAIMED Code จะรวมถึงแต่ไม่จำกัดเพียงเรื่องต่อไปนี้

- การเป็นเจ้าภาพให้การศึกษาหรืออบรมเกี่ยวกับผลิตภัณฑ์
- การสนับสนุนในการประชุมวิชาการ
- การประชุมส่งเสริมการขายกับผู้ประกอบวิชาชีพทางการแพทย์และสาธารณสุข
- การจ้างที่ปรึกษา
- การให้ของกำนัลและการเลี้ยงรับรอง และ
- การให้เงินอุดหนุนและเงินบริจาคการกุศลอื่นๆ

แม้จะมีข้อกำหนดข้างต้นก็ตาม THAIMED Code
ไม่ได้กำหนดบทลงโทษสำหรับสมาชิกของสมาคมฯ ที่ฝ่าฝืน THAIMED Code นี้

<u>ยา</u>

บริษัทยาในประเทศไทยซึ่งเป็นสมาชิกของสมาคมผู้วิจัยและผลิตเภสัชภัณฑ์ ("พรีม่า")
อาจนำหลักเกณฑ์ทางการขายและการตลาดของพรีม่า ("หลักเกณฑ์พรีม่า")
มาใช้ตามความสมัครใจ

หลักเกณฑ์พรีม่าได้กำหนดข้อบังคับและ/หรือข้อห้ามเกี่ยวกับการขาย
การตลาดและการส่งเสริมการขายผลิตภัณฑ์ของสมาชิกเพื่อดูแลให้การดำเนินการดังกล่าวถูกต้องต
ามจรรยาบรรณ

Consequences of Breach

Professional Codes of Conduct

Medical Devices

The Thai Medical Device Technology Industry Association has issued its Code of Sales and Marketing Practices ("THAIMED Code") for its members to adopt on a voluntary basis.

The matters which are outlined under the THAIMED Code include, but are not limited to:

- hosting of educational events or training on products;
- co-hosting educational conferences;
- meeting with healthcare professionals for sales promotion;
- the hiring of consultants;
- the provision of gifts and hospitalities; and
- the provision of subsidies and charity donations.

Notwithstanding the above, the THAIMED Code does not appear to stipulate any sanctions for the members of THAIMED who violate the THAIMED Code.

Drugs

Pharmaceutical companies in Thailand who are members of the Pharmaceutical Research & Manufacturers Association ("PReMA") may adopt PReMA's Code of Sales and Marketing Practices ("PReMA Code") on a voluntary basis.

The PReMA Code outlines certain requirements and/or prohibitions in relation to the sales, marketing and promotion of the member's products in order to ensure that such practices are conducted in an ethical manner.

The matters which are controlled under the PReMA Code include, but are not limited to:

- advertising through journals;
- promotional activities undertaken by sales representatives and the materials used by such sales representatives;
- the use of trade displays and audio-visual materials;
- the provision of samples;

เรื่องที่ถูกควบคุมภายใต้หลักเกณฑ์พรีม่ารวมถึงแต่ไม่จำกัดเพียงเรื่องต่อไปนี้

- การโฆษณาในวารสาร
- กิจกรรมส่งเสริมการขายที่ดำเนินการโดยผู้แทนเวชภัณฑ์และสื่อที่ผู้แทนเวชภัณฑ์ใช้
- การจัดการแสดงสินค้าและโสตทัศนูปกรณ์
- การให้ของตัวอย่าง
- การให้ของกำนัลหรือการเลี้ยงรับรอง และ
- การเป็นผู้สนับสนุนให้ผู้ประกอบวิชาชีพทางการแพทย์และสาธารณสุขเข้าร่วมในการประชุมสัมมนาหรือการประชุมทางวิชาการ

การที่สมาชิกกระทำการฝ่าฝืนหลักเกณฑ์พรีม่าอาจมีโทษตามที่ระบุไว้ในหลักเกณฑ์พรีม่า ซึ่งรวมถึงการระงับสมาชิกภาพของสมาชิกรายนั้นเป็นการชั่วคราว และการถูกพรีม่าปรับ

<u>ความรับผิดทางอาญาและทางแพ่ง</u>

การฝ่าฝืนกฎหมายว่าด้วยการโฆษณาที่ระบุไว้ในพรบ. เครื่องมือแพทย์และพรบ. ยา รวมทั้งการฝ่าฝืนกฎหมายต่อต้านการให้สินบนนั้นอาจนำไปสู่โทษทางอาญา (จำคุกและ/หรือถูกปรับ) สำหรับผู้ทำการฝ่าฝืน

นอกจากนี้กรรมการผู้จัดการ
ผู้จัดการหรือบุคคลที่รับผิดชอบในการประกอบธุรกิจของนิติบุคคลซึ่งกระทำความผิดอาญาอาจต้องร่วมรับผิดในความผิดซึ่งนิติบุคคลรายดังกล่าวกระทำด้วย

ประการสุดท้าย อย. มีอำนาจสั่งให้แก้ไขเปลี่ยนแปลงโฆษณาที่ฝ่าฝืนข้อบังคับที่เกี่ยวข้อง หรือห้ามใช้ข้อความบางข้อความ หรือระงับโฆษณาดังกล่าว

การจัดซื้อจัดจ้างของทางราชการและการฉ้อโกง

พระราชบัญญัติว่าด้วยความผิดเกี่ยวกับการเสนอราคาต่อหน่วยงานของรัฐ พ.ศ. 2542 (พรบ. ว่าด้วยความผิดเกี่ยวกับการเสนอราคาต่อหน่วยงานของรัฐ)
ห้ามการกระทำที่เป็นการสมยอมระหว่างผู้ประมูลในขั้นตอนการประมูลที่ทางราชการจัดขึ้น ข้อห้ามดังกล่าวจะรวมถึงแต่ไม่จำกัดเพียงการสมยอมในการตั้งราคาที่กำหนดไว้ล่วงหน้าเพื่อให้ฝ่ายหนึ่งชนะการประมูล
และการให้ผลประโยชน์แก่อีกฝ่ายเพื่อให้ฝ่ายนั้นสมยอมในขั้นตอนการประมูลเป็นต้น

- the provision of gifts or entertainment; and
- sponsorship of healthcare professionals to attend symposia or medical congresses.

Violation of the PReMA Code by members of PReMA may lead to sanctions under the PReMA Code, which includes suspension of membership and fines.

Criminal and Civil Liability

Violations of the advertising laws outlined under the Medical Device Act and the Drug Act, as well as the relevant anti-bribery laws, may lead to criminal liability (imprisonment and/or fines) for the violator.

Furthermore, the managing director, manager or any person responsible for the business operation of a juristic person which commits a criminal offense may also be jointly liable for the said offense which was committed by the juristic entity.

Lastly, the FDA itself has the authority to order advertisements which violate the relevant requirements to be amended, or to prohibit the use of certain statements, or to suspend the advertisements.

Public Procurement and Fraud

The Act Concerning Offenses Relating to the Submission of Bids to Government Agencies, B.E. 2542 (A.D. 1999) ("Bidding Act") seeks to prohibit acts of collusion undertaken by and between bidders in a government-held bidding process. The prohibitions include, but are not limited to, acts of collusion in setting a predetermined price in order for one party to win the bid, and the provision of benefits to another party in order for such party to collude in the bidding process.

Parties which collude in the submission of bids in violation of the Bid Rigging Act may also violate and be liable for an offense under the Trade Competition Act, B.E. 2542 (A.D. 1999), as such an act may be deemed to limit or eliminate fair competition.

ผู้ที่สมยอมในการยื่นเสนอราคาซึ่งเป็นการฝ่าฝืน พรบ.
ว่าด้วยความผิดเกี่ยวกับการเสนอราคาต่อหน่วยงานของรัฐอาจฝ่าฝืนและมีความผิดตามพระราชบัญญัติแข่งขันทางการค้า พ.ศ. 2542 ด้วย
เนื่องจากการกระทำดังกล่าวอาจถือว่าเป็นการจำกัดหรือทำลายการแข่งขันที่เป็นธรรม

การทำสัญญากับผู้ประกอบวิชาชีพทางการแพทย์และสาธารณสุขและสถาบันการแพทย์

ไม่มีกฎหมายหรือระเบียบข้อบังคับที่บังคับกับสัญญาที่ทำกับผู้ประกอบวิชาชีพทางการแพทย์และสาธารณสุขและสถาบันการแพทย์อย่างชัดแจ้ง

แต่แม้ว่าจะไม่มีกฎหมายหรือระเบียบตามที่ระบุไว้ข้างต้นก็ตาม
ก็ควรพิจารณาปัจจัยต่อไปนี้เมื่อเข้าทำสัญญากับผู้ประกอบวิชาชีพทางการแพทย์และสาธารณสุขและสถาบันการแพทย์
โดยเฉพาะอย่างยิ่งสัญญาที่ทำกับเจ้าหน้าที่ของรัฐหรือหน่วยงานของทางราชการ

- มูลค่าของสัญญาควรจะต้องเป็นมูลค่าตลาดที่เป็นธรรม
- ในกรณีที่ผู้ประกอบวิชาชีพทางการแพทย์และสาธารณสุขและสถาบันการแพทย์ได้รับค่าตอบแทนสำหรับบริการที่ผู้ประกอบวิชาชีพทางการแพทย์และสาธารณสุขและสถาบันการแพทย์ได้ให้แก่ผู้ประกอบการ
  ค่าตอบแทนที่ได้รับควรจะต้องสอดคล้องกับบริการที่ผู้ประกอบวิชาชีพทางการแพทย์และสาธารณสุขได้ให้ไว้จริง
- สัญญาควรจะต้องทำเฉพาะเมื่อมีวัตถุประสงค์ที่ชอบด้วยกฎหมายที่จะทำเท่านั้น
- ห้ามทำสัญญาเพื่อให้ผู้ประกอบการมีความได้เปรียบหรือได้รับประโยชน์ที่ไม่เหมาะหรือผิดกฎหมายจากผู้ประกอบวิชาชีพทางการแพทย์และสาธารณสุขและสถาบันการแพทย์
- ผู้ประกอบการควรจะเข้าใจกฎหมายและระเบียบข้อบังคับที่เกี่ยวข้องตามที่กล่าวถึงข้างต้นเป็นอย่างดีเนื่องจากอาจมีกฎหมายและระเบียบข้อบังคับหลายประการที่ใช้บังคับกับการโฆษณาหรือกิจกรรมส่งเสริมการขายโดยเฉพาะ
- การโฆษณาหรือกิจกรรมส่งเสริมการขายซึ่งผู้ประกอบการอาจดำเนินการ
  ควรจะต้องมีการวางแผนโดยนำกฎหมายและระเบียบข้อบังคับที่เกี่ยวข้องมาพิจารณาประกอบ
  เพื่อให้การโฆษณาหรือกิจกรรมส่งเสริมการขายเป็นไปตามกฎหมายและระเบียบข้อบังคับดังกล่าว รวมทั้งเพื่อให้ได้รับการอนุมัติจาก อย.ในที่สุด

Contracts with Healthcare Professionals and Medical Institutions

There are no laws or regulations that expressly govern contracts with healthcare professionals and medical institutions.

Notwithstanding the above, the following factors should be considered when any contracts are entered into with healthcare professionals or medical institutions, specifically contracts with government officials or agencies:

- The contract should be of fair market value.
- In the event that the healthcare professional or medical institution is receiving any compensation for services which the healthcare professional or medical institution renders to the business operator, then the compensation which the healthcare professional or medical institution receives should be commensurate with the actual services which are performed by the healthcare professional.
- The contract should only be entered into if there is a legitimate purpose.
- The contract must not be entered into in order for the business operator to gain any improper or illegitimate advantage or benefit from the healthcare professional or medical institution.

Recommendations

We provide below our general recommendations for conducting advertising and promotional activities in relation to medical products in Thailand:

- The business operator should fully understand the relevant laws and regulations which are outlined above as there may be various laws and regulations which may apply to a specific advertising or sales promotion activity.
- Any advertising or sales promotion activity which the business operator may conduct should be planned by also taking into account the relevant laws and regulations, in order to ensure that the advertising or sales promotion activity will comply with the said laws and regulations, as well as to ensure approval may ultimately be obtained from the FDA.

- ตามที่ระบุไว้ข้างต้น
  มีกฎหมายและระเบียบข้อบังคับหลายประการที่ใช้บังคับกับการโฆษณาหรือกิจกรรมส่งเสริมการขาย
  ซึ่งกฎหมายและระเบียบข้อบังคับดังกล่าวอาจมีความคลุมเครือว่าข้อความใดสามารถใช้ในโฆษณาได้ หรือกิจกรรมส่งเสริมการขายประเภทใดที่สามารถกระทำได้ ดังนั้น
  ผู้ประกอบการควรจะพิจารณาใช้บริการจากผู้ที่มีประสบการณ์ในการตรวจสอบและวิเคราะห์ว่าโฆษณาหรือกิจกรรมส่งเสริมการขายนั้นเหมาะสมหรือไม่เพื่อที่จะได้รับคำแนะนำที่ชัดเจนและเป็นข้อมูลสำหรับการวางแผนของผู้ประกอบการในการโฆษณาหรือกิจกรรมส่งเสริมการขายต่อไป

<u>ข้อแนะนำ</u>

เราขอให้คำแนะนำทั่วไปในการดำเนินการโฆษณาหรือการทำกิจกรรมส่งเสริมการขายผลิตภัณฑ์ทางการแพทย์ในประเทศไทยดังต่อไปนี้

<u>หมายเหตุ</u>

ขณะนี้ สำนักงานกรุงเทพมหานครของเบเคอร์แอนด์แม็คเค็นซี่มีฝ่ายงานด้านขึ้นทะเบียนผลิตภัณฑ์ (Regulatory Affairs Services Department) เพื่อให้บริการเกี่ยวกับเรื่องที่เกี่ยวข้องกับ อย. รวมถึงแต่ไม่จำกัดเพียงการให้ความช่วยเหลือในการตรวจทานและแก้ไขโฆษณาและสื่อที่ใช้ในการส่งเสริมการขายผลิตภัณฑ์ทางการแพทย์
เพื่อให้โฆษณาและ/หรือสื่อดังกล่าวเป็นไปตามกฎหมายและระเบียบข้อบังคับที่เกี่ยวข้อง

- เนื่องจาก อย. อาจมีระเบียบข้อบังคับภายในของอย. เองด้วย
  ผู้ประกอบการควรจะประสานงานกับ อย.
  อย่างใกล้ชิดในการจัดทำโฆษณาหรือกิจกรรมส่งเสริมการขาย
- ผู้ประกอบการควรทำให้มั่นใจว่ากิจกรรมส่งเสริมการขายที่กระทำต่อผู้ประกอบวิชาชีพทางการแพทย์และสาธารณสุขซึ่งเป็นเจ้าหน้าที่ของรัฐ
  ไม่เป็นการฝ่าฝืนกฎหมายต่อต้านการให้สินบน
  โดยเฉพาะอย่างยิ่งในกรณีที่ผู้ประกอบการอาจให้ทรัพย์สินหรือประโยชน์แก่เจ้าหน้าที่ของรัฐ

- As noted above, there are various laws and regulations which govern advertising and sales promotion activities. Such laws and regulations may be ambiguous on what statements may be used in an advertisement or what type of sales promotion activities may be conducted. Thus, the business operator should consider utilizing services of persons who have experience in reviewing and analyzing the adequacy and appropriateness of the advertising or promotional activity, in order to obtain clear guidance and input into the business operator's planning process in relation to its advertisements and sales promotion activities.
- As the FDA may also have its own internal regulations, the business operator should work closely with the FDA in preparing advertisements or promotional activities.
- The business operator should ensure that any sales promotion activities which are conducted with healthcare professionals who are government officials, specifically where the business operator may provide properties or benefits to the government official, must not violate any relevant anti-bribery laws.
- The business operator should ensure that any persons who are acting on its behalf, such as employees, agents, representatives and contractors, must also understand and comply with the relevant laws and regulations which apply to advertisements or promotional activities.

Note:

Baker & McKenzie's Bangkok office now has the Regulatory Affairs Department to provide services in relation to FDA-related matters, including, but not limited to, assistance in reviewing and revising medical product advertisements and promotional materials, in order to ensure that such advertisements and/or materials are in compliance with the relevant laws and regulations.

- *ผู้ประกอบการ*ควรทำให้มั่นใจว่าบุคคลที่กระทำการแทนผู้ประกอบการ เช่น พนักงาน ตัวแทน ผู้แทน ผู้รับจ้าง
  เข้าใจและปฏิบัติตามกฎหมายและระเบียบข้อบังคับซึ่งใช้บังคับกับโฆษณาหรือกิจกรรมส่งเสริมการขายด้วย

Vietnam

Vu Minh Ha

Legislation on Advertising Pharmaceuticals

Regulatory Framework

The advertising of pharmaceutical products is governed primarily by the Law on Pharmacy[1], Circular No. 13[2], and the Advertisement Ordinance[3] along with their implementing regulations.

Advertising of medicines means the activity of introducing medicines as directly performed by an entity conducting business in medicines or by another entity that a medicine company coordinates, sponsors, or authorizes in order to promote the prescription, supply, sale and/or appropriate, safe and effective use of medicines[4].

Permitted and Prohibited Practices

Information about pharmaceutical products must be true, accurate, clear, objective, and substantiated by scientific evidence. Such information must be presented with a high ethical standard, in compliance with the latest product information approved by the Ministry of Health ("MOH"), and in such a way as not to be misleading or ambiguous.

Medicines on the over-the-counter ("OTC") medicines list issued by the MOH with an effective registration number may be advertised in print, outdoor, and digital media. In order for an OTC medicine to be advertised on radio or television, however, the OTC medicine must contain active pharmaceutical ingredients permitted by the MOH.

[1] Pharmacy Law No. 34/2005/QH11 promulgated by the National Assembly of Vietnam on 14 June 2005 ("Pharmacy Law").
[2] Circular No.13/2009/TT-BYT of the Ministry of Health dated 1 September 2009 guiding information and advertising of drugs ("Circular No. 13").
[3] Advertisement Ordinance No.39/2001/PL-UBTVQH10, dated 16 November 2001 ("Advertisement Ordinance").
[4] Article 2.3, Circular No.13.

The law prohibits the advertising of prescription medicines, vaccines, or medical biological products used for disease prevention, as well as of OTC medicines that should be restricted or require doctor supervision[5].

The following indications are not permitted to be included in medicine advertisements: indications for treatment of tuberculosis and leprosy; indications for treatment of sexually transmitted diseases; indications for treatment of chronic insomnia; indications as an aphrodisiac; indications for treatment of cancer and neoplastic diseases; and indications for treatment of diabetes or other similar metabolic diseases[6].

Off-label uses of medicines are not allowed to be promoted in Vietnam.

The law also prohibits the following acts:

- Providing information on and advertising cosmetics, functional foods, and non-drug products with unclear contents that may lead to consumers' misunderstanding of those products as drugs
- Using material or financial benefits in any form to influence physicians and drug users in order to promote the prescription and use of drugs
- Making use of drug circulation registration numbers granted by the Drug Administration of Vietnam or the drug management agencies of other countries to advertise drugs
- Using the name, symbol, image, position, prestige, or letters of a medical or pharmaceutical organization to advertise or recommend drugs
- Using medical workers or thank-you letters from patients to advertise or recommend drugs
- Advertising drugs in the form of physicians' instructions on disease prevention or treatment, or in the form of drug use instructions in newspaper articles and radio or television broadcast programs
- Using clinical research results that lack scientific grounding and medical evidence for drug information provision and advertising
- Making use of test results and certifications issued by competent agencies or medals granted to products and/or units in exhibitions and fairs to advertise drugs
- Providing information on and advertising drugs with contents irrelevant to Vietnam's fine traditions and customs

[5] Article 5.1, Circular No. 13.
[6] Article 25, Circular No. 13.

- Making use of animal images or other irrelevant images to provide information on and advertise drugs, leading to users' confusion
- Making publically-available drug information documents intended solely for medical workers
- Using sentences, words, images, and sounds suggesting that a drug is optimal or best in its effects
- Making comparisons for the purpose of advertising that suggest one's drugs are better than those of other organizations and individuals
- Advertising and providing information on drugs without registration numbers or with expired registration numbers
- Providing information on and advertising drugs before submitting registration dossiers of drug information provision and advertisings to competent state management agencies
- Providing information on and advertising drugs at variance with registered contents
- Providing information on and advertising drugs whose dossiers are being considered and processed under regulations

Consequences of Breach

Depending on the specifics of a given violation, the monetary fine can range from VND5 million (approximately USD250[7]) to VND40 million (approximately USD2,000). Additional sanctions can also be imposed, such as revocation of the pharmaceutical practice certificate, the certificate of satisfaction of conditions for drug trading, or the license for foreign companies conducting operations in medicine in Vietnam[8].

Other Promotional Activities

Samples

The provision of drug samples to healthcare professionals ("HCP") is prohibited. However, this restriction does not apply to medical devices.

[7] At the exchange rate of US$1:VND20,000.
[8] Decree No. 93/2011/ND-CP, on sanctioning of administrative violations related to medicines, cosmetics and medical devices, issued by the Government on 18 October 2011 ("Decree No. 93").

Gifts

Gifts are regulated under Vietnam's anti-corruption laws. According to Decision No. 64[9], gifts or gratuities include, but are not limited to, the following:

- Vietnamese currency, foreign currencies, saving certificates, stocks, bonds, checks and valuable papers
- Material items, goods and assets
- Entertainment including, without limitation, services of domestic or overseas sightseeing tours and travels
- Healthcare services, education/training, internship and refresher training, and other kinds of services
- Rights to buy assets, houses, land use rights and equipment use rights; non-State prescribed privileges; use of assets, houses, land and equipment of other persons, which are free of charge or undercharged[10]

State officials and public employees can receive gifts given by their relatives or family members, or by agencies, units or individuals have no relations with the State duties of such State officials and public employees[11].

Apart from the above-specified case, State officials/public employees can receive gifts of less than VND500,000 (approximately USD25) when they are ill or suffering from an accident, or for occasions of mourning, weddings, or traditional festivals such as the Lunar New Year, provided that the gift-giving is not related to prohibited acts and purposes — for instance, the giver having relations with State duties that the State official/public employee is handling, the gift-giving having no clear purpose, or having a corrupt intent[12].

Gimmicks

"Gimmicks" or "give-aways" are an industry term and are not regulated by Vietnamese law. There is no specific threshold regulated by law for the value

[9] Decision No. 64/2007/QD-TTg promulgating the regulation on giving, receipt and hand-over of gifts by State budget-funded agencies, organizations and units and cadres, public employees and servants, issued by the Prime Minister on 10 May 2007 ("Decision No. 64").
[10] Article 3, Decision No. 64.
[11] Article 11, Decision No. 64.
[12] Article 12.4, Decision No.64.

of gimmicks or give-aways. However, please note that the value of gifts regulated by Decision No. 64 is less than VND500,000, therefore, using this value for gifts as a reference, give-away items should only be nominal as not to be considered an "influence" on HCPs.

Hospitality and Sponsorship

Sponsorships for HCPs to attend events are generally permitted if properly structured and subject to specific ethical control procedures with medical institutions.

Hospitality during events should be limited to refreshments and meals incidental to the main purpose of the event. The value should be moderate and reasonable as judged by local standards. Hospitality should not be extended to persons other than the HCP participating in the event.

Liability Under Criminal Law

In Vietnam, there are two different sets of law dealing with corruption-related issues.

The Law on Anti-Corruption[13] is considered a "code of conduct" for State officials and public employees in the discharge of their official duties. The Law on Anti-Corruption covers prohibited acts of State officials and public employees with official positions or powers and forms the basis for the application of the Penal Code[14] with respect to bribery offenses. It does not address the act of giving bribes or provide specific sanctions for noncompliance.

For noncompliance, the Law on Anti-Corruption refers to either the Penal Code or the Law on Cadres and State Officials[15] and the Law on Public Employees[16] on handling violations pertaining to the receipt of bribes, depending on the seriousness of such violations.

[13] Law on Anti-Corruption, passed by the National Assembly on 29 November 2005, effective on 1 June 2006 as amended in 2007 ("Law on Anti-Corruption").
[14] Penal Code, passed by the National Assembly on 21 December 1999, effective on 1 July 2000 as amended in 2009 ("Penal Code").
[15] Law on Cadres and State Officials, passed by the National Assembly on 13 November 2008, effective on 1 January 2010 ("Law on Cadres and State Officials").
[16] Law on Public Employees, passed by the National Assembly on 15 November 2010, effective on 1 January 2012 ("Law on Public Employees").

The Penal Code deals with both acts of giving and receiving bribes. It provides the following crimes: giving bribes; receiving bribes; and acting as intermediary for bribes by meeting elements constituting such crimes.

Violations of the Penal Code will trigger individual criminal liability. The Penal Code does not provide for corporate criminal liability.

Provisions on Bribery Under the Penal Code

Under Article 279 of the Penal Code, those who abuse their positions and/or power, have accepted or will accept, directly or through intermediaries, money, property, or other material interests in any form valued at VND2 million (approximately USD100) or above, or under VND2 million with an element of serious consequence, for performing or not performing certain jobs for the benefit or at the request of the bribe givers, shall be subject to criminal liability for the crime of receiving a bribe. Depending on the seriousness of the case, criminal liability for receiving a bribe can includes the death sentence.

Under Article 289 of the Penal Code, those who give a bribe valued at VND2 million or more, or under VND2 million with an element of serious consequence, or those who have given bribes before, shall be subject to criminal liability for the crime of giving a bribe. Depending on the seriousness of the case, criminal liability for giving a bribe can include life sentence.

Contracts with HCP and Medical Institutions

If a member of the industry wants to sign a contract with an HCP in order to engage the HCP for services such as speaking at and chairing meetings, translating medical documents, writing a medical article, or giving medical training, the arrangements covering legitimate provisions of such services should meet the following conditions:

- Written pre-approval should be obtained from the medical institution's head, which proves that the HCP is permitted to engage in the service contract and that the execution and performance of the contracts does not violate internal regulations of the medical institution.
- There should be a written contract that specifies the nature of the services to be provided and the basis for payment of those services.
- Payment to HCP service providers should be based on market criteria and be proportionate to the time devoted, the work done and the responsibilities assumed, and must be adequately documented.

Payments of service fees must not be made in advance. Cash payment is prohibited.

- There should be a legitimate need for the services of the HCP and the relevant person should be an appropriate candidate based on their qualifications and experience in the relevant subject matter or activity.
- The hiring of the HCP to provide the relevant services must not be an inducement to recommend, prescribe, purchase, supply, sell or administer a particular medicine (i.e., no *quid pro quo*).

However, please note that HCPs are not allowed to be consultants for companies, organizations, or individuals in affairs related to State secrets, professional secrets, or for affairs the HCP has the power to resolve or for which they participate in the resolution process[17].

[17] Article 37.1c, Law on Anti-Corruption

Europe

Österreich

Daniel Larcher, Agata Wolinska

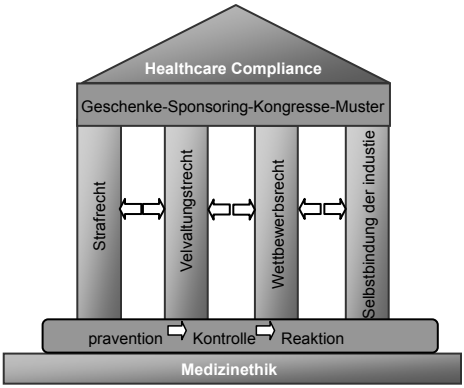
Einleitung

Kleine Geschenke verbessern bekanntlich die Geschäftsbeziehungen. Diese Freiheit endet dort, wo höherwertige Interessen Dritter gefährdet werden. Dies ist gerade im Heilmittelbereich der Fall, in dem es insbesondere die Gesundheitsinteressen der Patienten vor der wirtschaftlichen Einflussnahme der medizinischen Industrie auf die verschreibungs- und abgabeberechtigten Angehörigen der Heilberufe, so vor allem Ärzte und Apotheker, zu schützen gilt. Daher werden den Werbemaßnahmen im Heilmittelbereich enge gesetzliche Grenzen gesetzt, etwa durch Restriktionen bei der Gewährung von Vorteilen oder der Abgabe von Heilmittelmustern.

Das österreichische Heilmittelrecht war in den letzten Jahren durch einige Veränderungen gekennzeichnet, die in der Umsetzung der einschlägigen EU-rechtlichen Vorhaben, der Errichtung einer neuen Kontrollbehörde im Gesundheitswesen sowie der Verschärfung der diesbezüglichen verwaltungs- und strafrechtlichen Bestimmungen bestehen. Für die Zukunft ist eine genauere Ausgestaltung der heilmittelwerberechtlichen Bestimmungen durch die zuständigen Behörden oder die Rechtsprechung zu erwarten.

Gesetzliche Beschränkungen der Heilmittelwerbung

Rechtliche Grundlagen



Austria

Daniel Larcher, Agata Wolinska

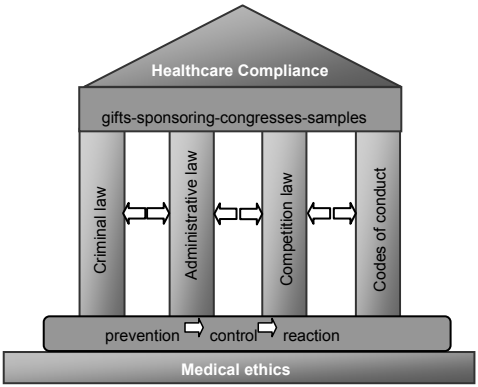
Introduction

It is generally known that small gifts can enhance business relations. This rule is restricted where more significant interests of third parties are infringed. Especially in the medical business, the patients' health interests must be protected against the industry's economic influence on the healthcare professionals such as physicians and pharmacists. For this reason, promotional activities in the field of healthcare are strictly limited by law, e.g., by restrictions regarding the granting of gifts or free samples.

Austrian law on the promotion of medicinal remedies (*Heilmittel*) has gone through significant changes in the last years. This is due to the implementation of European Union ("EU") directives, the installation of a monitoring authority in the healthcare sector, and the tightening of the applicable provisions of administrative and criminal law. For the future, a more detailed definition of the provisions dealing with promotional activities in the health sector through the competent authorities and/or case law may be expected.

Restrictions Under Medical Advertising Law

The Regulatory Framework



Die Umsetzung der Richtlinie 92/28/EWG über die Werbung für Humanarzneimittel, der Richtlinie 2001/83/EEG zur Schaffung eines Gemeinschaftskodexes für Humanarzneimittel sowie der Richtlinie 2004/27/EG erfolgte in Österreich im Wesentlichen im Bundesgesetz über die Herstellung und das Inverkehrbringen von Arzneimitteln (Arzneimittelgesetz – AMG). Entsprechende Regelungen finden sich im Bundesgesetz betreffend Medizinprodukte (Medizinproduktegesetz – MPG).

Gemäß § 50 AMG gelten als Werbung für Arzneimittel alle Maßnahmen zur Information, zur Marktuntersuchung und Marktbearbeitung und zur Schaffung von Anreizen mit dem Ziel, die Verschreibung, die Abgabe, den Verkauf oder den Verbrauch von Arzneimitteln zu fördern. Dieser Werbebegriff (vgl Artikel 86 der geänderten Richtlinie 2001/83/EG) umfasst, neben der Fach- und Laienwerbung insbesondere

- Anreize zur Verschreibung oder Abgabe von Arzneimitteln durch das Gewähren, Anbieten oder Versprechen von finanziellen oder materiellen Vorteilen,
- das Sponsern von Verkaufsförderungsveranstaltungen, an denen Personen teilnehmen, die zur Verschreibung oder zur Abgabe von Arzneimitteln befugt sind,
- die Übernahme der Reise- und Aufenthaltskosten und Teilnahmegebühren im Zusammenhang mit berufsbezogenen wissenschaftlichen Veranstaltungen für Personen, die zur Verschreibung oder zur Abgabe von Arzneimitteln befugt sind,
- die Abgabe von Ärztemustern, sowie
- den Besuch von Pharmareferenten bei Personen, die zur Verschreibung oder zur Abgabe von Arzneimitteln berechtigt sind.

Nicht vom Werbebegriff des § 50 AMG umfasst sind

- der Schriftwechsel und gegebenenfalls alle Unterlagen, die nicht Werbezwecken dienen und die zur Beantwortung einer konkreten Anfrage über ein bestimmtes Arzneimittel erforderlich sind,
- Verkaufskataloge und Preislisten, sofern diese keine Angaben über Arzneimittel enthalten, sowie
- Informationen über die Gesundheit oder Krankheiten von Mensch und Tier, sofern darin nicht, auch nicht in indirekter Weise auf ein Arzneimittel Bezug genommen wird.

Medical Products and Medical Devices

EU Directive 92/28/EEC on advertising of medicinal products for human use, EU Directive 2001/83/EEC on the community code relating to medicinal products for human use, as well as EU Directive 2004/27/EC have essentially been implemented in the Act on Medical Products (*Arzneimittelgesetz,* "AMG"). Corresponding provisions dealing with the promotion of medical devices are laid down in the Act on Medical Devices (*Medizinproduktegesetz,* "MPG").

Pursuant to the AMG, "advertising" is defined as all measures with respect to information, market investigation and market development, and all inducement measures aimed at enhancing the prescription, supply, sale or consumption of a medical product. This definition of advertising includes, besides advertising to health professionals and to the general public, in particular (see the human use directive, as amended):

- inducements to prescribe or supply medical products by the gift, offer or promise of any benefit or bonus, whether in money or in kind;
- sponsorship of promotional events attended by persons qualified to prescribe or supply medical products;
- payment of travel and accommodation expenses and attendance fee in connection with scientific congresses attended by persons qualified to prescribe or supply medical products;
- supply of samples; and
- visits by medical sales representatives to persons qualified to prescribe medical products.

The following are not covered by this definition:

- correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medical product;
- trade catalogues and price lists, provided they include no product claims; and
- statements relating to human or non-human health or diseases, provided there is no reference, even indirect, to medical products.

This provision does not apply to "general image advertising," provided there is no reference to medical products.

Prinzipiell nicht erfasst ist ferner die sogenannte „allgemeine Imagewerbung" eines Unternehmens ohne gleichzeitige Absatzwerbung für bestimmte Arzneimittel oder Medizinprodukte.

Wettbewerbsrecht

Der vorgenannte heilmittelwerberechtliche Rahmen wird durch das Wettbewerbsrecht ergänzt. Gemäß dem Bundesgesetz gegen den unlauteren Wettbewerb (UWG) kann zivilrechtlich gegen Mitbewerber vorgegangen werden, die unlautere Handlungen im geschäftlichen Verkehr zu Zwecken des Wettbewerbs vornehmen. Werbemaßnahmen haben in der Regel das Ziel, den eigenen Warenabsatz zu steigern, und sind daher potentiell geeignet, Mitbewerber in ihrem Geschäftsbereich zu stören. Nach den Kriterien des UWG ist diesbezüglich zu beurteilen, ob die Mittel, durch welche der störende Wettbewerber eine Steigerung des Warenabsatzes erreichen will, zu billigen sind oder diese mit dem Gesetz, dem lauteren Anstandsgefühl der Mitbewerber oder der Allgemeinheit unvereinbar sind (§ 1 UWG). Ergänzend wird im UWG ein Verbot der Irreführung (siehe auch § 7 AMG und § 102 MPG) und/oder ein Verbot aggressiver Geschäftspraktiken gegenüber Konsumenten normiert. Weiters wird vergleichende Werbung für zulässig erklärt, sofern diese nicht irreführend oder aggressive ist. Anzumerken ist jedoch, dass die Zulässigkeit vergleichender Werbung im Arzneimittelbereich durch den Verhaltenskodex der Pharmig erheblich eingeschränkt wird (siehe dazu unten).

Eine Verletzung der Werbebestimmungen des AMG oder der MPG wird regelmäßig auch als unlautere im Sinne des Wettbewerbsrechts gewertet.

Der Anspruch nach dem UWG kann auf Unterlassung, Beseitigung, Schadenersatz oder Veröffentlichung eines stattgebenden Urteils gerichtet sein. Gemäß § 85a AMG können außerdem Unterlassungsklagen gegen die Verletzungen heilmittelwerberechtlicher Regeln auch von bestimmten Verbänden und Körperschaften des öffentlichen Rechts angestrengt werden.

Zulässigkeit von Werbepraktiken im Heilmittelbereich

Unternehmen im Gesundheitsbereich bedienen sich zur Verbesserung der Geschäftsbeziehungen mit Ärzten und medizinischen Einrichtungen einer Vielzahl mittelbarer Werbemaßnahmen, die etwa in der Gewährung von Geschenken und Gastfreundschaft oder der Überlassung von Gratismustern bestehen kann. Das Gesetz ordnet ausdrücklich an, dass bei solchen Werbepraktiken jeglicher Anschein der unsachlichen Beeinflussung von zur Verschreibung und Abgabe berechtigten Personen in ihrer

Competition Law

In addition to the aforementioned statutory provisions on the advertising of medical products, there are several relevant provisions under competition law. The Austrian Unfair Competition Act (*Bundesgesetz gegen den unlauterenWettbewerb,* "UWG") provides for the possibility of taking action under civil law against competitors who engage in unfair commercial practices for advertising purposes. Advertising measures usually serve the purpose of increasing one's own sales and can therefore be used as a means of interfering with competitors in their respective areas of business. According to the criteria set forth in the UWG, in this context, it needs to be investigated whether the means by which the interfering competitor hopes to achieve an increase of sales are permissible or incommensurate with the law, fairness to competitors or to the general public (section 1 UWG). Additionally, the UWG prohibits misleading commercial practices (see also AMG and MPG) and/or aggressive commercial practices *vis-à-vis* consumers. Furthermore, comparative advertising is deemed permissible unless it is misleading or aggressive. However, it has to be noted that the permissibility of comparative advertising in the area of drugs is constricted to a considerable extent by the provisions of the code of conduct of Association of Austrian Pharmaceutical Companies ("Pharmig") (see below).

Any violation of the provisions on advertising as set forth in the AMG or the MPG is usually also deemed unfair, and thus illegal, from a competition law perspective.

Any claim arising under the UWG can be directed towards a cease and desist order, removal, damages or the publication of a court decision sustaining the claim. Pursuant to the AMG, certain associations and corporations under public law are also entitled to apply for cease and desist orders against the violation of statutory provisions on the advertising of remedies.

Permitted and Prohibited Practices

Enterprises operating in the healthcare sector apply a multitude of indirect advertising measures to improve their business relations with physicians and medical facilities that may constitute the provision of gifts or hospitality or the supply of free samples. The law expressly provides that with respect to these advertising practices, any action however slightly implying that improper influence is exercised over any person qualified to prescribe or supply drugs in his or her decision to administer a certain therapy or

Therapieentscheidung oder Empfehlung vermieden werden muss (Unabhängigkeitsprinzip).

Die Artikel 94, 95 und 96 der geänderten Richtlinie 2001/83/EG wurden vom österreichischen Gesetzgeber in §§ 55a, 58 AMG umgesetzt.

Geschenke und Sonstige Vorteile (§ 55a AMG)

Gemäß § 55a Abs 1 AMG ist es verboten, im Rahmen der Verkaufsförderung für Arzneimittel den zur Verschreibung oder Abgabe berechtigten Personen eine Prämie, finanzielle oder materielle Vorteile zu gewähren, anzubieten oder zu versprechen. Ferner wird verboten, eine Prämie, finanzielle oder materielle Vorteile zu fordern, sich versprechen zu lassen oder anzunehmen (§ 55a Abs 4 AMG). Eine Regelung entsprechenden Inhalts wird überdies für die Verkaufsförderung von Medizinprodukten in § 108 MPG normiert.

Das Annahmeverbot bezieht sich auf Geschenke und andere Vermögensvorteile im weitesten Sinn. Es genügt, wenn sich der empfangene Vorteil in Geld ausdrücken lässt, wie bei Urlaubsreisen, Überlassung von Fahrzeugen, Erbringung von Dienstleistungen, Verzicht auf Kreditzinsen etc. Andererseits fallen unter das Verbot noch sonstige Vorteile, zB Begünstigungen von dritten Personen, die Verschaffung einer Nebenbeschäftigung und die Annahme einer Einladung.

Die Gewährung von Zuwendungen ist jedoch auch in diesem sensiblen Bereich der Fachwerbung nicht gänzlich untersagt, da sich das Verbot ausdrücklich nicht gegen solche Vorteilsgewährungen richtet, die von geringem Wert und außerdem für die medizinische, pharmazeutische oder medizintechnische Praxis von Belang sind (das heißt, nicht auch privaten Zwecken des Vorteilsempfängers gewidmet sind). Der zuständige Bundesminister ist ermächtigt, durch Verordnung zu regeln, wann von einem geringen Wert auszugehen ist. Allerdings wurde eine diesbezügliche Verordnung vom zuständigen Bundesminister (Bundesminister für Gesundheit und Frauen) bisher nicht erlassen. Eine Wahrnehmung der Verordnungsermächtigung ist laut Angaben des Bundesministers für die nächste Zeit nicht zu erwarten. Dies wird damit begründet, dass die Festlegung einer starren Geringfügigkeitsgrenze rechtspolitisch wenig zweckmäßig erscheint. Die Zulässigkeitsgrenze müsse vielmehr im Einzelfall beurteilt werden. Damit werde eine erhöhte Präventivwirkung erzielt. Überdies solle verhindert werden, dass sich vor allem in der Ärzteschaft die Meinung herausbildet, dass ein Rechtsanspruch auf Geschenke in Höhe der Geringfügigkeitsgrenze bestehe. Anzumerken ist ferner, dass es auch keine

makes a certain recommendation, has to be avoided (principle of independence, *Unabhängigkeitsprinzip*).

Gifts and Other Benefits (section 55a AMG)

Pursuant to the AMG, it is prohibited to grant, offer or promise an incentive or, financial or material benefits to any person who is qualified to prescribe or supply drugs within the scope of advertising measures for drugs. It is also prohibited to demand, accept the promise of or accept any incentive or, financial or material benefits. The MPG provides for a corresponding regulation with respect to the advertising of medical devices.

The prohibition of acceptance refers to gifts and other pecuniary benefits in the broadest sense of the definition. It is sufficient if the benefit received can be expressed in money, as is the case with vacation trips, the provision of vehicles, services, the waiving of interest on loans, etc. On the other hand, the prohibition also applies to other benefits, such as granting preferential treatment to third parties, placement services for additional occupation and the acceptance of invitations.

As the prohibition explicitly excludes the grant of benefits that are of low (minor) value and furthermore relevant to the practice of medicine, pharmaceutical or medical technology (i.e., do not serve the private purposes of the person receiving the benefit), the granting of benefits is, however, not entirely prohibited in this sensitive area of advertising. The competent Federal Minister (i.e., Federal Minister for Health and Women) is entitled to stipulate by way of ordinance what is supposed to qualify as low value. However, the competent Federal Minister has not yet issued an ordinance to that effect. According to the Federal Minister, the authority to issue such ordinance will not be exercised anytime soon. The reason given for this is that determining a fixed threshold for benefits of low value does not seem to be legally useful. The question of what is admissible would instead have to be investigated on a case-by-case basis. This would also intensify the preventive effect. The Minister furthermore intends to avoid giving physicians the impression that they have a legal claim to gifts that meet the low-value criteria. It must also be noted that there is no Austrian case law on the issue of the low-value threshold, thus enterprises operating in the healthcare sector are facing a considerable degree of legal uncertainty.

österreichische Rechtsprechung zur Frage der Geringfügigkeitsgrenze gibt, sodass sich Unternehmen im Heilmittelbereich diesbezüglich mit einer erheblichen Rechtsunsicherheit konfrontiert sehen.

Auszugehen ist davon, dass bei Vorteilsgewährungen große Vorsicht und Zurückhaltung geboten ist, da nach dem strengen Wortlaut der Regelung Zuwendungen nicht nur von geringem Wert, sondern überdies für die medizinische Praxis von Belang sein müssen. Ferner wird bei regelmäßigen Vorteilsgewährungen – schon zur Vermeidung einer Gesetzesumgehung – eine wirtschaftliche Gesamtbetrachtung vorzunehmen sein, in deren Rahmen die einzelnen Leistungen zusammengerechnet werden können. Aus Vorsichtsgründen empfiehlt es sich daher, die Geringfügigkeitsgrenze auf Ebene der typischen Werbegeschenke anzusetzen. Üblicherweise fallen darunter Gegenstände des Alltagsgebrauchs von geringfügigem Handels- und Verkehrswert, wie beispielsweise Schreibutensilien, Papierblöcke, Kalender etc, die regelmäßig auch für die medizinische Praxis von Belang sein können.

In der Literatur wird die Geringfügigkeitsgrenze, teilweise mit Blick auf Zulässigkeitsgrenzen anderer Rechtsordnungen, auch höher bewertet. Erwägenswert ist im gegebenen Zusammenhang die strafrechtliche Geringfügigkeitsgrenze im Korruptionsbereich, die in etwa bei EUR70 angesiedelt ist, als Ausgangspunkt heranzuziehen. Dabei ist jedoch zu bedenken, dass die Wertgrenze für strafrechtliche Konsequenzen naturgemäß höher anzusetzen ist als jene für heilmittelwerberechtliche Übertretungen, sodass der Wert der Vorteilsgewährung deutlich unter EUR70 liegen muss. Anzuraten ist, dass der Vorteil nicht der Fachperson selbst, sondern allenfalls der medizinischen Einrichtung gewährt werden sollte (Unmittelbarkeitsprinzip).

Letztendlich ist hierbei jedoch größte Zurückhaltung geboten, da die einschlägigen Richtlinien und Verhaltenskodizes strengere Kriterien formulieren können (siehe dazu unten) und bei einem Verstoß gegen diese Verhaltensregeln empfindliche Geldstrafen und/oder sonstige Sanktionen drohen.

Nicht geregelt wird in den Heilmittelgesetzen, inwieweit Geschenke auch nach ihrer „Sozialadäquanz" bewertet werden dürfen. Wird etwa einem Arzt anlässlich seiner Beförderung ein Geschenk gemacht, ist fraglich, ob dadurch bereits ein Verstoß gegen heilmittelwerberechtliche Bestimmungen vorliegt. Anzunehmen ist, dass Geschenke aus Anlass der Höflichkeit und der Sitte zulässig sind, soweit sie im betreffenden Verkehrskreis üblich, anlassbezogen

One has to act on the assumption that whoever is granted benefits has to act with great caution and restraint because, according to the strict wording of the provision, benefits must not only be of low value, but also relevant to the practice of medicine. Where benefits are being granted on a regular basis, if only to avoid (fraudulent) evasion of the law, the overall economic circumstances will have to be investigated. In the course of such investigation, the individual benefits may be added together. Consequently, as a precaution, it is advisable to take typical advertising gifts as the basis for determining the low-value threshold. This usually includes objects of daily use of low commercial or market value, such as writing materials, paper pads, calendars, that can often be relevant to the practice of medicine.

In legal literature, there are authors who, partially referring to admissibility thresholds applicable in other jurisdictions, assume higher thresholds. In this context, one should think about taking the low value threshold under criminal law as a basis, which amounts to approximately EUR70. It must, however, be borne in mind that naturally, the value threshold for consequences under criminal law needs to be higher than the one for infringements of provisions regarding the advertising of remedies, so the value of the benefit granted must be considerably lower than EUR70. It is advisable not to grant the benefit to the medical professional but, if at all, to the medical facility (principle of immediacy, *Unmittelbarkeitsprinzip*).

However, in doing so, one needs to act with great care, as the relevant guidelines and codes of conduct might provide for stricter criteria (see below), and any violation of such rules of conduct could result in severe fines and/or other sanctions.

The statutory provisions on remedies do not stipulate whether gifts may be evaluated according to their "social adequacy." If, for example, a physician receives a gift on the occasion of his promotion, it is uncertain whether this constitutes a breach of the provisions regarding advertising of remedies. It can be assumed that gifts that are made out of courtesy and custom are permissible in so far as they are customary for the relevant group of persons, related to the occasion and are of low value. In this context, the low-value threshold can by all means be a little higher, i.e., within the scope of what is socially conventional for the respective occasion and does not meet the criterion of medical supply. A typical example that is often mentioned is the giving of a bottle of wine or a bouquet of flowers.

und geringwertig sind. Die Geringfügigkeitsgrenze kann hierbei durchaus auch etwas höher angesetzt werden, also im Rahmen des für den jeweiligen Anlass sozial Üblichen sowie außerhalb des Kriteriums des medizinischen Bedarfs. Häufig genannt wird beispielsweise die Schenkung einer Weinflasche oder eines Blumenstraußes.

Repräsentationsaufwendungen und Übernahme von sonstigen Kosten bei Marketing- und wissenschaftlichen Veranstaltungen (§ 55a Abs 2 AMG)

Marketingveranstaltungen

Gemäß § 55a Abs 2 AMG muss der Repräsentationsaufwand (das sind Kosten der Bewirtung und der Unterhaltung) im Zusammenhang mit Veranstaltungen zur Verkaufsförderung immer streng auf den Hauptzweck der Veranstaltung begrenzt sein. Ferner darf der Repräsentationsaufwand nicht anderen Personen als den zur Verschreibung oder Abgabe berechtigten Personen zukommen.

Bei Marketingveranstaltungen sind daher die Übernahme von Kosten des Arztes durch den Veranstalter, etwa Unterhaltungs- oder Bewirtungskosten, die die Grenze der Geringfügigkeit überschreiten, unzulässig. Die Geringfügigkeitsgrenze im Rahmen von Marketingveranstaltungen ist mit denselben Unsicherheiten behaftet wie im Fall der Gewährung von Geschenken. Aus Vorsichtsgründen ist deshalb anzuraten, diese möglichst niedrig anzusetzen. Auf die Übernahme der Kosten für Unterhaltung, zB Kultur- oder Sportveranstaltungen, ist tunlich zu verzichten. Zulässig erscheint aber das Angebot eines Rahmenunterhaltungsprogramms, für welches die Veranstaltungsteilnehmer bei Teilnahme selbst bezahlen müssen.

Auch die Verpflegung wird sich auf das Notwendigste beschränken müssen. So wird beispielsweise das Anbieten eines einfachen Buffets zulässig sein, nicht jedoch einer ausgiebigen Mahlzeit in einer Gaststätte. Die Bezahlung eines Arztes für die Teilnahme an einer Veranstaltung, ohne dass der Arzt etwa durch Vorträge oder Präsentationen im Rahmen der Veranstaltung aktiv wird, ist verboten.

Die vom Veranstalter übernommenen Kosten sind aus Beweisgründen präzise und nachvollziehbar zu dokumentieren (Dokumentationsprinzip). Ratsam ist es, dass die Einladung an die medizinische Einrichtung selbst gerichtet wird, nicht jedoch an deren Fachpersonal (Unmittelbarkeitsprinzip).

Hospitality Expenses and Assumption of Responsibility for Other Costs in Connection with Marketing and Scientific Events (section 55a para 2 AMG)

Marketing Events

Pursuant to the AMG, hospitality expenses (e.g., business entertainment expenses) incurred in connection with sales promotion events must always be strictly limited to the main purpose of the event. Neither may the expenditure on hospitality be extended to persons other than those qualified to prescribe or supply drugs.

As far as marketing events are concerned, an organizers assuming responsibility for costs incurred by the physician, such as business entertainment expenses, that exceed the low-value threshold, is impermissible. In connection with marketing events, the low-value threshold therefore bears the same uncertainties, as is the case with the giving of gifts. As a precaution, it is therefore advisable to assume as low a threshold as possible. Assuming responsibility for entertainment expenses, e.g., cultural or sports events, should under all circumstances be abstained from. Offering an entertainment program, the costs of which need to be borne by the participants themselves, on the other hand, seems permissible. Meals will also have to be limited to what is absolutely necessary. While offering a simple buffet will, in all likelihood, be permissible, it is probably unacceptable to offer a large meal at a restaurant. Paying a physician for his/her participation in an event where the physician does not play an active role, e.g., as lecturer or presenter, is prohibited.

For purposes of evidence, any costs borne by the organizer must be documented in detail so that they can be traced (principle of documentation, *Dokumentationsprinzip*). It is advisable to address the invitation to the medical facility rather than to the medical professionals working there (principle of directness). If a medical professional receives a personal invitation, his or her participation in the event requires the prior authorization of his or her employer (principle of authorization, *Genehmigungsprinzip*).

Scientific Events

The restrictive approach applied in legislation with respect to marketing events is slightly less strict when it comes to scientific events. The AMG provides that the low-value threshold is not applicable in case of scientific events that are exclusively profession-related. The law explicitly permits

Wird ein Mediziner persönlich eingeladen, ist die Teilnahme an der Veranstaltung vorher vom Dienstherrn zu genehmigen (Genehmigungsprinzip).

Wissenschaftliche Veranstaltungen

Der restriktive Standard, den das Gesetz bei Marketingveranstaltungen anlegt, wird bei wissenschaftlichen Veranstaltungen etwas gelockert. § 55a Abs 3 AMG bestimmt, dass bei ausschließlich berufsbezogenen wissenschaftlichen Veranstaltungen die Geringfügigkeitsgrenze nicht gilt. Die direkte oder indirekte Übernahme von angemessenen Reise- und Aufenthaltskosten sowie Teilnahmegebühren wird vom Gesetz ausdrücklich gestattet.

Zu beachten ist dabei, dass aufgrund des Angemessenheitskriteriums die Übernahme der Kosten eines Luxushotels oder eines 1. Klasse-Tickets unzulässig ist. Diese sind von den Angehörigen der Heilberufe selbst zu zahlen. Hinzuweisen ist, dass auch bei wissenschaftlichen Veranstaltungen der Repräsentationsaufwand immer streng auf den wissenschaftlichen Hauptzweck der Veranstaltung begrenzt sein muss. Ferner darf bei wissenschaftlichen Veranstaltungen die Übernahme von Reise- und Aufenthaltskosten und der Teilnahmegebühren sowie der Repräsentationsaufwand nicht anderen Personen als den verschreibungs- und abgabeberechtigten Medizinern zukommen.

Auch für wissenschaftliche Veranstaltungen gilt, dass die vom Veranstalter übernommenen Kosten präzise und nachvollziehbar zu dokumentieren sind. Überdies ist anzuraten, dass die Einladung an die medizinische Einrichtung selbst gerichtet wird. Wird ein Mediziner persönlich eingeladen, ist die Teilnahme an der Veranstaltung vorher vom Dienstherrn zu genehmigen.

Von Interesse ist hierbei vor allem die Abgrenzung zwischen einer Marketing- und einer wissenschaftlichen Veranstaltung. Das Gesetz gibt hierzu keine klaren Auskünfte. Anzunehmen ist, dass eine

Gesamtbetrachtung der Veranstaltung vorzunehmen ist, die sich an verschiedenen Indikatoren orientieren wird, z.B. wie oft im Rahmen der Veranstaltung auf Erzeugnisse des Veranstalters hingewiesen wird. In Anbetracht des strengen Wortlauts der Bestimmung, die von „ausschließlich berufsbezogenen wissenschaftlichen Veranstaltungen" spricht, ist davon auszugehen, dass Veranstaltungen bereits bei geringfügigen Marketingelementen als „Veranstaltungen zur Verkaufsförderung" qualifiziert werden müssen.

the assumption of any direct or indirect responsibility for travel and subsistence costs and attendance fees.

In this context, it must be noted that, due to the criteria of reasonable limits, assuming responsibility for the costs of a luxury hotel or a first-class ticket is impermissible. These costs need to be borne by the members of the medical profession themselves. What needs to be emphasized is that, with respect to scientific events, the expenditure on hospitality must be strictly limited to the scientific main purpose of the event as well. Furthermore, the travel and subsistence costs and attendance fees, as well as the expenditure on hospitality incurred in connection with scientific events may not be extended to persons other than medical professionals who are qualified to prescribe and supply drugs.

Likewise, for any scientific event, the costs for which the organizer assumes responsibility need to be documented in detail so that they can be traced. It is furthermore advisable that the relevant invitation is addressed to the medical facility itself. If a medical professional receives a personal invitation, his or her participation in the event requires the prior consent of his or her principal.

In this context, the differentiation between a marketing and a scientific event is of particular interest. The law does not provide a clear answer. One can assume that the event as a whole needs to be taken into consideration, paying attention to different factors, such as how often in the course of the event reference is made to the organizer's products. Considering the strict wording of the provision that speaks of "events for purely professional and scientific purposes," it can be assumed that any event including even minor marketing elements has to be classified as a "sales promotion event."

By issuing ordinances, the Federal Minister for Health and Women can enact more specific provisions with respect to the AMG's public event regulations. The Federal Minister has not yet exercised such authority. The reason for this is as described above in the context of the low value threshold applicable in the event of gifts.

The MPG does not provide for any comparable rules governing events related to medical devices. Nevertheless, the valuations of the legislator are also relevant with respect to marketing and scientific events for medical devices, as they may also serve the purpose of economically influencing the physician's independence to the patients' detriment. Furthermore, comparable limits of permissibility can also be established by means of competition law.

Der Bundesminister für Gesundheit und Frauen kann im Verordnungsweg nähere

Bestimmungen zu den Fragen des Veranstaltungsrechts des AMG erlassen. Diese Kompetenz wurde vom Bundesminister bis dato nicht wahrgenommen. Zur rechtspolitischen Begründung ist auf die obigen Ausführungen zur Geringfügigkeitsgrenze bei Geschenken hinzuweisen.

Das MPG kennt keine vergleichbaren Veranstaltungsregelungen für Medizinprodukte. Dennoch sind die gesetzgeberischen Wertungen auch bei Marketing- und wissenschaftlichen Veranstaltungen für Medizinprodukte einschlägig, da hierbei ebenfalls eine wirtschaftliche Beeinflussung der ärztlichen Unabhängigkeit zu Lasten der Patienten erfolgen kann. Zudem können vergleichbare Grenzen der Zulässigkeit auch mittels des Wettbewerbsrechtes gezogen werden.

Naturalrabatte (§ 55b AMG)

Die Gewährung, das Anbieten und das Versprechen von Naturalrabatten an zur Verschreibung oder Abgabe berechtigte Personen ist verboten, sofern es sich dabei um Arzneimittel handelt, die im vom Hauptverband der österreichischen Sozialversicherungsträger herausgegebenen Erstattungskodex enthalten sind. Der Erstattungskodex ist ein Register, in dem alle in Österreich zugelassenen und auf Rechnung der Sozialversicherung erstattungsfähigen Arzneispezialitäten verzeichnet sind. Gemäß § 55b AMG ist auch das Fordern, das Sich-Versprechen-Lassen oder das Annehmen von Naturalrabatten durch die zur Verschreibung oder Abgabe berechtigten Personen verboten.

Durch die Bestimmung soll verhindert werden, dass aufgrund der gewährten Rabatte das Vertrauen in die allein nach fachlichen Überlegungen zu treffende Verschreibung bzw Abgabe von Arzneimitteln beeinträchtigt wird

(Unabhängigkeitsprinzip). Überdies soll vermieden werden, dass die Gewährung von Naturalrabatten zu Lasten der gesetzlichen Krankenversicherungen geht, welche die Kosten für Arzneimittel letztendlich zu tragen haben.

Zu beachten ist, dass Naturalrabatte umgekehrt bei jenen Arzneimitteln zulässig sind, die nicht im Erstattungskodex verzeichnet sind. Die Gewährung von Naturalrabatten darf jedoch nicht wettbewerbswidrig sein. Gemäß § 9a Abs 2 UWG sind Naturalrabatte in einer bestimmten oder

Rebates in Kind (section 55b AMG)

Granting, offering and promising rebates in kind to persons qualified to prescribe or supply drugs is prohibited in so far as the drugs concerned are included in the Reimbursement Code (*Erstattungskodex*) published by the Association of Austrian Social Security Authorities (*Hauptverband der Österreichischen Sozialversicherungsträger*). The Reimbursement Code is a register including all pharmaceutical specialties, for which a marketing authorization has been issued in Austria and which are reimbursed by national insurance. Pursuant to the AMG, any person who is qualified to prescribe or supply drugs must not solicit or accept any promise of or accept rebates in kind.

The purpose of the provision is to prevent the negative impact that the granting of rebates might have on the trust in the physician's prescription or supply of drugs, which need to be exclusively based on professional considerations (principle of independence). Another intended effect is to prevent rebates in kind being granted on the account of the statutory health insurances as the ones who have to ultimately bear the costs of drugs.

Conversely, when it comes to drugs that are not registered in the Reimbursement Code, rebates in kind are permissible. The granting of rebates in kind may, however, not be in violation of fair trade practices. Pursuant to the UWG, rebates in kind are permitted in a certain quantity or in a quantity to be calculated on the basis of only fragments of one and the same product. Therefore, rebates in kind are only permissible for the same type of drugs. This means that it would be permissible to provide a group X drug as a rebate in kind for the purchased group Y.

Rebates in cash are not covered by the regulation and are therefore admissible under competition law.

With respect to medical devices, there are no comparable regulations. The limits of admissibility are in this case drawn by competition law.

Provision of Samples

Pursuant to the AMG, marketing authorization holders may only provide samples of pharmaceutical specialties for which a marketing authorization has been granted to physicians, dentists and veterinarians:

lediglich nach Bruchteilen zu berechnenden Menge derselben Ware erlaubt. Daher sind nur Naturalrabatte derselben Arzneimittelart erlaubt. Daraus folgt, dass die Zugabe eines Arzneimittels der Gruppe X als Naturalrabatt zur gekauften Gruppe Y unzulässig wäre.

Geldrabatte werden von der Regelung des § 55b AMG nicht erfasst und sind sohin nach Maßgabe des Wettbewerbsrechts zulässig.

Für den Bereich der Medizinprodukte existieren keine dem § 55b AMG vergleichbaren Vorschriften. Die Grenzen der Zulässigkeit sind hierbei durch das Wettbewerbsrecht zu ziehen.

Abgabe von Mustern (§ 58 AMG)

Gemäß § 58 Abs 1 AMG dürfen Zulassungsinhaber von Arzneimitteln Muster von zugelassenen Arzneimittelspezialitäten an Ärzte, Zahnärzte, Tierärzte und Dentisten nur

- über deren schriftliche Aufforderung,
- ausschließlich unentgeltlich,
- unter Aufbringung des deutlich lesbaren und nicht entfernbaren Hinweises „unverkäufliches Ärztemuster", sowie
- in einer nicht größeren als der kleinsten im Handel befindlichen Packung abgeben.

Dies lässt die Möglichkeit offen, Ärztemuster auch in kleineren Packungsgrößen als der kleinsten im Handel befindlichen Packung abzugeben. Die Abgabe von Ärztemustern, die psychotrope Substanzen oder Suchtstoffe enthalten, wird ausdrücklich verboten.

Nach Maßgabe des § 58 Abs 2 AMG ist die Menge der abgegebenen Arzneimittel pro Empfänger vom Zeitraum der erstmaligen Abgabe abhängig.

- Im ersten Jahr darf eine Menge von so vielen Ärztemustern abgegeben werden, wie zur Beurteilung des Behandlungserfolgs bei höchstens 10 Patienten ausreichend ist. Maximal sind jedoch 30 Ärztemuster pro Empfänger zulässig.
- Nach Ablauf eines Jahres dürfen pro Anforderung höchstens 2 Ärztemuster, jedoch pro Empfänger höchstens 5 Ärztemuster einer Arzneispezialität pro Jahr abgegeben werden.

- in response to their written request;
- free of charge;
- bearing the legible and non-removable information “free medical sample – not for sale”; and
- in a package not larger than the smallest presentation on the market.

This provides the opportunity to supply samples in package sizes smaller than the smallest presentation on the market. The supply of samples containing psychotropic or narcotic substances is strictly prohibited.

Pursuant to the AMG, the quantity of drugs that may be supplied per recipient is dependent on the period of time that has lapsed after the date they were first provided.

- In the first year, samples may be supplied in a range that is sufficient for evaluating the success of the treatment of a maximum of 10 patients. However, no more than 30 samples per recipient are permissible.
- After one year, a maximum of two samples per request, but no more than five samples of one pharmaceutical specialty per year and recipient, may be supplied.

Pursuant to the AMG, records must be kept for the recipients of medical samples that are not for sale, as well as for the type, scope and date of provision thereof (principle of documentation). Such records have to be presented to the competent health authority by request.

Additional criteria for the supply of drug samples on the occasion of events (congresses and conferences) are specified in codes of conduct. In this context, reference is made to the chapter dealing with the code of conduct as prepared by Pharmig (“Pharmig code”).

There are no comparable regulations applicable to medical devices. The limits of admissibility are to be determined on the basis of competition law.

Legal Consequences Breach

Any violation of a provision on advertising as set forth in the AMG or MPG is punished within the scope of criminal proceedings before administrative bodies. Any person acting in violation of AMG provisions on grant

Gemäß § 58 Abs 3 AMG sind über die Empfänger von unverkäuflichen Ärztemustern sowie über Art, Umfang und Zeitpunkt ihrer Abgabe Nachweise zu führen (Dokumentationsprinzip). Auf Verlangen der zuständigen Gesundheitsbehörde sind diese Nachweise vorzulegen.

Im Verhaltenskodex der Pharmig werden noch zusätzliche Kriterien für die Abgabe von Arzneimittelmustern anlässlich von Veranstaltungen (Kongressen und Tagungen) spezifiziert. Siehe dazu das Kapitel zum Verhaltenskodex der Pharmig.

Für den Bereich der Medizinprodukte existieren keine vergleichbaren Vorschriften. Die Grenzen der Zulässigkeit sind mittels des Wettbewerbrechts zu ziehen.

Rechtsfolgen einer Verletzung von heilmittelwerberechtlichen Bestimmungen

Verstöße gegen werberechtliche Vorschriften des AMG oder MPG werden im Rahmen des Verwaltungsstrafverfahrens geahndet. Wer entgegen §§ 55a, 55b AMG (Vorteilsgewährungen, Veranstaltungen und Naturalrabatte) oder § 108 MPG (Vorteilsgewährungen) handelt, macht sich, sofern die Tat keine strafbare Handlung bildet, einer Verwaltungsübertretung schuldig und ist mit Geldstrafe bis zu EUR25.000, im Wiederholungsfall bis zu EUR50.000 zu bestrafen. Wer entgegen § 58 AMG (Abgabe von Arzneimittelmustern) handelt, ist mit Geldstrafe bis zu EUR7.500, im Wiederholungsfall bis zu EUR14.000 zu bestrafen.

Das Bundesamt für Sicherheit im Gesundheitswesen kann gemäß § 85 Abs 1 AMG die Zulassung einer Arzneispezialität aufheben, sofern der Zulassungsinhaber mindestens drei Mal wegen ein und derselben Übertretung werberechtlicher Vorschriften bestraft wurde. Zusätzlich kann ein Verstoß gegen heilmittelwerberechtliche Bestimmungen für das Unternehmen den Verlust der Gewerbeberechtigung gemäß § 87 Abs 1 Z 3 Gewerbeordnung nach sich ziehen, sofern der Gewerbeinhaber die für die Ausübung des Gewerbes erforderliche Zuverlässigkeit nicht mehr besitzt. Für den Angehörigen des Heilberufs kann ein Verstoß gegen die heilmittelwerberechtlichen Bestimmungen auch standesrechtliche Folgen, etwa nach dem Ärztegesetz oder dem Beamtendienstrechtsgesetz, haben, die in letzter Konsequenz zu einem Berufsverbot führen können.

Ferner können Mitbewerber nach dem UWG zivilrechtlich gegen einen Verstoß wider heilmittelwettbewerbsrechtliche Vorschriften vorgehen. Der

of benefits, events and rebates in kind or MPG provisions on grant of benefits commits an administrative offense, provided that the action taken does not qualify as a criminal offense, and is subject to a fine in the amount of up to EUR25,000 or up to EUR50,000 in case of recurrence. Any infringement of AMG supply of drug samples is subject to a fine in an amount of up to EUR7,500 or up to EUR14,000 in case of recurrence.

Pursuant to the AMG, the Federal Office for Security in Health Care (*Bundesamt für Sicherheit im Gesundheitswesen*) may revoke the marketing authorization for a pharmaceutical specialty if the marketing authorization holder is punished at least three times for the same infringement. The violation of provisions regarding the advertising of remedies may also result in the enterprise losing its authorization to carry on its trade or business within the meaning of the Austrian Trade Code (*Gewerbeordnung*) if the holder of such trade license can no longer be trusted with the execution of the trade or business. As regards medical professionals, any violation of the provisions with respect to the advertising of remedies may also have disciplinary consequences, such as under the Austrian Physicians' Act (*Ärztegesetz*) or the Austrian Public Service Act (*Beamtendienstrechtsgesetz*), that can ultimately lead to their being prohibited from exercising their profession.

In addition, competitors are also entitled to seek remedies for the violation of competition law provisions under civil law in accordance with the UWG. Such claim can in particular be aimed at a cease-and-desist order (section 14 UWG) and/or damages (section 16 UWG). Since damages incurred as a consequence of a competitor's violation of provisions with respect to remedies are hard to prove, the claim for a cease-and-desist order is of higher practical relevance. Another option is to file a motion for a temporary injunction against the competitor with the courts (section 24 UWG). In order to do so, the claimant must only certify that fair trade practices were violated and the court can grant the temporary injunction without hearing the competitor. As regards the costs of the proceedings, it is not relevant whether prior to the complaint the competitor was asked to abstain from any future infringement of fair trade practices by means of a warning letter. If, however, the competitor acknowledges the violation of fair trade practices upon service of the action, the plaintiff's claim has to be limited to the costs of the proceedings.

Additionally, it has to be stated that any breach of regulations regarding remedies may also result in penalties under the codes of conduct of the professional associations (see below).

Anspruch kann vor allem auf Unterlassung (§ 14 UWG) und/oder Schadenersatz (§ 16 UWG) gerichtet sein. Da ein Schaden durch den Verstoß eines Mitbewerbers gegen heilmittelrechtliche Vorschriften schwer zu beweisen ist, steht in der Praxis der Unterlassungsanspruch im Vordergrund. Zusätzlich kann bei Gericht eine einstweilige Verfügung gegen den Mitbewerber beantragt werden (§ 24 UWG). Dabei muss die Wettbewerbsverletzung vom Antragsteller lediglich bescheinigt werden und die einstweilige Verfügung kann vom Gericht ohne vorherige Anhörung des Mitbewerbers erlassen werden. Für die Verfahrenskosten hat es keine Bedeutung, ob der Mitbewerber vor der Klage mittels eines Abmahnschreibens aufgefordert wurde, die Wettbewerbsstörung künftig zu unterlassen. Wird jedoch die Wettbewerbsstörung vom Mitbewerber bei Klagezustellung anerkannt, muss die Klage auf Kosten eingeschränkt werden.

Ergänzend ist anzuführen, dass ein Verstoß gegen heilmittelrechtliche Bestimmungen auch Sanktionen nach den Verhaltenskodizes der Berufsverbände nach sich ziehen kann (dazu siehe unten).

Kontrolle der Heilmittelwerbung

Die Kontrolle heilmittelwerberechtlicher Vorschriften beschränkte sich in Österreich bisher auf eine Kontrolle im Einzelfall. Diese erfolgte anhand der Überprüfung eines Verhaltens im Rahmen des Verwaltungsstrafverfahrens, durch die betroffenen Verkehrskreise selbst oder durch sonstige Klageberechtigte nach § 85a AMG (Pharmig, Österreichische Ärztekammer etc).

Anfang 2006 wurde vom Gesetzgeber eine neue Kontrollbehörde, das Bundesamt für Sicherheit im Gesundheitswesen, eingerichtet und mit den erforderlichen Befugnissen zur Durchführung allfälliger Kontrollmaßnahmen ausgestattet.

Werbemaßnahmen müssen nicht von den zuständigen Gesundheitsbehörden genehmigt werden. Jedoch kann das Bundesamt für Sicherheit im Gesundheitswesen gemäß § 56a AMG (§ 68 MPG) verlangen, dass alle Unterlagen übermittelt werden, die nach Ansicht des Bundesamts zur Kontrolle der Einhaltung der Werbebestimmungen des AMG erforderlich sind. Dies umfasst alle Unterlagen über Verkaufsförderungsveranstaltungen und berufsbezogene wissenschaftliche Veranstaltungen. Die Organe des Bundesamts für Sicherheit im Gesundheitswesen und die von diesem beauftragten Sachverständigen sind berechtigt, alle Räumlichkeiten zu

Monitoring the Advertising of Remedies

In Austria, the monitoring of provisions regarding the advertising of remedies was, until 2006, limited to the monitoring of individual cases. This was done by investigations of a certain behavior performed within the scope of criminal proceedings before administrative bodies, by the relevant groups of persons themselves, or by other persons entitled to bring an action within the meaning of the AMG (Pharmig, Austrian Medical Chamber, etc.)

At the beginning of 2006, the legislator established a new regulatory authority, namely the Federal Office for Security in Health Care (*Bundesamt für Sicherheit im Gesundheitswesen*) and equipped it with the powers necessary to take inspection measures.

Advertising measures do not need to be authorized by the competent health authorities. Pursuant to the AMG, the Federal Office for Security in Health Care, can, however, demand to be provided with all records it deems necessary to investigate compliance with the provisions on advertising as set forth in the AMG. This includes all records relating to sales promotion events and profession-related scientific events. The Federal Office for Security in Health Care and the experts commissioned by it are authorized to access all premises and inspect all documents and make copies thereof as necessary to monitor the provisions on advertising.

In the event that the Federal Office for Security in Health Care becomes aware of any violation of the provisions on advertising, it may take all measures necessary to establish compliance with statutory provisions. These measures include ordering that advertising material may no longer be distributed or needs to be recalled. The Federal Office for Security in Health Care, however, does not have the authority to require the advertising company to issue a corrective statement.

The establishment of the Federal Office for Security in Health Care has drastically increased the pressure on members of the medical community to comply with the provisions regarding the advertising of remedies as provided for in the AMG and the MPG. It remains to be seen whether, as a consequence of the establishment of the new regulatory authority, the number of proceedings following violations of provisions regarding the advertising of remedies will increase as well. Companies operating in the medical sector would therefore be well advised to pay particular attention to the documentation and transparency of their advertising practices.

betreten sowie Einsicht in alle Unterlagen zu nehmen und davon Kopien anzufertigen, soweit dies zur Kontrolle der werberechtlichen Bestimmungen erforderlich ist.

Erlangt das Bundesamt für Sicherheit im Gesundheitswesen Kenntnis von einem Verstoß gegen werberechtliche Bestimmungen, kann es alle Maßnahmen ergreifen, die zur Herstellung eines gesetzeskonformen Zustands erforderlich sind. Unter diese Maßnahmen fällt etwa, dass Werbematerialien nicht weiter verbreitet werden dürfen oder zurückbeordert werden müssen. Zu einer Richtigstellung kann das werbende Unternehmen von der Behörde jedoch nicht angehalten werden.

Mit der Einrichtung des Bundesamts für Sicherheit im Gesundheitswesen wird der Druck auf die Teilnehmer des Gesundheitswesens beträchtlich erhöht, die heilmittelwerberechtlichen Vorschriften des AMG und des MPG zu befolgen. Abzuwarten bleibt es, ob durch die Einrichtung der neuen Kontrollbehörde auch die Anzahl der Verfahren wegen eines Verstoßes gegen heilmittelwerberechtliche Vorschriften ansteigen wird. Medizinische Unternehmen sind gut beraten, diesbezüglich verstärkt auf die Dokumentation und Transparenz ihrer Werbepraktiken zu achten.

Selbstbindungsinstrumente der Berufskreise

In Österreich gibt es diverse Verhaltenskodizes der medizinischen Fachverbände, die Verhaltensregeln für die Zusammenarbeit der Industrie mit den Angehörigen der Heilberufe sowie ethische Leitlinien im Auftreten der Berufskreise im Wettbewerb aufstellen. Zweck dieser Selbstbindungsinstrumente ist es, die Qualität, Sicherheit und Fairness des Gesundheitswesens zu gewährleisten.

Von den zahlreichen Verhaltenskodizes der Berufsverbände und Interessensvertretungen sollen hier die drei zentralen Regelungswerke, nämlich der „Verhaltenskodex der Pharmig" (Verband der pharmazeutischen Industrie Österreichs), der Austromed- Kodex sowie der „Ärztliche Verhaltenskodex bei der Zusammenarbeit mit der Pharma- und Medizinprodukteindustrie" herausgegriffen werden. Andere wichtige Selbstbindungsinstrumente, etwa der „Werbekodex der IGEPHA" (Interessengemeinschaft Österreichischer Heilmittelhersteller und Depositeure), die „Richtlinie Arzt und Öffentlichkeit" oder der „Verhaltenskodex der UIADM" streifen die hier behandelte Zusammenarbeit der Industrie mit den Angehörigen der Heilberufe nur mittelbar.

Professional Codes of Conduct

In Austria, the medical associations have adopted various codes of conduct that stipulate rules for cooperation between the industry and members of the medical profession as well as ethical guidelines with respect to competition. The objective of these professional codes of conduct is to ensure quality, security and fairness in the healthcare sector.

The three central codes of conduct, namely, the Pharmig Code, the "Austromed Code" and the "Physician's Code for the Cooperation with the Medical Industry" must be singled out at this point. Other codes of conduct, such as the Austrian Self-Medication Industry code ("IGEPHA's code"), the "Physician and Public" code or the UIADM's code only indirectly deal with the subject of cooperation between the industry and the members of the medical profession.

Pharmig Code

General

Since 1964, Austrian pharmaceutical companies have as a rule voluntarily subscribed to the restrictions imposed by Pharmig. These restrictions concern marketing activities after the approval of a medical product and regulate the conditions for providing scientific information to the community of specialists.

Since that time, around 95 percent of Austrian pharmaceutical companies have become members of Pharmig. This association has accepted responsibility for ensuring the observation of the regulations in its code of conduct ("Pharmig Code"), which was adopted in 1970 and has subsequently been amended several times. It is considered one of the strictest pharmaceutical codes of conduct in the European Union. Failure to observe the code's regulations may have far-reaching consequences for the company concerned, such as fines of up to EUR100,000 and/or even expulsion from Pharmig. The code thereby proves to be successful in the field of prevention and an inquiry to Pharmig may prevent violations in the future. Furthermore, the code also establishes guidelines on permissibility regarding marketing activities of companies that are not members of Pharmig.

General Principles

One of the Pharmig Code's primary rules is that a violation of the advertising restrictions in the AMG is automatically considered as a violation of the code.

Verhaltenskodex der Pharmig

Allgemeines

Seit 1964 unterwerfen sich österreichische Arzneimittelunternehmen in der Regel freiwillig den vom Interessenverband der pharmazeutischen Industrie Österreichs (Pharmig) auferlegten Beschränkungen. Diese betreffen Marketing- Aktivitäten nach der Zulassung eines Arzneimittels und regeln die Modalitäten der wissenschaftlichen Information der Fachkreise.

Mittlerweile sind rund 95% der österreichischen Pharmaunternehmen Mitglieder der Pharmig. Diese Interessensvertretung hat die Aufgabe übernommen, für die Einhaltung der Bestimmungen des von ihr im Jahr 1970 erlassenen und zwischenzeitlich mehrmals novellierten Verhaltenskodexes zu sorgen. Der Kodex gilt als eines der strengsten Selbstbindungsinstrumente im Gemeinschaftsraum. Die Missachtung seiner Regeln hat weitreichende Konsequenzen für die betroffenen Unternehmen, unter anderem Geldstrafen bis zu EUR100.000 und/oder sogar den Ausschluss aus der Interessensvertretung. Dabei zeitigt der Verhaltenskodex durchaus präventive Wirkung, und potentielle Verstöße gegen den Kodex können durch Anfrage an die Pharmig schon im Vorfeld verhindert werden. Überdies bildet der Kodex auch einen Richtwert für die Zulässigkeit von Marketing-Aktivitäten von Unternehmen, die nicht Mitglieder der Pharmig sind.

Allgemeine Verhaltensregeln

- Eine tragende Grundregel des Kodexes ist, dass Verstöße gegen arzneimittelwerberechtliche Bestimmungen des AMG automatisch als Verstöße gegen den Verhaltenskodex der Pharmig betrachtet werden. Der Kodex knüpft damit eng an die gesetzlichen Bestimmungen an und verschärft diese teilweise sogar.
- Der Verhaltenskodex verbietet es den pharmazeutischen Firmen, in ihren Schriften oder Werbematerialien auf Marken von Konkurrenzfirmen Bezug zu nehmen, es sei denn, die Bewilligung ist erteilt worden. Damit wird der Zulässigkeitsrahmen für vergleichende Werbung des § 2 UWG (siehe dazu oben) im Arzneimittelbereich noch weiter eingeschränkt.

The Pharmig Code forbids pharmaceutical companies to mention brands of their competitors in their documentation or advertising materials, unless permission has been granted to do so. This regulation further restricts the rules of comparative advertising as stipulated in section 2 UWG (see above) for the pharmaceutical field.

Provisions

The Pharmig Code provides for rules on the following subjects:

- Information on medical products
- Advertising medical products
- Information and advertisement via the internet
- Events
- Cooperation with specialist circles or third parties
    - Cooperation with physicians
    - Non-interventional studies
    - Medical samples
    - Hospitality
    - Give-aways
- Cooperation with patients' organizations
- Gifts
- Raffles
- Company employees
- Clinical trials

Complaint Proceedings and Penalties

In the event of a violation of the Pharmig Code's rules, a written complaint can be filed with the Secretary General of Pharmig by members of the management of the complainant. Complaints directed against non-members of Pharmig are to be forwarded by Pharmig to the Trade Association of the Austrian Chemical Industry (*Fachverband der Chemischen Industrie Österreichs,* "FCIO"). Complaints must contain exact information about which facts the complaint concerns and which point of the code has been violated by that fact. The company concerned must state its position within five working days. A committee of experts appointed by Pharmig is authorized to deal with the complaint.

Materielle Regelungen

Der Pharmig Verhaltenskodex regelt die folgenden Bereiche:

- Information über Arzneimittel
- Werbung über Arzneimittel
- Information und Werbung über das internet
- Veranstaltungen
- Zusammenarbeit mit Fachkreisen oder Dritten
  - Zusammenarbeit mit Ärzten
  - Nicht-Interventionelle Studien
  - Ärztemuster
  - Gastfreundschaft
  - Werbehilfsmittel
- Zusammenarbeit mit Patientenorganisationen
- Geschenke
- Gewinnspiele
- Mitarbeiter in den Unternehmen
- Klinische Prüfungen

Beschwerdeverfahren und Strafen

Im Falle einer Verletzung der Regeln des Verhaltenskodexes kann von einem Mitglied der Geschäftsleitung des Beschwerdeführers schriftlich Beschwerde beim Generalsekretär der Pharmig eingereicht werden. Beschwerden, die sich gegen Nicht-Mitglieder der Pharmig richten, sind von der Pharmig an den Fachverband für klinische Industrie weiterzuleiten. Beschwerden müssen genaue Angaben darüber enthalten, welcher Sachverhalt in Beschwerde gezogen wird und gegen welchen Punkt des Verhaltenskodexes der in Beschwerde gezogene Sachverhalt verstößt. Das betroffene Unternehmen hat innerhalb von fünf Werktagen zur Beschwerde Stellung zu nehmen. Mit der Beurteilung der Beschwerde wird ein von der Pharmig eingerichteter Fachausschuss befasst.

Falls eine Verletzung des Verhaltenskodexes durch den Fachausschuss festgestellt wird, ist dieser befugt, folgende Sanktionen im Rahmen eines Beschlusses zu verhängen:

- Bekanntgabe der Verletzung mit Namensnennung des betroffenen Unternehmens in einer Pharmig-Publikation,
- Information der Muttergesellschaft des betroffenen Unternehmens,

If a violation of the code of conduct is established by the committee of experts, the committee may impose the following sanctions:

- Disclosing the violation, including the name of the company concerned, in a Pharmig publication
- Informing the parent company of the firm concerned
- Informing the general secretariats of the European Federation of Pharmaceutical Industries ("EFPIA")
- In the case of a serious violation, imposing a fine of at least EUR5,000 and at most EUR100,000 (EUR 200,000 in case of repetition), which shall be donated to charities
- Expelling the firm concerned (an expulsion from Pharmig does not release the expelled or withdrawing member company from its financial obligations; neither does it release the company from the duty to pay a fine imposed)

The sanctions mentioned above may be combined as well. A serious violation is a violation repeated within 24 months or a violation of the code committed for the same reason. It must be mentioned that a violation against the regulations concerning gifts or medical events is considered as a serious violation in any case, even when committed for the first time.

Within four weeks after service of the resolution of the committee of experts, the company concerned may file an action for annulment of the resolution with the arbitral tribunal of Pharmig. The tribunal's arbitral award is final, enforceable, and may overturn the decision of the committee of experts.

Austromed Code

Until recently, no code of conduct for the field of medical devices existed in Austria. A relevant code of conduct was adopted in 2007 by the Association of Medical Device Manufacturers and Suppliers in Austria (*Vereinigung der Medizinprodukte-Unternehmen Österreich,* "Austromed").

The Austromed Code essentially complies with the principles set out in Eucomed's "Code of Business Practice."

The Austromed Code stipulates four "general rules," compliance with which is a prerequisite for lawful sponsoring practice. These rules are as follows (see "Recommendations" below for further details):

- The principle of separation
- The principle of transparency

- Information des Generalsekretariats der EFPIA (Europäische Föderation der Verbände der pharmazeutischen Industrie),
- im Fall eines schwerwiegenden Verstoßes Verhängung einer Geldstrafe im Betrag von mindestens EUR5.000 und höchstens bis zu EUR100.000 (EUR200.000 im Wiederholungsfall), welche vom
- Vorstand der Pharmig binnen drei Monaten ab Zahlungseingang für karitative Zwecke zu verwenden ist, und/oder
- Ausschluss aus der Interessensvertretung (ein Ausschluss aus der Pharmig entbindet das ausgeschlossene oder austretende Mitgliedsunternehmen nicht von seinen bestehenden Zahlungsverpflichtungen. Der Ausschluss befreit auch nicht von der Zahlung einer verhängten Geldstrafe.)

Die Sanktionen des Verhaltenskodexes können kombiniert werden. Ein schwerwiegender Verstoß liegt dann vor, wenn innerhalb von 24 Monaten ein Verstoß wiederholt oder aus gleichem Grund gegen den Verhaltenskodex gesetzt wurde. Zu beachten ist, dass eine Verletzung der Bestimmungen betreffend die Geschenkannahme oder betreffend Veranstaltungen auch bei erstmaliger Verletzung als schwerwiegender Verstoß gilt.

Gegen den Beschluss des Fachausschusses kann innerhalb von vier Wochen nach Zustellung eine Klage auf Aufhebung des Beschlusses durch das betroffene Unternehmen beim Schiedsgericht der Pharmig eingebracht werden. Der Entscheid des Schiedsgerichts ist endgültig, vollstreckbar und kann vom Entscheid des Fachausschusses abweichen.

Austromed-Kodex

Für den Bereich der Medizinprodukteindustrie gab es in Österreich bisher kein eigenes Selbstbindungsinstrument. Ein entsprechender Kodex wird jedoch von der Vereinigung der Medizinprodukte-Unternehmen Österreich (Austromed) im Jahr 2007 erlassen werden.

Der Austromed-Kodex übernimmt die Grundsätze des vom europäischen Dachverband der Medizinprodukteindustrie, Eucomed herausgegebenen „Code of Business Practice".

Im Austromed-Kodex werden vier „Allgemeine Grundsätze" aufgestellt, deren Einhaltung Vorraussetzung für eine rechtmäßige Sponsoringpraxis sind. Diese Grundsätze sind (vgl unten „Empfehlungen")

- der Grundsatz der Trennung,
- der Grundsatz der Transparenz,

- The principle of equivalence
- The principle of documentation

Moreover, the Austromed Code sets out more specific rules for the field of research and development, rules for contracts between physicians and the industry, rules for the granting of gifts and sponsoring activities, as well as rules for fair competition.

A minor violation of the Austromed Code's rules may result in a reprimand. In the case of a serious violation of the rules, the company may be expelled from Austromed. Decisions rendered by the arbitral court of Austromed may be published.

Physician's Code for the Cooperation with the Medical Industry

In 2005, the Austrian Medical Chamber (*Österreichische Ärztekammer;* "ÖÄK") adopted a code of conduct that stipulates far-reaching rules for doctors and dentists *vis-à-vis* the pharmaceutical and medical devices industry. The Austromed Code's prime target is to ensure that cooperation between physicians and the industry does not result in an "unhealthy" commercial influence or a conflict of interests, which, as a consequence, could negatively affect the treatment of patients or the reputation of the medical profession (principle of independence). The Physician's Code is not to be understood as a mere guideline, but as a body of disciplinary rules. For this reason, a violation of the Physician's Code may result in disciplinary charges against the physician. The ÖÄK has installed a committee of experts (*Ehrenrat*) competent to observe the physicians' compliance with the regulations of the code. The committee of experts is instructed to pursue a "zero tolerance policy" towards violations against the rules of the Physician's Code.

The Physician's Code, similar to the rules in the Pharmig Code described above, deals with the following issues:

- Acceptance of gifts and other benefits
- Scientific medical events
- Acceptance of samples
- Clinical trials and research
- Formalities

- der Grundsatz der Ausgewogenheit und
- der Grundsatz der Dokumentation.

Ferner werden im Austromed-Kodex spezielle Verhaltensregeln für die Bereiche der Forschung und Entwicklung, Verträge zwischen Ärzteschaft und Industrie, Geschenke und Spenden, als auch Wettbewerbs- und Verhaltensregeln der Medizinprodukteindustrie untereinander aufgestellt.

Als Sanktionen sind im Austromed-Kodex bei geringfügigen Verfehlungen der Ausspruch eines Verweises, oder in schwereren Fällen der Ausschluss aus der Austromed, vorgesehen. Entscheidungen des Schiedsgerichts der Austromed können veröffentlicht werden.

Ärztlicher Verhaltenskodex bei der Zusammenarbeit mit der Pharma- und Medizinprodukteindustrie

Die Österreichische Ärztekammer (ÖÄK) hat im Jahr 2005 in ihrem Verhaltenskodex weitreichende Umgangsregeln für Ärzte und Zahnärzte gegenüber der Pharma- und Medizinprodukteindustrie festgeschrieben.

Leitvorgabe des Kodexes ist es, dass es durch die Zusammenarbeit der Ärzteschaft mit der Industrie nicht zu einem „unheilsamen" kommerziellen Einfluss oder zu Interessenskonflikten kommen darf, aufgrund derer die Behandlung von Patienten negativ beeinflusst oder der Ruf des medizinischen Standes beschädigt wird (Unabhängigkeitsprinzip). Der Verhaltenskodex ist nicht als reine Empfehlung zu verstehen, sondern als standesrechtliches Regelungswerk. Daher sind Vergehen gegen den Kodex auch als Disziplinarverfehlungen des Arztes zu ahnden. Die ÖÄK hat einen Ehrenrat mit der Überprüfung der Einhaltung der Bestimmungen eingerichtet. Dieser soll eine „Null-Toleranz-Politik" der Standesvertretung gegenüber Ärzten gewährleisten, die den Bestimmungen des Regelwerks zuwider handeln.

Der ärztliche Verhaltenskodex behandelt, ähnlich zu den oben beschriebenen Regeln des Pharmig Kodexes, folgende Themen:

- Annahme von Geschenken und anderen Vorteilen
- Medizinisch wissenschaftliche Veranstaltungen
- Annahme von Ärztemustern
- Klinische Prüfung und Forschung
- Formvorschriften

A violation of the Physician's Code's rules is considered as a disciplinary offense pursuant to the Austrian Physicians' Act (*Ärztegesetz 1998*). Disciplinary punishments are a written reprimand; fines amounting to EUR36,340; or a temporary suspension or deletion from the register of physicians (Austrian Physicians' Act).

Criminal Law Provisions

Austria, as compared with other EU member states, has so far experienced only a small number of major medical scandals involving the difficult economic relationship between industry and physicians. Even minor scandals, however, pose a high risk for companies as, in addition to criminal penalties, the reputation of the company in the area now exposed to increased public scrutiny may suffer severely.

In Austria, most criminal law provisions aimed to prevent corruption are contained in the Austrian Criminal Code ("StGB"). The conduct of both the party granting a benefit including bribery, granting of benefits; or granting a benefit for "sweetening"/grooming, and the party accepting such benefit breach of trust acceptance of gifts by proxy holders corruptibility, acceptance of benefit or accepting a benefit as "sweetening"/"grooming" may be punishable. This regulative framework is complemented by the criminal law provisions contained in the Austrian Unfair Competition Act and in the Act on the Criminal Liability of Companies (*Verbandsverantwortlichkeitsgesetz,* VbVG).

Austrian anti-bribery law (*Anti-Korruptionsrecht*) has gone through significant changes in recent years. A further amendment of Austrian bribery laws will enter into force on 1 January 2013. This edition sets out the said amendment.

The following sections exclusively discuss the regulations concerning the offense of offering of bribes, so-called "active bribery."

Anti-Corruption Provisions for the Public Sector

These strict anti-corruption provisions only apply where the bribed party can be classified as a public office-holder.

Eine Verletzung der ärztlichen Pflichten im Sinne des Verhaltenskodexes ist gemäß § 136 Abs 1 Ärztegesetz 1998 als Disziplinarvergehen zu ahnden. Disziplinarstrafen sind der schriftliche Verweis, eine Geldstrafe bis zum Betrag von EUR36.340, die befristete Untersagung der Berufsausübung oder die Streichung aus der Ärzteliste (§ 139 Abs 1 Ärztegesetz 1998).

Strafrechtliche Bestimmungen

Im Vergleich zu anderen Staaten der EU haben sich in Österreich große Medizinskandale im wirtschaftlichen Spannungsverhältnis zwischen Industrie und Ärzteschaft bisher in Grenzen gehalten. Dennoch stellen selbst kleinere Skandale ein hohes Risiko für Unternehmen dar, da neben den strafrechtlichen Konsequenzen für Unternehmen auch ein beträchtlicher Imageschaden in dem von der Öffentlichkeit mit gesteigertem Interesse beobachteten Medizinbereich einhergehen kann.

Das Anti-Korruptionsstrafrecht ist in Österreich zu großen Teilen im Strafgesetzbuch (StGB) geregelt. Strafbar kann zunächst sowohl das Verhalten der einen Vorteil gebenden Partei (Bestechung, § 307 StGB; Vorteilszuwendung, § 307a StGB; Vorteilszuwendung zur Beeinflussung, § 307b StGB) als auch der den Vorteil annehmenden Partei sein (Untreue, 153 StGB; Geschenkannahme durch Machthaber, § 153a StGB; Bestechlichkeit, § 304 StGB; Vorteilsannahme, § 305 StGB; Vorteilsannahme zur Beeinflussung, § 306 StGB).

Dieser regulative Rahmen des StGB wird durch strafrechtliche Bestimmungen des Wettbewerbsrechts (§ 10 UWG) und des Verbandsverantwortlichkeitsgesetzes (VbVG) ergänzt.

Das österreichische Anti-Korruptionsrecht wurde in den vergangenen Jahren mehrfach umfassend novelliert. Eine weitere Novellierung des österreichischen Korruptionsstrafrechts ist derzeit in Planung. Die Änderungen sollen mit 1. Jänner 2013 in Kraft treten. Im Folgenden wird diese Novellierung bereits berücksichtigt.

Im Folgenden werden nur die Regelungen zur aktiven Bestechung behandelt.

The following physicians can be classified as office-holders:

- Physicians (*Ärzte*) who are employed in a public hospital
- Physicians who practice in a privately organized hospital that is held (minimum stake of 50%) or is run by local authorities (*Gebietskörperschaft*) or by authorities abroad or is audited by an audit court
- Physicians who practice as medical health officers (*Amtsärzte*)
- Physicians who practice in hospitals operated by social insurance institutions (*Sozialversicherungsträger*)
- Physicians who practice at medical universities

The following physicians are not qualified as office-holders:

- Private (residential) physicians
- Physicians employed in private hospitals or in hospitals of order (*Ordensspital*)

It is important to point out that these qualifications are only practical guidelines. Due to the complexity of the term office-holder under Austrian law, the classification of a physician or healthcare professional ("HCP") as office-holder should always be assessed on a case-by-case basis.

Bribery

Whoever offers, promises or grants an office-holder (*Amtsträger*) or an arbitrator a benefit for himself or a third person for illegally performing or omitting an official act (*Amtsgeschäft*) shall be punished by imprisonment of up to three years. Whoever commits the crime of bribery by using a benefit exceeding EUR3,000/ EUR50,000 shall be punished by imprisonment from at least six months up to five years/imprisonment from at least one year up to 10 years.

Granting of Benefits

Whoever offers, promises or grants an office-holder or an arbitrator an inappropriate benefit (*ungebührlicher Vorteil*) for himself or a third person for the legal performance or omission of an official act shall be punished by imprisonment of up to two years. Whoever commits the crime by using an amount exceeding EUR3,000/EUR50,000 shall be punished by imprisonment for up to three years/imprisonment from at least six months up to five years.

Anti-Korruption im öffentlichen Bereich:

Die Anti-Korruptionsbestimmungen für den öffentlichen Bereich sind nur anwendbar, sofern die den Vorteil annehmende Person Amtsträgereigenschaft aufweist.

Folgende Ärzte sind Amtsträger:

- Ärzte, die in einer öffentlichen Krankenanstalt beschäftigt sind;
- Ärzte, die für ein privat organisiertes Krankenhaus tätig sind, das unmittelbar einer Gebietskörperschaft mit einer Beteiligung von zumindest 50%untersteht oder direkt von einer in- oder ausländischen Gebietskörperschaft betrieben oder tatächlich beherrscht wird,oder dessen Gebahrung der Überprüfung durch einen Rechnungshof unterliegt;
- Ärzte, die ihre Tätigkeit als Amtsärzte ausüben;
- Ärzte, die in von Sozialversicherungsträgern betriebenen Kranken- und Pflegeanstalten tätig sind oder
- Ärzte, die an den medizinischen Universitäten beschäftigt sind.

Keine Amtsträger sind:

- niedergelassene Ärzte (ungeachtet eines Kassenvertrages);
- Spitalsärzte in Privat- und Ordensspitälern.

Es gilt zu beachten, dass es sich dabei nur um Richtwerte handelt. Im Einzelfall muss stets geprüft werde, ob der jeweilige Arzt (bzw Angehörige von Heilberufen) nicht doch unter den vielschichtigen Amtsträgerbegriff fällt und damit Amtsträgereigenschaft aufweist.

Bestechung

Eine Bestechung gemäß § 307 Abs 1 StGB begeht, wer einem Amtsträger oder Schiedsrichter für die pflichtwidrige Vornahme oder Unterlassung eines Amtsgeschäfts für ihn oder einen Dritten einen Vorteil anbietet, verspricht oder gewährt. Ein Verstoß gegen diese Bestimmung ist mit Freiheitsstrafe bis zu drei Jahren zu bestrafen. Hingegen begeht eine Bestechung nach § 307 Abs 2 StGB, wer die Tat in Bezug auf einen EUR 3.000/EUR 50.000 übersteigenden Wert des Vorteils begeht (Wertqualifikation). Ein diesbezüglicher Verstoß ist mit Freiheitsstrafe von sechs Monaten bis zu fünf Jahren/mit Freiheitsstrafe von einem bis zu zehn Jahren zu bestrafen.

According to the StGB, the following benefits are not inappropriate benefits:

- Benefits' acceptance of which is permitted by law or granted in the context of events, provided that participation in the event is justified by an official interest
- Benefits for charitable purposes as defined under tax law, provided that the office-holder or arbitrator does not exert any decisive influence over the use of the granted benefits
- In the absence of legal permission as per the first point, benefits that are customary at the place where they are granted and that are of a minor value, provided that the acceptance and/or the granting of the benefits is not committed on a regular/commercial basis.

Granting a Benefit for "Sweetening"/"Grooming"

Whoever intentionally offers, promises or grants an office-holder or an arbitrator an inappropriate benefit for himself or a third person in order to influence the office-holder in the course of his action as an office-holder shall be punished by imprisonment for up to two years. Whoever commits the crime by using a benefit exceeding EUR3,000/EUR50,000 shall be punished by imprisonment for up to three years/imprisonment of at least six months up to five years.

Forbidden Intervention

Whoever claims, accepts or promises a benefit for himself or a third person for exerting an inappropriate influence on the decision-making of an office-holder or an arbitrator or whoever offers, promises or grants a benefit to a person so that the person exerts an inappropriate influence on the decision–making of an office-holder or an arbitrator, shall be punished by imprisonment of up to two years. Whoever commits this crime in relation to a benefit exceeding EUR3,000/EUR50,000 shall be punished by imprisonment of up to three years/imprisonment ranging from six months up to five years.

Vorteilszuwendung

Eine Vorteilszuwendung gemäß § 307a Abs 1 StGB begeht, wer einem Amtsträger oder Schiedsrichter für die pflichtgemäße Vornahme oder Unterlassung eines Amtsgeschäfts einen ungebührlichen Vorteil für ihn oder einen Dritten anbietet, verspricht oder gewährt. Ein Verstoß gegen diese Bestimmung ist mit Freiheitsstrafe bis zu zwei Jahren zu bestrafen. Wer hingegen die Tat in Bezug auf einen EUR 3.000/EUR 50.000 übersteigenden Wert des Vorteils begeht (Wertqualifikation), ist mit Freiheitsstrafe bis zu drei Jahren/mit Freiheitsstrafe von sechs Monaten bis zu fünf Jahren zu bestrafen.

Nach § 305 Abs 4 StGB sind die folgenden Vorteile keine ungebührlichen Vorteile:

- Vorteile, deren Annahme gesetzlich erlaubt ist, oder die im Rahmen von Veranstaltungen gewährt werden, an deren Teilnahme ein amtliches oder sachlich gerechtfertigtes Interesse besteht;
- Vorteile für gemeinnützige Zwecke (§ 35 BAO), auf deren Verwendung der Amtsträger oder Schiedsrichter keinen bestimmenden Einfluss ausübt, sowie
- in Ermangelung von Erlaubnisnormen im Sinne von (i) orts- oder landesübliche Aufmerksamkeiten geringen Werts, es sei denn, dass die Tat gewerbsmäßig begangen wird.

Vorteilszuwendung zur Beeinflussung

Eine Vorteilszuwendung zur Beeinflussung gemäß § 307b Abs 1 StGB begeht, wer einem Amtsträger oder Schiedsrichter einen ungebührlichen Vorteil für ihn oder einen Dritten mit dem Vorsatz anbietet, verspricht oder gewährt, ihn dadurch in seiner Tätigkeit als Amtsträger zu beeinflussen. Ein Verstoß gegen diese Bestimmung ist mit Freiheitsstrafe bis zu zwei Jahren zu bestrafen. Wer hingegen die Tat in Bezug auf einen EUR 3.000/EUR 50.000 übersteigenden Wert des Vorteils begeht (Wertqualifikation), ist mit Freiheitsstrafe bis zu drei Jahren/mit Freiheitsstrafe von sechs Monaten bis zu fünf Jahren zu bestrafen.

Verbotene Intervention

Eine verbotene Intervention gemäß § 308 StGB begeht, wer für sich oder einen Dritten dafür einen Vorteil fordert, annimmt oder sich versprechen lässt, dass er einen ungebührlichen Einfluss auf die Entscheidungsfindung

Anti-Corruption Provisions for the Private Sector

Acceptance of Gifts and Offering Bribes to Employees or Authorized Representatives

An employee or an authorized representative of a company, who claims, accepts or promises a benefit for himself or a third person for the illegal performance or the omission of an act in a business transaction, or whoever offers, promises or illegally grants an employee or an authorized representative a benefit for himself or a third person for the performance or omission of an act in a business transaction, shall be punished by imprisonment of up to two years. Whoever commits this crime by using an amount exceeding EUR3,000/EUR50,000 shall be punished by imprisonment for up to three years/imprisonment from at least six months up to five years.

Offering Bribes to Employees or Authorized Representatives

The Austrian Unfair Competition Act ("UWG") contains its own anti-bribery provisions; competitors may claim protection under these provisions in the course of a private criminal action (which will only be instituted upon request of the injured competitor).

Pursuant to the UWG, whoever in the scope of business dealings and for advertising purposes offers, promises or grants gifts or other benefits to an employee or an authorized representative of a company in order to obtain an advantage in procuring goods or services for him/herself or a third party as a result of the unfair conduct of the employee or authorized representative will be punished.

The penalty for offering bribes to employees or authorized representatives will be imprisonment for up to three months; alternatively, the courts may impose a fine of up to 180 daily rates (company fine) must not be applied if the offense triggers the same or a more severe penalty under other legal provisions.

Corporate Criminal Law Provisions

On 1 January 2006, the Act on the Criminal Liability of Companies ("VbVG") entered into effect in Austria. In addition to administrative penalties, the VbVG provides for criminal penalties against companies, in the event that decision makers or employees of the company committed a criminal offense for the benefit of the company or if such act violated any

eines Amtsträger oder eines Schiedsrichters nehme (Abs 1), oder wer einem anderen dafür einen Vorteil anbietet, verspricht oder gewährt, dass dieser einen ungebührlichen Einfluss auf die Entscheidungsfindung eines Amtsträgers oder eines Schiedsrichters nehme (Abs 2). Ein Verstoß ist mit Freiheitsstrafe bis zu zwei Jahren zu bestrafen. Wer hingegen die Tat in Bezug auf einen EUR 3.000/EUR 50.000 übersteigenden Vorteil begeht (Wertqualifikation), ist mit Freiheitsstrafe bis zu drei Jahren/mit Freiheitsstrafe von sechs Monaten bis zu fünf Jahren zu bestrafen (Abs 3).

Anti-Korruption im Privatbereich:

Geschenkannahme und Bestechung von Bediensteten oder Beauftragten

Ein Bediensteter oder Beauftragter eines Unternehmens, der im geschäftlichen Verkehr für die pflichtwidrige Vornahme oder Unterlassung einer Rechtshandlung von einem anderen für sich oder einen Dritten einen Vorteil fordert, annimmt oder sich versprechen lässt (Abs 1), oder wer einem Bediensteten oder Beauftragten eines Unternehmens im geschäftlichen Verkehr für die pflichtwidrige Vornahme oder Unterlassung einer Rechtshandlung für ihn oder einen Dritten einen Vorteil anbietet, verspricht oder gewährt (Abs 2), ist mit Freiheitsstrafe bis zu zwei Jahren zu bestrafen. Wer hingegen die Tat in Bezug auf einen EUR 3.000/EUR 50.000 übersteigenden Vorteil begeht (Wertqualifikation), ist mit Freiheitsstrafe bis zu drei Jahren/mit Freiheitsstrafe von sechs Monaten bis zu fünf Jahren zu bestrafen (Abs 3).

Bestechung von Bediensteten oder Beauftragten

Auch das Wettbewerbsrecht sieht einen eigenen Korruptionstatbestand vor, der von Mitbewerbern in einem Privatanklageverfahren (d.h. die Klageerhebung erfolgt nur auf Verlangen des verletzten Mitbewerbers) geltend gemacht werden kann.

Gemäß § 10 UWG ist strafbar, wer im geschäftlichen Verkehr zu Zwecken des Wettbewerbs einem Bediensteten oder einem Beauftragten eines Unternehmens Geschenke oder andere Vorteile anbietet, verspricht oder gewährt, um durch unlauteres Verhalten des Bediensteten oder Beauftragten beim Bezug von Waren oder Leistungen eine Bevorzugung für sich oder einen Dritten zu erlangen.

obligations incumbent upon the company (section 3 VbVG). According to the Act on the Criminal Liability of Companies (section 4 VbVG), the courts may impose on companies fines in the amount of up to 180 daily rates; the number of daily rates will be determined individually, in each case depending on the crime or offense committed. The amount of the daily rates must be determined in accordance with the profit situation of the respective company taking into account its general economic efficiency. The amount to be determined must correspond to the 360th share of the annual profit plus/minus one-third. A daily rate must at least amount to EUR50 but may not exceed EUR10,000. Therefore, the maximum fine that can be imposed under the VbVG amounts to EUR1,800,000.

Contracts with Healthcare Professionals and Medical Facilities

Cooperation in the heathcare sector works both ways. While medical professionals need the products and donations provided by the industry, the industry, in turn, benefits from the expert knowledge and skills of the medical professionals. For this reason, contracts for the provision of services or funding, e.g., donation and sponsoring contracts, are common and, in general, legal. Where the give-and-take relationship of the contracting parties appears non-transparent, it may easily be assumed that a contract is fictitious and merely serves to conceal unethical agreements, placing the patients at a disadvantage or jeopardizing fair competition. Considering the legal concerns connected with such contracts, it has proved expedient for companies to develop binding internal conduct rules ("compliance guidelines") as well as standardized contracts for the collaboration with healthcare professionals.

In addition, some key principles should be observed which may serve as a valuable guideline in drafting such contracts. As a basic principle, contracts may never influence the independence of a physician by indirectly or directly obliging him or her to prescribe or buy products of a specific company (principle of independence). The grant of donations or benefits may therefore not be related to sales transactions with the recipient of such donations or benefits. Another requirement for the permissibility of donations is that the service and the consideration offered for such service are in due proportion and that both the contract and the exchange of services are documented in writing and can be traced (principle of equivalence and documentation). The performance to be rendered under the contract must be a scientific or professional activity performed for the company (principle of activity). Contracts should, if possible, be concluded with the medical facility rather

Das Strafausmaß bei einem Verstoß gegen § 10 UWG (Bestechung von Bediensteten oder Beauftragten) beträgt bis zu drei Monate Freiheitsstrafe oder kann mit einer Geldstrafe von bis zu 180 Tagessätzen geahndet werden. § 10 UWG ist nicht anzuwenden, wenn die Tat nach anderen Bestimmungen mit gleicher oder strengerer Strafe bedroht ist.

Unternehmensstrafrecht

Am 1. Jänner 2006 ist in Österreich das Verbandsverantwortlichkeitsgesetz (VbVG) in Kraft getreten. Damit können neben verwaltungsrechtlichen auch strafrechtliche Sanktionen über ein Unternehmen verhängt werden, wenn Entscheidungsträger oder Mitarbeiter des Unternehmens eine strafbare Handlung zu Gunsten des Unternehmens begangen haben oder durch die Tat Pflichten verletzt worden sind, die das Unternehmen treffen (§ 3 VbVG). Nach Maßgabe des Verbandsverantwortlichkeitsgesetzes (§ 4 VbVG) können über ein Unternehmen Geldstrafen von bis zu 180 Tagessätzen verhängt werden, deren Zahl vom jeweils begangenen Verbrechen oder Vergehen abhängt. Der Betrag der Tagessätze (Verbandsgeldbuße) ist nach der Ertragslage des Unternehmens unter Berücksichtigung von dessen sonstiger wirtschaftlicher Leistungsfähigkeit zu bemessen. Er ist mit einem Betrag festzusetzen, der dem 360-sten Teil des Jahresertrags entspricht oder diesen um höchstens ein Drittel über- oder unterschreitet; mindestens jedoch mit EUR 50 oder höchstens mit EUR 10.000. Daher kann nach dem VbVG maximal eine Geldsstrafe von EUR 1.800.000 verhängt werden.

Verträge mit Fachpersonen und Medizinischen Einrichtungen

Die Zusammenarbeit im Gesundheitswesen ist wechselseitig bedingt: So wie die Angehörigen der medizinischen Berufe die Erzeugnisse und Spenden der Industrie benötigen, nützt auch die Industrie das fachliche Wissen und die Fertigkeiten der Mediziner. Aus diesem Grund werden regelmäßig Dienstleistungs- oder Drittmittelverträge, das sind zB Spenden- oder Sponsoringverträge, abgeschlossen, die nach Maßgabe der rechtlichen Rahmenbedingungen grundsätzlich zulässig sind. Dort wo das Austauschverhältnis der Partner jedoch undurchsichtig erscheint, kann bald ein Scheinvertrag zur Verschleierung unethischer Abmachungen zu Lasten der Patienten oder einer lauteren Branchenkultur vermutet werden. In Hinblick auf die rechtlichen Unsicherheiten, die solchen Verträgen anhaften, hat es sich in der Praxis für die Unternehmen bewährt, verpflichtende interne Verhaltensregelungen („Compliance-Richtlinien") sowie standardisierte Verträge für die Zusammenarbeit zu erarbeiten.

than with individual persons (principle of immediacy). If this is not the case, any services rendered should be disclosed to and approved in writing by the employer (principle of authorization).

It is understood that these principles are not necessarily all applicable in each case but form a flexible system. If one principle is not complied with at all or only to a minor degree in a certain type of contract, this must be compensated by the stronger presence of other principles in order to make the contract appear permissible. The following sections will discuss the aforementioned principles on the basis of certain types of contracts most commonly used in practice.

Research Contracts

Contract research is one of the most common forms of cooperation between the industry and physicians. In this context, if at all possible, it should be ensured that the research contract is concluded with the respective medical facility, but not, however, with the experts conducting the research at the level of the facility.

The consideration the enterprise pays for the research must be adequate, i.e., at arm's length. Care should be taken not to agree on any lump-sum considerations if this can be avoided. The remuneration paid for the examination and research activities shall be based on the time and effort spent. Any publications of research results must indicate the name of the sponsor. In addition, any services rendered must be documented. The contract should furthermore include a specific "legal compliance clause" by which the medical facility confirms that the contract neither violates internal regulations nor statutory provisions (i.e., civil service law, professional codes of conduct, etc.) or, as the case may be, that such regulations will be complied with in the performance of the contract.

Services that only apparently serve a medical-scientific purpose or in which the other party can have no justified interest (fictitious services, sham contracts) raise concerns from an anti-corruption perspective. It may be suspected that they merely serve to conceal unethical benefits granted by the industry to members of the medical profession. Practices that may raise concerns are, e.g., renewed studies of (the relevant company's own) remedies for which a marketing authorization has already been granted, unless there is a specific reason to repeat the examination, pseudo-scientific studies or the monitoring of new drug combinations. When drafting such contracts, special care should be taken to ensure that the documentation is traceable and that the purpose of and/or reason for the research is indicated (principle of documentation and activity).

Zusätzlich können einige Leitprinzipien formuliert werden, die einen dienlichen Richtwert für die Ausgestaltung der Verträge bieten. Das Grundprinzip lautet, dass Verträge niemals die ärztliche Unabhängigkeit beeinflussen dürfen, indem sie den Arzt mittelbar oder unmittelbar zur Verschreibung bzw zum Ankauf von Erzeugnissen des Unternehmens verpflichten (Unabhängigkeitsprinzip). Zuwendungen dürfen daher nicht in Abhängigkeit von Umsatzgeschäften erfolgen. Eine weitere Zulässigkeitsvoraussetzung ist es, dass Leistung und Gegenleistung in einem angemessenen Verhältnis zueinander stehen müssen und sowohl der Vertrag, als auch der Leistungsaustausch schriftlich und nachvollziehbar dokumentiert werden (Äquivalenz- und Dokumentationsprinzip). Bei der zu erbringenden vertraglichen Leistung muss es sich um eine wissenschaftliche oder fachliche Tätigkeit für den Unternehmer handeln (Leistungsprinzip). Verträge sind möglichst mit der medizinischen Einrichtung selbst abzuschließen (Unmittelbarkeitsprinzip). Ist dies nicht der Fall, sollten Leistungen gegenüber dem Dienstherrn offengelegt sowie von diesem schriftlich genehmigt werden (Genehmigungsprinzip).

Es versteht sich, dass diese Prinzipien nicht kumulativ gegeben sein müssen, sondern ein bewegliches System bilden. Ist eines der Prinzipien bei einem bestimmten Vertragstyp nicht oder nur im minderen Maß gegeben, so muss es verstärkt durch andere ausgeglichen werden, damit der Vertrag zulässig erscheint. Im Folgenden soll der angeführte Prinzipienkatalog anhand der in der Praxis häufigsten Vertragstypen erläutert werden.

Forschungsverträge

Die Auftragsforschung ist eine häufige Erscheinungsform der Zusammenarbeit zwischen Industrie und Ärzteschaft. In diesem Rahmen ist darauf zu achten, den Forschungsvertrag möglichst mit der jeweiligen medizinischen Einrichtung selbst abzuschließen, nicht jedoch mit den mit der Forschung betrauten Fachpersonen der Einrichtung. Die für die Forschungstätigkeiten erbrachte Gegenleistung des Unternehmens muss angemessen sein, das heißt, sie muss einem Drittvergleich standhalten können. Dabei ist zu beachten, dass möglichst keine Pauschalvergütungen vereinbart werden. Grundlage für die Bezahlung der Prüfungs- und Forschungstätigkeit muss der damit verbundene Aufwand und die benötigte Zeit sein. Ergebnisse dieser Forschungstätigkeit sind unter Angabe des Sponsorunternehmens zu veröffentlichen. Die erfolgten Leistungen müssen außerdem dokumentiert werden. Anzuraten ist ferner, eine sogenannte „Rechtstreueklausel" in den Vertrag einzuarbeiten, in welcher die

Consultancy Agreements

In practice, consultancy agreements are most likely concluded with the expert himself rather than with a medical facility. If the expert is working for a medical facility, it is advisable to obtain the authorization of the institution concerned. The company must pay adequate remuneration for the consultancy services rendered; what is adequate in each individual case may depend on the qualifications and reputation of the expert in question. The consultancy services should be documented, and the expert should issue fee statements that would allow third parties to understand the facts and circumstances of the business relationship. The remuneration paid for the consultancy services should be based on the time and effort spent.

Contracts on Presentations and Lectures

These are also contracts that are often entered into with the speaker. In this case, the written authorization of the lecturer's employer must be obtained. The speaker must be remunerated for the lecture given reasonably, i.e., at conditions customary in the particular market. The remuneration paid for giving a lecture shall be based on the time and effort spent. The amount of the remuneration can certainly take into account the speaker's reputation and/or position as well.

Unilateral Funding Contracts

The industry's granting of funds to medical facilities or universities is common practice in Austria and is considered necessary. A detailed definition of the term "external funds" (*Drittmittel*) is contained in section 28 of the Vienna Medical Facility Act (*Krankenanstaltsgesetz 1987*). According to such definition, external funds are financial allocations to hospitals, particular units, departments or other organizational units that do not or not directly serve as remuneration for a specific service rendered, or are being provided in addition to the occasion of a specific service. This collective term covers in particular donation contracts, sponsoring contracts, contracts on the supply of devices or outsourcing contracts.

In general, as far as funding contracts are concerned, attention needs to be paid to the fact that the reason behind a grant of benefits must not be to promote the prescription of drugs, and thus constitute an infringement of the physician's independence. In particular, in university and hospital sectors, funding contracts are often directly entered into with university or hospital personnel. These contracts are only admissible if the principal has given his or her prior consent (Austrian University Act 2002). In no case should the

medizinische Einrichtung bestätigt, dass der Vertrag nicht gegen interne Richtlinien oder gesetzliche Regelungen (etwa Beamtendienstrecht, Berufsordnungen etc) verstößt bzw diese bei der Durchführung des Vertrags beachtet werden.

Korruptionsrechtlich bedenklich sind Leistungen, die nur vordergründig einem medizinisch-wissenschaftlichen Zweck dienen bzw an denen die Gegenseite kein begründetes Interesse haben kann (Scheinleistungen, Scheinverträge). Hierbei kann schnell der Verdacht entstehen, dass unethische Vorteilsgewährungen der Industrie an die Angehörigen der Heilberufe verschleiert werden sollen. Zu den bedenklichen Praktiken zählen etwa die Neuüberprüfungen bereits zugelassener (eigener) Medikamente ohne Anlass, pseudowissenschaftliche Studien oder die Überprüfung neuer Medikamentenkombinationen. Bei solchen Verträgen ist verstärkt auf eine nachvollziehbare Dokumentierung unter Angabe des Forschungszwecks und/oder des Forschungsanlasses zu achten (Dokumentations- und Leistungsprinzip).

Beratungsverträge

In der Praxis werden Beratungsverträge meist nicht mit einer medizinischen Einrichtung, sondern mit dem Sachverständigen selbst abgeschlossen. Ist der Berater in einer medizinischen Einrichtung tätig, empfiehlt es sich, den Beratungsvertrag von der medizinischen Einrichtung genehmigen zu lassen. Die erbrachte Beratungstätigkeit muss vom Unternehmen angemessen vergütet werden, wobei die Angemessenheit der Vergütung von der Qualifikation und Reputation des Beraters abhängen kann. Die Beratungsleistung sollte dokumentiert und vom Berater nach außen hin nachvollziehbar abgerechnet werden. Grundlage für die Bezahlung der Beratungstätigkeit sollte der damit verbundene Aufwand und die benötigte Zeit sein.

Verträge über Präsentationen und Vorträge

Auch solche Verträge werden häufig mit dem Referenten selbst abgeschlossen. In diesem Fall ist eine schriftliche Genehmigung des Dienstherrn des Vortragenden einzuholen. Der Vortrag des Referenten ist angemessen, das heißt, zu marktüblichen Konditionen zu vergüten. Grundlage für die Bezahlung der Referatstätigkeit sollten der damit verbundene Aufwand und die benötigte Zeit sein. Dabei kann die Höhe der Bezahlung selbstverständlich nach Maßgabe der Reputation und/oder der beruflichen Stellung des Referenten ausgerichtet sein.

funds be transferred to the account of the person procuring the funds, i.e., in most cases university personnel or physicians, but rather to the respective facility's official account. It is recommendable to include a provision stipulating that the applicable statutory provisions will be complied with into the contract. This assures that the funds are in fact used for the intended purpose and that the granting of funds has no bearing on the prescription of medicinal products.

In particular, when it comes to mere donations, the principle of equivalence is completely left aside because they do not involve an exchange of performances. Consequently, there is the risk that the donation might be treated as a grant of benefits that gives cause for concern in terms of corruption. Donation contracts should therefore be as detailed as possible as far as the intended purpose, the donated amount and the intended recipient are concerned. In the event that the contract also contains elements of sponsoring, i.e., if the company uses the support provided for image purposes (e.g., in contracts relating to exhibitions), the scope and type of performances need to be specified in detail in the contract.

The granting of funds for social events (social donations), such as providing financial support for intra-company festivities of medical facilities, is not permitted.

Recommendations

In the course of the cooperation with medical professionals, various civil (UWG), administrative (AMG, MPG) and criminal provisions (StGB, UWG, VbVG) must be observed. The granting of benefits to healthcare professionals, especially to those that have the status of civil servants, is permissible only to a very limited degree.

If the suspicion of a violation against the doctoral independence is raised, even the granting of minor gifts may have administrative consequences and may be sanctioned by the codes of conduct.

Where no such suspicion is entertained, a contractual cooperation may be freely agreed upon. In order, to avoid unpleasant consequences and possible damage to a company's public image, it is advisable to regard the following rules when entering into an agreement and performing it:

- The principle of independence – Benefits must not appear to be intended to hollow out the independence of professionals qualified to

Einseitige Drittmittelverträge

Die Gewährung von Drittmitteln durch die Industrie an medizinische Einrichtungen bzw Universitäten ist in Österreich üblich und wird als notwendig anerkannt. Ausdrücklich definiert wird der Begriff des Drittmittels in § 28 des Wiener Krankenanstaltsgesetzes 1987. Danach sind Drittmittel finanzielle Zuwendungen an Krankenanstalten, einzelne Abteilungen, Departments oder sonstige Organisationseinheiten, die nicht oder nicht unmittelbar der Abgeltung einer konkreten Leistung dienen oder anlässlich einer konkreten Leistung zusätzlich zur Verfügung gestellt werden. Unter diesen Sammelbegriff fallen vor allem Spenden-, Sponsoring-, Geräteüberlassungs- oder Outsourcingverträge.

Im Allgemeinen gilt es bei Drittmittelverträgen zu beachten, dass die Vorteilsgewährung nicht auf die Förderung der Verschreibung von Arzneimitteln abzielt und damit die ärztliche Unabhängigkeit verletzt. Vor allem im Universitäts- und Krankenanstaltenbereich werden Drittmittelverträge häufig direkt mit Universitäts- oder Spitalsbediensteten abgeschlossen. Diese Verträge sind nur insofern zulässig, als sie zuvor vom Dienstherrn genehmigt wurden (vgl etwa § 27 Universitätsgesetz 2002). Die finanziellen Mittel sollten keinesfalls auf das Konto des Drittmittelwerbers, das ist meist ein Universitätsbediensteter oder ein Arzt, überwiesen werden, sondern auf das offizielle Konto der jeweiligen Einrichtung. Ratsam ist es, eine „Rechtstreueklausel" in den Vertrag aufzunehmen. Mit dieser wird zugesichert, dass die Beträge tatsächlich dem Widmungszweck zugeführt werden und die Drittmittelgewährung keinen Einfluss auf die Medikamentenverschreibung hat.

Vor allem bei reinen Spenden ist das Äquivalenzprinzip gänzlich ausgeschaltet, da hierbei kein gegenseitiger Austausch von Leistungen erfolgt. Aus diesem Grund besteht die Gefahr, dass die Spende als korruptionsrechtlich bedenkliche Vorteilsgewährung gewertet wird. Der Spendenvertrag ist daher in Bezug auf Widmungszweck, Höhe der Spende und deren Empfänger möglichst detailliert zu dokumentieren. Sind im Vertrag zusätzlich auch Sponsoringelemente enthalten, wird also die Unterstützung vom Unternehmen zur Imagewerbung genützt (etwa bei Ausstellungsverträgen), sind Umfang und Art der Leistungen im Vertrag genau auszuweisen.

Drittmittelgewährungen für betriebssoziale Anlässe (Sozialspenden) sind nicht erlaubt, so etwa die finanzielle Unterstützung von betriebsinternen Feiern von medizinischen Einrichtungen.

prescribe or supply medical remedies. From this basic principle follows that benefits must not be granted in dependence on orders or sales transactions.

- The principle of writing – For reasons of evidence, agreements must generally be in writing.
- The principle of equivalence – Performance and consideration should be reasonably balanced. Unilateral agreements should be avoided as much as possible.
- The principle of activity – Any contractual performance for a company must be a scientific or medicine-related activity. Sham contracts are not permissible.
- The principle of documentation – Performance and consideration must be recorded traceably and in writing. The payment must be based on the work related to and the time needed for the performance. Lump-sum payments should be avoided. The results of research must be published indicating the name of the sponsor involved.
- The principle of immediacy – The acceptance of a benefit must exclusively and directly serve healthcare purposes and, accordingly, the interests of the medical facility, university or the patient. Conversely, the acceptance of a benefit must not serve private purposes of a recipient. As a consequence, agreements should, as much as possible, be directly entered into with the medical facility/university, but not with its employees. Invitations to a medical event are preferably to be addressed to the medical facility/university itself. Correspondingly, benefits are to be transferred to the official accounts of the medical facility/university, but not to the private accounts of an employee.
- The principle of authorization – Agreements that have been concluded with an employee of a medical facility or university should, before they are executed, be approved by the employer (head of administration) in writing. The same rule applies to invitations to medical events.
- The principle of compliance – It is advisable to draft a clause into the agreement stipulating that the medical facility or university shall, in the course of the execution of the agreement, comply with the regulations applicable (such as the provisions dealing with the procurement of funds) as well as its internal guidelines. Furthermore, it is advisable to draft the principle of independence into the agreement.

Empfehlungen

Bei der Zusammenarbeit zwischen Industrie und den Angehörigen der Heilsberufe sind eine Vielzahl zivil- (UWG), verwaltungs- (AMG, MPG) und strafrechtlicher Bestimmungen (StGB, UWG, VbVG) zu beachten. Vorteilsgewährungen an Angehörige der Heilberufe, vor allem an jene, die Beamteneigenschaft haben, sind nur in sehr engem Rahmen zulässig. Verwaltungsstrafrechtliche Sanktionen und Strafen nach den Verhaltenskodizes können bereits bei geringfügigen Zuwendungen verhängt werden, soweit der Verdacht einer Verletzung der ärztlichen Unabhängigkeit besteht.

Soweit dieser Verdacht nicht gegeben ist, kann eine vertragliche Zusammenarbeit frei vereinbart werden. Zur Vermeidung von für das Unternehmen unangenehmen Rechtsfolgen und eines Imageschadens empfiehlt es sich, beim Abschluss des Vertrags und bei dessen Durchführung folgende Gebote zu beachten:

- Unabhängigkeitsprinzip: Zuwendungen dürfen nicht den Anschein erwecken, dass damit die Unabhängigkeit der zur Verschreibung oder Abgabe berechtigten Angehörigen der Heilberufe ausgehöhlt werden soll. Aus diesem Grundsatz folgt, dass Zuwendungen weder bestell- noch umsatzabhängig gewährt werden dürfen.
- Schriftlichkeitsprinzip: Verträge sind aus Beweisgründen grundsätzlich schriftlich abzuschließen.
- Äquivalenzprinzip: Leistung und Gegenleistung sollten einander wertmäßig die Waage halten. Einseitige Leistungen sind möglichst zu vermeiden.
- Aktivitätsprinzip: Bei der zu erbringenden vertraglichen Leistung muss es sich um eine wissenschaftliche oder fachliche Tätigkeit für ein Unternehmen handeln. Scheinverträge sind unzulässig.
- Dokumentationsprinzip: „Korruption ereignet sich im Dunklen". Leistung und Gegenleistung müssen schriftlich und nachvollziehbar festgehalten werden. Grundlage für die Bezahlung der Leistungen müssen der damit verbundene Aufwand und die benötigte Zeit sein. Pauschale Vergütungen sind zu vermeiden. Forschungsergebnisse sind unter Nennung des Sponsors zu veröffentlichen.

- Unmittelbarkeitsprinzip: Die Annahme einer Zuwendung soll ausschließlich unmittelbaren medizinischen Zwecken dienen bzw dem Interesse der Krankenanstalt, der Universität oder des Patienten. Umgekehrt darf die Zuwendung nicht privaten Zwecken des Empfängers gewidmet sein. Aus diesen Grundsätzen folgt, dass Verträge möglichst mit der medizinischen Einrichtung/Universität direkt zu schließen sind, nicht jedoch mit Bediensteten der Einrichtung/Universität. Auch Einladungen zu medizinischen Veranstaltungen sind besser an die Einrichtung/Universität selbst zu richten. Dementsprechend sind Zuwendungen auf die offiziellen Konten der medizinischen Einrichtung/ Universität zu leisten, nicht aber auf Privatkonten ihrer Bediensteten.
- Genehmigungsprinzip: Verträge, die mit einem Angestellten einer medizinischen Einrichtung oder Universität geschlossen werden, sollten vor der Durchführung schriftlich vom jeweiligen Dienstherrn (Verwaltungsleiter) genehmigt werden. Gleiches gilt für Einladungen zu medizinischen Veranstaltungen.
- Rechtstreueprinzip: Beim Abschluss von Verträgen empfiehlt es sich, eine Klausel einzuarbeiten, mit der sich die medizinische Einrichtung verpflichtet, die einschlägigen gesetzlichen Vorschriften (etwa zur Drittmittelbeschaffung) oder internen Richtlinien bei der Durchführung des Vertrags einzuhalten. Ratsam ist auch die schriftliche Festlegung des Unabhängigkeitprinzips.

Belgium

Annabelle Bruyndonckx

Introduction

The success of the sale of a product depends on a whole range of factors, including among others, the price and the quality of the product, the usefulness and the necessity of the product, and also the advertising and promotion of the product. Successful promotion and advertising campaigns offer the customer a particular reason to select a product. This is true in any market; the Belgian healthcare market is no exception.

However, because of the nature and the risks associated with medical products, the promotion of medical products is subject to rather strict European and Belgian regulations. The purpose of this chapter is to provide guidance for pharmaceutical and medical device companies in the promotion of their products to the public and to healthcare professionals, and in their contacts with healthcare professionals, by giving an overview of the legal and ethical rules in Belgium which may form the basis of ethical, civil and even criminal liability.

The Regulatory Framework

The promotion of medical products in Belgium is regulated by a complex amalgam of acts, royal decrees, circulars, industry and professional codes of conduct, the content of which is not always very clear and subject to various interpretations.

A distinction needs to be made under Belgian law between medicinal products and medical devices:

- A medicinal product is “any substance or combination of substances, presented as having therapeutic or prophylactic qualities with regard to diseases in human beings or animals”. According to the same definition, “any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying organic functions in human beings or animals is likewise considered a medicinal product”.
- A medical device is defined as “any instrument, apparatus, equipment, material or other article, whether used alone or in combination,

including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means."

The Act of March 25, 1964 on Medicinal Products

The promotion of medical products is mainly governed by the Act of March 25, 1964 on Medicinal Products ("the Act"), and more specifically by its Article. 10. This article applies to medicinal products and medical devices[1], with the exception of *in vitro* diagnostic medical devices[2].

According to Article 10 of the Act, "it is prohibited in the context of the supply, prescription, delivery or administration of medicinal products to promise, offer or grant, directly or indirectly, premiums, monetary benefits or benefits in kind to wholesalers, to persons entitled to prescribe, deliver or administer medicinal products as well as to institutions where the prescription, delivery or administration of medicinal products takes place."

However, this prohibition does not apply:

- to premiums or benefits of a negligible value and which relate to the practice of medicine, dentistry, pharmacy or veterinary medicine;

[1] According to Article 10, §7 of the Act of March 25, 1964, Article 22 of the Royal Decree of March 18, 1999 on medical devices and Article 2 of the Royal Decree of July 15, 1997 on active implantable medical devices, the prohibition laid down in Article 10 of the Act of March 25, 1964 also applies to medical devices and active implantable medical devices.

[2] With respect to *in vitro* diagnostic medical devices, while there is no legal ground to support that Article 10 of the Act is also applicable to them, the Belgian Federal Agency for Medicinal and Health Products tends to support that *in vitro* diagnostic medical devices should be treated like other medical devices and therefore follow the rule of Article 10 of the Act.

- to hospitality and participation costs at scientific events provided that specific conditions are met; and
- to compensation for legitimate services of a scientific nature provided that it remains within reasonable limits.

The scope of these exceptions is further explained in "Permitted and Prohibited Practices", below

For the sake of completeness, it should be noted that Article 9 of the Act further regulates the advertising of medicinal products and implantable medical devices to the general public. It lays down several prohibitions and restrictions with regard to advertising of medicinal products and implantable medical devices to the general public.

Other Legal Provisions

In addition to the Act, the following legal provisions also govern the promotion of medical products:

- Article 18, §2 of the Royal Decree of November 10, 1967 on the Performance of Medical Profession explicitly prohibits "agreements between practitioners, i.e., physicians, pharmacists, midwifes, and physiotherapists and third parties, particularly, manufacturers of medical products and suppliers of medical or prosthesis equipment, if said agreements have an influence on their profession and provide any direct or indirect benefit or advantage for either party".

  Agreements are thus only prohibited if they have an influence on the practitioner's profession and if they bring a direct or indirect benefit to the practitioner.

- The Royal Decree of April 7, 1995 on the Information on and the Advertising of Medicinal Products contains rules on advertising of medicinal products that is aimed at the general public and at healthcare professionals. This royal decree also includes rules on disease awareness campaign[3]. It further provides rules for the activities of

[3] According to Article 2, §1, 3° of the Royal Decree of April 7, 1995 as amended by the Royal Decree of November 22, 2006, information campaign means "the information campaign to the public on human disease or human health which refers directly or indirectly to a medicinal product or to a group of medicinal products broadcasted by one or more broadcasting means".

medical representatives. This royal decree applies to medicinal products only.

- The Royal Decree of January 11, 1993 which regulates the distribution of samples for human use also deserves brief mention. According to Article 2 of this royal decree, medicinal samples can only be distributed to persons qualified to prescribe on specific request. Article 3 of this royal decree also stipulates that persons who are entitled to prescribe medicinal products may not receive more than 600 samples per civil year and that of a given medicinal product, only eight samples a year can be given by the marketing authorization holder per person qualified to prescribe.

Permitted and Prohibited Practices

Gifts, Seminars, Hospitality and Entertainment

The practice of offering gifts and inviting healthcare professionals to restaurants and scientific events such as seminars, congresses, roundtable discussions, workshops is a customary practice in the pharmaceutical sector. The limitations that apply to these practices are summarized below.

Gifts

It can be concluded from the legal provisions mentioned in "the regulatory framework" above that as a general rule, it is prohibited to offer any benefits, advantages or premiums to healthcare professionals or to institutions where the prescription, delivery or administration of medical products takes place. This prohibition applies regardless whether such offering is made pursuant to an agreement and whatever the nature or purpose of the gift may be: charity, continuous training, etc.

Consequently, pharmaceutical and medical device companies are not allowed to give voucher or cash, computers, TV or DVD players; nor wine, chocolates or flowers to healthcare professionals.[4]

The only exception to the abovementioned prohibition is the offering of gifts and advantages of negligible value which are relevant to the practice of

[4] It is to be noted that the term healthcare professional is very broadly defined and includes not only physicians (working both in public and private hospital, under an employee status or a self-employed status) but also nurses, dentists, pharmacists, wholesalers, private and public hospitals, revalidation centers and rest homes.

medicine, dentistry, pharmacy or veterinary medicine. The Act does not provide a definition of what is meant by "negligible value," but such definition may be provided later on by way of a royal decree. The notion of negligible value is discussed in the preparatory works of the Act of December 16, 2004 which has amended Article 10 of the Act. The preparatory works suggest taking into account the tax criteria. The preparatory works list examples of authorized gifts: subscription to scientific review, scientific books, scientific CD-ROM, stethoscope and spatula.

Seminars and Hospitality

Based on the legal provisions mentioned in "The regulatory framework" above, pharmaceutical and medical device companies may offer hospitality and participation costs at scientific events provided that the five following conditions are met:

- The event has an exclusive scientific nature.
- The hospitality offered is strictly limited to the scientific scope of the event. This means that most of the time must be dedicated to activities of scientific nature.
- The place, date and duration of the event do not create confusion as to the scientific nature of the event.
- The hospitality and participation costs are limited to the duration of the event; this means that if the healthcare professional wishes to extend his/her stay, he/she will have to bear all the costs related thereto.
- The hospitality and participation costs cannot be extended to any person other than the healthcare professional involved. It means that if the spouse, partner or any person other than the invited healthcare professional wishes to accompany the healthcare professional, he/she will have to bear all the costs related to his/her stay.

Neither the Act, nor the Royal Decree of April 7, 1995 on the Information on and the Advertising of Medicinal Products has defined the term "hospitality." However, the term "hospitality" is discussed in the preparatory works of the Act of 16 December 2004, which has amended Article 10 of the Act. According to the preparatory works, hospitality includes notably welcome costs, meals and lodging.

In its Circular n°465 of January 16, 2006 addressed to manufacturers, importers, distributors and holders of marketing authorization for medicinal

products and medical devices, the Directorate General for Medicinal Products ("DGMP")[5] stresses that a meal can only be offered to health professionals at the occasion of scientific meetings if duration and timing reasonably justify that such hospitality be offered.

Article 10,§3 of the Act puts in place a visa procedure for hospitality and participation costs offered at scientific events (i.e., congresses, symposia, technical meetings, seminars, training sessions, information sessions, advisory boards, investigators' meetings, etc.) taking place during several calendar days. Prior to any such event, pharmaceutical and medical device companies must obtain a visa (authorization) from Mdeon for the hospitality and participation costs it wishes to offer to healthcare professionals practicing in Belgium. If the visa is not granted, the participation costs in the event, including the hospitality, cannot be offered.

While agreements entered into with healthcare professionals do not have to be submitted to the approval of Mdeon, pharmaceutical and medical device companies entering into agreements which provide for reimbursement of transportation costs, lodging, meals, etc., with a healthcare professional practicing in Belgium, must file a visa request for the scientific event to which the healthcare professional will participate. Such request shall contain information on the various costs to be reimbursed but not on the fees paid for the services performed.[6]

Entertainment

It may be derived from the legal provisions mentioned in "The regulatory framework" above that pharmaceutical and medical device companies are allowed to entertain healthcare professionals provided that the entertainment is:

- reasonable in cost;
- secondary to the main purpose of a scientific meeting; and
- restricted to heath professionals (spouse or partner of the healthcare professional may not be invited).

[5] It should be noted that per 1 January 2007, the Belgian Federal Agency for Medicinal and Health Products has taken over the tasks and the staff of the DGMP.
[6] For more information on the visa procedure, see https://www.mdeon.be/en/index.html?langChanged=1

Consequently, it would not be acceptable, for example, to offer free tickets to healthcare professionals to attend a sports event, a concert, or the like. However, it would, in principle, be acceptable to invite healthcare professionals to a scientific meeting followed by a dinner.

Promotional Activities

Promotional sales to healthcare professionals such as "buy ten, get twelve" are prohibited by Article 10 of the Act.

The granting of price rebates or discounts to healthcare professionals is in principle allowed if the pharmaceutical or medical device company does not have a dominant position on the market.

There is no specific provision governing the granting of price rebates or discounts to healthcare professionals. However, in practice and as a general rule, price rebates are allowed by case law and by the Belgian Federal Agency for Medicinal and Health Products provided that the following conditions are met:

- Principle of non-discrimination: A rebate scheme that would be offered only to selected hospitals/clinics (as opposed to all hospitals/clinics) would constitute a prohibited advantage under Article 10 of the Act. In order to be acceptable under pharmaceutical law, the rebate scheme must be offered to all hospital/clinics. In addition, the rebate scheme must be the same for all hospital/clinics (no individually tailored rebate scheme) and apply objective standardized purchase targets that equally apply to all hospital/clinics.
- The price rebates may not provide a direct or indirect prohibited advantage under Article 10 of the Act to the beneficiary of the rebate. There is a prohibited indirect advantage when a hospital/clinic benefits from rebates and do not pass the rebates to the health reimbursement agency (*riziv/inami*) in case of refundable medical devices.

Samples

According to the Royal Decree of January 11, 1993, pharmaceutical companies may only distribute medicinal samples for human use to persons qualified to prescribe medicinal products if said persons have specifically requested so in writing.

Furthermore, a physician is not allowed to request more than 600 samples per year from pharmaceutical companies and he/she may only directly distribute

samples to patients when this is absolutely necessary due to urgent medical circumstances or social distress.

It should be noted, however, that certain medicinal products - more specifically those containing narcotics, anesthetics or hallucinogenics, such as tranquilizers and soporifics, may not be distributed at all by way of sample.

Drug samples must also be supplied in the smallest packaging available. In addition, drug samples may of course not be sold. The indication “free sample - may not be sold” must be clearly printed on the packaging. In addition, the royal decree restricts the distribution of samples even more, by providing that of a given medicinal product only eight samples a year can be given per person qualified to prescribe.

This restriction does not apply to the distribution of samples which have been requested to test the efficiency of a given medicinal product in the framework of an application for retribution by the government.

The marketing authorization holder must establish within its company a controlling system supervising the distribution of samples. A list must be drawn up, indicating which samples (identification numbers) have been distributed to which prescribers. In addition, the marketing authorization holder has to keep the written requests for the receipt of samples for a period of 10 years and must communicate before 1 March of each year to the Federal Agency for Medicinal and Health Products the total number of samples per product it has given to persons qualified to prescribe medicinal products.

The royal decree furthermore indicates that each medicinal sample should be accompanied by a scientific instruction leaflet as provided by Article 3, §1, 1° of the Royal Decree of April 7, 1995.

Consequences of Breach

As a preliminary remark, it should be noted that the Royal Decree of June 10, 2006; implementing Article 10, §5 of the Act, has created within the Federal Agency for Medicinal and Health Products, a contact point aimed to centralize all information regarding behaviors and acts that could potentially constitute an infringement to Article 10 of the Act. Anyone having information/knowledge on a potential infringement to Article 10 of the Act can communicate such information to the contact point who will then investigate if it decides it to be necessary.

Criminal Sanctions

Article 16 of the Act and Article 38,§1, 5° of the Royal Decree of November 10, 1967 on the Performance of Medical Profession contain criminal sanctions which may apply in case of a breach of certain legal provisions in connection with the promotion of medical products to healthcare professionals.

The following criminal sanctions apply in case of violation of the rules applicable to gifts, seminars, hospitality, entertainment and promotional activities:

- To any person violating Article 10 of the Act (including, amongst others, health professionals and officers of pharmaceutical and medical device companies): imprisonment from one month to one year and/or a fine from EUR1,200 up to EUR90,000
- To pharmaceutical and medical device companies (in their capacity of legal entities) violating Article 10 of the Act: EUR3,000 up to EUR144,000
- To healthcare professionals infringing Article 18, §2 of the Royal Decree of November 10, 1967: a fine in the amount of EUR156 to EUR3,000.

The following criminal sanctions apply in case of violation of the rules applicable to samples:

- To any person violating the provisions of the Royal Decree of January 11, 1993 (including, among others, health professionals and officers of pharmaceutical and medical device companies): imprisonment from eight days to one month and/or a fine from EUR600 up to EUR6,000.
- To pharmaceutical and medical device companies (in their capacity of legal entities) violating the provisions of the Royal Decree of January 11, 1993: EUR600 up to EUR12,000.

General Commercial Liability

Pharmaceutical and medical device companies which violate legal provisions in connection with the promotion of medical products to healthcare professionals can also be sued by competitors to cease and desist unfair trade practices.

Such lawsuit is to be filed with the president of the Court of First Instance. In addition to an injunction to cease the so challenged unfair trade practice

(possibly with an amount to be paid per breach to this injunction), the president of the Court of First Instance may order that the judgment be publicized.

Professional Codes of Conduct

In Belgium, the promotion of medicinal products is also governed by a code of conduct for pharmaceutical companies. The provisions of the code of conduct are self-regulatory rules adopted by "pharma.be," the Belgian association of the pharmaceutical industry. Over 90 percent of Belgian pharmaceutical companies are member of pharma.be and must therefore comply with the code of conduct.

The pharma.be code of conduct contains general rules with respect to the promotion of medicinal products. The most important are the following:

- Any communication that presents the properties of a medicinal product shall incite to a rational use of the product only and must be based on observations that are correct, true, objective, sufficient and verifiable; are in accordance with the most recent content of the approved file for marketing authorization; reflect the current generally accepted scientific opinions; and where appropriate, are supported by bibliographical references. Any communication (except for "reminder" advertising) shall mention the composition of the product, therapeutic indications, contra-indications and precautionary measures, side-effects, dosage and method of administration, available packaging, and the name and address of the company responsible for placing the product on the market.

  Promotion of medicinal products should be identifiable as such. Whenever published studies are mentioned, clear references shall be given. Where quotations and visual material are used, the source must always be mentioned.

- Comparisons with competing medicinal products - if necessary or useful - must establish the specific properties of the product with which it is compared in a manner that is fair, complete and scientific. They shall be based on the most recently available data.
- It may not be mentioned that a medicinal product presents neither side effect nor risk of dependency. Wording like "safe" and "without danger" or any other similar concept can only be used if clearly defined.

- All communications with respect to medicinal products must be internally examined and approved by professionally and scientifically qualified persons.
- Information and promotion relating to medicinal products may only be aimed at persons who can reasonably be supposed to need them or to be interested in them. The frequency of the promotion will depend on real needs and may not in any way hinder the recipient.
- Information or promotion from abroad is treated in the same way as that which originates in Belgium and must comply with the same regulations.

With respect to a number of practices regarded as promotional activities, the pharma.be code of conduct contains notably the following specific rules:

Samples - Article 29 stipulates that drug samples can only be given to persons qualified to prescribe medicinal products if they have submitted a written, signed and dated request to the company. It furthermore provides that companies must have an appropriate system for controlling distribution of samples. The words "free sample- may not be offered for sale" or any other words of similar meaning must appear on the outer packaging of the sample. It is to be noted that the pharma.be code of conduct does not implement the "4x2 standard" of Article 16 of the EFPIA HCP Code, this provision being more restrictive than the provisions of the Belgian Royal Decree of January 11, 1993 (see above).

Collective scientific meetings - Articles 30 to 37 regulate the organization of scientific events such as scientific seminars, congresses, symposiums, and visits to pharmaceutical companies, etc.

Pharmaceutical companies are authorized to organize or support such events provided that the event is of a scientific and professional nature , the hospitality offered at the event is restricted to healthcare professionals, the hospitality is limited to the duration of the event, secondary to the principal scientific purpose of the meeting, and the costs for travel, meals, accommodation and registration remains reasonable in level. The hospitality offered will not under any circumstances include sports or leisure activities or any other form of entertainment. Upon explicit request, spouses or partners may join the event provided that they bears all the costs of joining the event.

Sponsoring and Donations - Article 38 allows pharmaceutical companies to make any financial resources or other means of functioning available to third parties provided that they take all useful measures to be informed of the

destination and use of the means available. “Financial means or other operating means” is understood as subsidies, grants, scientific prizes, sponsoring, provision of services for humanitarian purposes.

Premium and Benefits - Article 40 has been adopted to mirror Article 10 of the Act of March 25, 1964 on Medicinal Products. Some examples of forbidden gifts and benefits are given. For instance, it is forbidden to offer presents in the personal interest of the beneficiary’s personnel, such as tickets for private sports events or other entertainment events or offer any form of hospitality, except as part of a collective scientific meeting. The prohibition of Article 40 does not, however, apply to remuneration for legitimate services of a scientific nature, provided that this remuneration remains within reasonable limits.

Non-interventional Studies - The code also establishes specific rules for non-interventional studies carried out by pharmaceutical companies (Articles 43 and 44 of the code), with the assistance of healthcare professionals. For this kind of studies, specific requirements listed under Article 44 must be complied with.

Violations of the abovementioned rules are subject to the following sanctions:

- Reprimand
- Injunction to cease the unlawful practices
- Injunction to take corrective and appropriate measures
- Publication of the decision of pharma.be in a review having a scientific or economic importance in the pharmaceutical industry

In addition, it must be noted that pharma.be may inform the Belgian Federal Agency for Medicinal and Health Products of substantial infringements. The Federal Agency for Medicinal and Health Products has the power to take further measures including filing a criminal complaint with the public prosecutor.

The pharma.be code of conduct supplements the EFPIA Code of Practice on the Promotion of Medicines and the IFPMA Code, the IFPMA Code of Pharmaceutical Marketing Practices, and since 2006, the Mdeon Code of Conduct. In case of inconsistency, the most constraining provision will prevail.

Professional Code of Conduct for Medical Devices

In Belgium, the promotion of medical devices is also governed by a code of conduct for medical device companies. The provisions of the code of conduct are self-regulatory rules adopted by the *Association des fabricants, importateurs et distributeurs des dispositifs médicaux ASBL / Beroepsvereniging van fabrikanten, invoerders en verdelers van medische hulpmiddelen VZW* ("UNAMEC"). This code has been substantially modified in 2011 to bring it in line notably with the Mdeon visa procedure.

The UNAMEC Code of Conduct contains *mutatis mutandis* the same general rules with respect to the promotion of medical devices as the pharma.be code of conduct. Those rules are set forth hereabove.

With respect to a number of practices regarded as promotional activities, the UNAMEC code of conduct also contains specific rules. Those rules are mainly similar to the rules set forth in the pharma.be code of conduct. Some minor differences, however, exist, notably the following:

Samples - Article 28 of the code states that samples can only be given to persons that have submitted a written request to the company provided that the samples are given to obtain an opinion on the quality of the product and supplied in limited quantity.

Loan or Putting at disposal of equipment - Article 29 of the code provides that equipment for medical, scientific or technical use can only be lent or put at disposal to medical or paramedical institutions in limited quantity to the benefit of patients, the medical community and the medical or paramedical institutions. Such loan or putting at disposal must be compliant with Article 10 of the Act of March 25, 1964 on Medicinal Products.

Collective Scientific Meetings - Articles 30 to 40 of the code define the rules for collective scientific meetings. Except for some details, these rules are basically similar to the rules provided in the pharma.be code of conduct.

Violations of the abovementioned rules are subject to the following sanctions: reprimand, publication, or exclusion from the UNAMEC. In addition, it must be noted that UNAMEC may decide to inform the Belgian Federal Agency for Medicinal and Health Products, who has the power to take further measures including filing a criminal complaint with the public prosecutor of substantial infringements.

Professional Code of Conduct for Physicians

The Code of Conduct for Physicians contains self-regulatory rules adopted by the *Ordre des Medécins/Orde van geneesheren* (i.e., Physicians Association). Each physician must comply with the code of conducts and is subject to disciplinary sanctions (warning, censure, reprimand, maximum of two years of suspension, disbarment) in case of non-compliance.

The code of conduct does not contain any specific rules which regulate the promotion of medicinal products or medical devices and the relationship between physicians and the healthcare industry.

However, as a general rule, Article 9 stipulates that "physicians must refrain from acting in a way that would jeopardise the honor and the dignity of his/her profession".

According to Article 173, any agreement between a physician (private/public employee and self-employed) and a non-physician which could have an impact on the ethical aspects of the physician's profession must prior to its signing be submitted in writing to the relevant provincial authority (i.e., *Ordre des médecins/ Orde van geneesheren*).

Article 174 further prohibits any agreement between a physician and a third party, which may restrict the "diagnostic or therapeutic freedom of the physician".

As a result, any agreement that provides for a pecuniary advantage for the physician in case he/she would decide on the use of medical devices of a specific brand could be considered as a restriction of the physician's freedom to determine, in the exclusive interest of his/her patients, whether or not certain medical devices must be used.

Mdeon's Common Deontological Code

Mdeon became operational on 15 November 2006. Mdeon is the common deontological platform created by the associations of physicians and pharmacists together with the pharmaceutical and medical device industries on 23 May 2006.

Mdeon's mission is to determine proactively the principles of a modern, transparent and effective self-regulatory instrument for the information on and promotion of drugs and medical devices and to ensure compliance.

In this respect, Mdeon has adopted a code of conduct that relates to premiums and benefits, collective scientific meetings and services of a scientific nature. The Mdeon Code of Conduct also provides for visas and consultation procedures:

- Visas procedure – Mdeon has been appointed to handle visa applications as provided in Article 10 §3 of the Act of March 25, 1964 on Medicinal Products. This legal provision puts in place a visa procedure for hospitality and participation costs offered at scientific events taking place during several calendar days. Prior to an event, pharmaceutical and medical device companies must obtain a visa from Mdeon for the hospitality and participation costs it wishes to offer to healthcare professionals practicing in Belgium. The procedure has been laid down in Mdeon's common deontological code.
- Consultation procedure – The healthcare industry and healthcare professionals can ask Mdeon's advice on questions with respect to premiums and benefits, collective scientific meetings and services of a scientific nature.

Liability Under Criminal Law

The Regulatory Framework

Anti-bribery rules apply potentially to everyone. The Belgian Criminal Code makes a distinction between public bribery (Articles 246 to 252 of the Belgian Criminal Code); and private bribery (Articles 504bis and 504ter of the Belgian Criminal Code). While the provisions on public bribery (see below) apply to individuals/legal entities exercising a public function[7], the provisions on private bribery (see below) apply to private individuals and legal entities of the private sector.

Public Bribery

According to Article 246 of the Belgian Criminal Code, any person holding a public office who accepts an offer, a gift or a promise in compensation of any

[7] The following legal entities are, however, not criminally liable under Belgian law: the federal state, the regions, the communities, the provinces, Brussels and its suburbs, the municipalities (multi-district zones), intra-local territorial organs, the French Community Commission, the Flemish Community Commission, the Joint Community Commission and the public centers for social welfare.

act or decision made in the framework of his/her function (even if the act or decision is, as such, legal and/or justified), commits public bribery.

According to the same article, any offer, gift or benefit granted or promised to a person holding a public office with a view to encouraging the latter to adopt a particular attitude within the scope of his/her responsibilities, may be qualified as public bribery.

Furthermore, Article 247, §4 of the Belgian Criminal Code prohibits influence peddling. Influence peddling may be defined as a tripartite process whereby one person exercises his/her influence on another person in order to obtain a favor for a third person.

For the purpose of applying public bribery regulations, a distinction must be made between healthcare professionals working in municipal hospitals ("CPAS-OCMW") or in hospitals run by state-owned universities and healthcare professionals working in private university hospitals subsidized by the government on the one hand, and healthcare professionals working for private hospitals on the other.

The regulations on public bribery only apply to the first category of healthcare professionals, as they are considered to hold a public office.

Private Bribery

According to Article 504bis and 504ter of the Belgian Criminal Code, any person who:

- in his/her capacity as director or manager of a legal entity, proxy holder or employee of a legal entity, or proxy holder or employee of a natural person;
- requests or accepts an offer, promise or benefit, on his/her own or on behalf of a third party, in exchange for adopting a particular attitude within the scope of his/her responsibilities; and
- without the authorization and knowledge of the board of directors, the general meeting of shareholders, the principal, or the employer, whichever case applies;

Commits Private Bribery

The same is possibly committed by any person offering a bribe to a private person, provided that the former is acting without authorization or knowledge of his/her superior(s).

Contrary to the regulations on public bribery, regulations on private bribery do apply to healthcare professionals working for private hospitals.

Permitted and Prohibited Activities

Gifts

Based on the legal provisions on public and private bribery mentioned above, any offer, gift or benefit granted or promised by a pharmaceutical company to a healthcare professional, with a view to encouraging him/her to cause the hospital to purchase certain medical products is prohibited.

It must be noted that even if the gift, offer or benefit is given to a third party (such as patient, medical association, family member), public and private bribery's provisions will apply.

However, customary gifts remain acceptable under the bribery regulations, provided that they are of a negligible value and relevant to the practice of medicine, dentistry, pharmacy or veterinary medicine. Neither in the law nor in the case law is there any indication as to what the value limit could be in order for a customary gift to be considered inexpensive. Due to the criminal nature of the offense, it can be assumed that the gift should in any case be of a very small value (e.g., diaries, calendars, pencils, post-its, writing paper).

Seminars and Hospitality

Based on the provisions on public bribery, healthcare professionals holding a public office (see "Public Bribery*"* above) may be invited to scientific seminars or conferences and may be offered the same seminar materials, writing materials, ordinary meals or refreshments as provided to all attendees. However, healthcare professionals holding a public office may not be offered travel and living expenses incurred for attending a seminar or conference, unless they are invited to speak at such seminar or conference. If permitted at all, travel and living expenses are in any case subject to the prior approval of the public official's supervisor, must be reasonable in level, restricted to healthcare professionals and directly related to the seminar or conference, and not for any extended stay, side trips, etc.

Based on the provisions on private bribery, healthcare professionals working for private hospitals (see "Private Bribery" above) may be invited to scientific seminars or conferences and may be provided with the same seminar materials, writing materials, ordinary meals or refreshments as provided to all attendees. Contrary to healthcare professionals holding a public office, healthcare professionals working for private hospitals may be

reimbursed for travel expenses related to seminars or conferences. However, the travel and living expenses must still remain reasonable in level, restricted to healthcare professionals and related to the seminar or conference.

With respect to scientific events taking place during several calendar days, reference is made to the information in "Seminars and Hospitality" and "Professional Codes of Conduct," above.

Entertainment

Based on the legal provisions on public and private bribery, pharmaceutical and medical device companies are allowed to invite healthcare professionals for entertainment if reasonably priced (e.g., business breakfast or business dinner following a scientific meeting).

However, it would not be considered appropriate to invite healthcare professionals to locations such as a cabaret, night club. Entertainment must indeed be customary, business-orientated and infrequent.

Public Procurement and Fraud

Pharmaceutical and medical device companies which are involved in public procurement procedures and which commit public bribery may be excluded from participating in any present or future public procurement.

Furthermore, healthcare professionals involved in public procurement's fraud may be dismissed from their function and bared from any public function for a period of five to 10 years and/or any other function listed in Article 31 of the Criminal Code.

Article 314 of the Belgian Criminal Code should also be briefly mentioned. This provision sanctions the individuals who, in adjudicating procedure, perturb the freedom of auctions and/or submissions by way of violence, force, gifts, promises or any other fraudulent means, by imprisonment of 15 days to six months and a fine from EUR550 up to EUR16,500.

Pharmaceutical and medical device companies (in their capacity of legal entities) who, in adjudicating procedure, perturb the freedom of auctions and/or submissions by way of violence, force, gifts, promises or any other fraudulent means, are punishable with a fine from EUR3,000 to EUR72,000.

Sanctions

Public Bribery

Public bribery committed by an individual is punishable with imprisonment from six months to 15 years and/or fines up to EUR600,000.

Public bribery committed by pharmaceutical and medical device companies (in their capacity as legal entities) is punishable with a fine from EUR18,000 up to EUR2,160,00.

Private Bribery

Private bribery committed by an individual is punishable with imprisonment from six months to three years and/or fines up to EUR300,000.

Private bribery committed by pharmaceutical and medical device companies (in their capacity of legal entities) is punishable with a fine from EUR18,000 up to EUR432,000.

Contracts with Healthcare Professionals and Medical Institutions

The Regulatory Framework

Article 18, §2 of the Royal Decree of November 10, 1967 on the Performance of Medical Profession explicitly prohibits "agreements between practitioners (i.e., physicians, pharmacists, midwives, and physiotherapists) and third parties, particularly, manufacturers of medical products and suppliers of medical or prosthesis equipment, if said agreements have an influence on their profession and provide any direct or indirect benefit or advantage for either party.

Although the royal decree does not give any indication as to what exactly is meant by "influence on their profession," one may reasonably assume that any influence on the prescription behavior of a physician is intended to be encompassed.

A physician who violates the above rule risks a fine in the amount of EUR156 to EUR3,000. Moreover, the contracting party (e.g., the pharmaceutical company) can be deemed an accomplice to said offense.

Any excessive compensation paid to a healthcare professional or medical institution for research or consultancy work shall also be caught by the

prohibition of Article 10 of the Act of March 25, 1964 on Medicinal Products.

According to Article 173 Code of the Conduct for Physicians, any agreement between a physician and a non-physician which could have an impact on the ethical aspects of the physician's profession must, prior to its signing, be submitted in writing to the relevant provincial authority of the Physicians' Association (i.e., *Ordre des médecins/Orde van geneesheren*).[8]

Article 174 further prohibits any agreement between a physician and a third party which may restrict the "diagnostic or therapeutic freedom of the physician."

Any agreement which provides for a pecuniary advantage for the physician in case he/she would prescribe, use medical products of a specific brand, or decide on the use of medical devices of a specific brand, could be considered as a restriction of the physician's freedom to determine, in the exclusive interest of his/her patient, whether or not certain medical products/medical devices must be prescribed or used.

The provisions of the Act of May 7, 2004 concerning experiments on the human person shall apply in case the contract with a healthcare professional or medical institution relates to an experiment or a clinical trial as defined in this Act.

Permitted and Prohibited Agreements

Although the wording of Article 18, §2 of the Royal Decree of November 10, 1967 on the Performance of Medical Profession is extremely broad, it cannot be interpreted as prohibiting all kind of agreements.

In this respect, a pharmaceutical company is allowed, under Belgian law, to enter into speaker agreements, consultancy agreements, research agreements proctorship agreements, clinical trial agreements., with physicians provided that the following principles are taken into consideration:

[8] This is an obligation of the physician, not of the pharmaceutical/medical device company. There is no sanction for the pharmaceutical/medical device company in the event the physician does not submit his/her agreement to the Physicians' Association. In practice, most of the Belgian physicians have a tendency to "conveniently" not submit such agreements, the approval procedure being extremely slow.

- The physician must remain free to determine his/her prescription behavior and in his/her use of medical devices. The compensation paid to the physician would be deemed illegal, if and to the extent it induces the physician to prescribe or use certain products, as it could possibly be linked to a purchase undertaking. Consequently, agreements should be drafted with due care, emphasizing as much as possible the freedom of the physician.
- The compensation paid to the physician for his/her research work, the services rendered, the clinical trial conducted must be reasonable and represent the fair market value.
- Before entering into any agreement with a physician, it is very important to take into account the possible employment contract the latter could have entered into with a hospital, and to obtain sufficient confirmation that no provision in such employment contract prohibits or restricts such agreement.

There exists a case in which an agreement between a physician and a third party was voided on the basis of Article 18,§2 of the Royal Decree of November 10, 1967 on the Performance of Medical Profession. The Belgian Supreme Court held that an agreement between a pathology laboratory and a physician pursuant to which the latter was entitled to a commission on every blood test that was carried out by the laboratory upon the physician's prescription, violates Article 18, §2 of the royal decree.

Czech Republic

Patrik Kastner

Úvod

V průběhu posledních let podnikla Česká republika množství významných kroků směřujících k harmonizaci právních norem a předpisů s legislativou Evropské unie (dále jen „EU"), a to včetně zákonů a předpisů vztahujících se na farmaceutický průmysl. V důsledku tohoto procesu jsou v současné době zákony a předpisy týkající se reklamy ve farmaceutickém průmyslu v České republice obecně v souladu s příslušnými předpisy EU. Stanoveným cílem české legislativy je soulad etiky a norem ve farmaceutickém průmyslu se zahrnutím odborného a objektivního poskytování zdravotní péče zákazníkům či pacientům.

Obdobně byly do české právní úpravy implementovány i hlavní směrnice EU týkající se farmaceutické oblasti, a to včetně směrnice č. 92/28/ES o reklamě na humánní léčivé přípravky, která byla začleněna do směrnice č. 2001/83/ES o kodexu společenství týkajícím se humánních léčivých přípravků (ve znění směrnice EU 2004/27/ES) a směrnice Rady č. 84/450/EHS o klamavé a srovnávací reklamě (ve znění Směrnice č. 97/55/ES). Český právní řád tedy splňuje požadavky stanovené příslušnou evropskou legislativou.

Omezení dle zákona o reklamě ve farmaceutické oblasti

Zákonný rámec

Základní pravidla upravující reklamu na humánní léčivé přípravky (jak je definována níže) jsou stanovena v zák. č. 40/1995 Sb., o regulaci reklamy, ve znění pozdějších úprav (dále jen „zákon o reklamě"), zák. č. 378/2007 Sb., o léčivech a změnách a doplnění některých souvisejících zákonů, ve znění pozdějších úprav (dále jen „zákon o léčivech") a zák. č. 513/1991 Sb., obchodní zákoník, v platném znění (dále jen „obchodní zákoník"). V případě, že reklama na humánní léčivé přípravky či jiné jednání v rámci farmaceutického průmyslu

mohou mít negativní dopad na hospodářskou soutěž, budou se na ně vztahovat také ustanovení zák. č. 143/2001 Sb., o ochraně hospodářské soutěže, ve znění pozdějších úprav (dále jen „zákon o hospodářské soutěži").

Czech Republic

Patrik Kastner

Introduction

The Czech Republic has taken a number of important steps towards harmonizing its legal norms and regulations with legislation of the European Union ("EU") during recent years, including relevant laws and regulations covering the pharmaceutical industry. As a result of this process, laws and regulations applicable to pharmaceutical advertising in the Czech Republic are generally in line with relevant EU directives. The stated objective of the Czech legislator is compliance with ethics and norms in the pharmaceutical industry, including professional and objective provision of healthcare to consumers/patients.

Accordingly, the principal EU directives in the pharmaceutical field have been implemented into Czech law, including the Directive on Advertising of Medicinal Products for Human Use, which has since been integrated into the Directive on Community Code relating to medicinal products for human use (as amended), and concerning misleading and comparative advertising (as amended). Thus, Czech law generally satisfies the requirements set forth in the relevant European legislation.

Restrictions Under Advertising Law

The Regulatory Framework

The principal rules governing the advertising of human pharmaceuticals (as defined below) are set out in Act No. 40/1995 Coll. on the Regulation of Advertising, as amended ("Act on Advertising"), Act No. 378/2007 Coll. on Pharmaceuticals and Changes and Amendments to Certain Related Laws, as amended ("Act on Pharmaceuticals"), and in Act No. 513/1991 Coll. Commercial Code, as amended ("Commercial Code"). In addition, the relevant provisions of Act No. 143/2001 Coll. on the Protection of Economic Competition ("Competition Act"), as amended, are applicable in the event that the advertising of pharmaceuticals or other conduct in the pharmaceutical industry is likely to have a negative effect on economic competition.

Zákon o reklamě

Zákon o reklamě stanovuje obecná pravidla reklamy zboží a služeb a jeho součástí jsou i zvláštní ustanovení týkající reklamy na humánní léčivé přípravky (ust. § 5, 5a a 5b zákona o reklamě). Tato zvláštní ustanovení zákona o reklamě se vztahují na jakoukoliv reklamu (včetně reklamy směrované na odborníky v oboru zdravotnictví i na širokou veřejnost) na humánní léčivé přípravky, včetně originálních, generických a homeopatických léčiv. Tato pravidla se dále vztahují na reklamu vyhrazených léčiv registrovaných u příslušného úřadu dle zákona o reklamě. Aplikace ustanovení zákona o reklamě musí být uvážena i u potravinových výrobků a potravinových doplňků v případě, že reklama odkazuje na diagnózu, prevenci, odstranění nebo vyléčení nemocí, stavu nebo zranění u lidí.

Jelikož původní ustanovení § 5c zákona o reklamě týkající se reklamy na zdravotnické prostředky bylo zrušeno dodatkem č. 25/2006 Sb. (dále jen „dodatek") k 26. lednu 2006, řídí se reklama na zdravotnické prostředky pouze obecnými ustanoveními zákona o reklamě a příslušnými právními předpisy.

Do zákona o reklamě bylo dodatkem začleněno nové ustanovení § 5h o reklamě na veterinární léčivé přípravky, kterým se zavádějí nová omezení reklamy této kategorie léčivých přípravků (viz podrobné informace v ustanovení o povolených a zakázaných činnostech).

Podle zákona o reklamě znamená „reklama" jakékoliv oznámení, předvedení či jinou prezentaci šířenou zejména komunikačními médii, mající za cíl podporu podnikatelské činnosti, především spotřeby či prodeje zboží, výstavby, nájmu či prodeje nemovitostí, prodeje či užívání práv nebo závazků, poskytování služeb nebo propagace ochranné známky.

Zákon o reklamě rozšiřuje definici reklamy na humánní léčivé přípravky následujícím způsobem: „reklama na humánní léčivé přípravky" znamená vedle činností uvedených v definici reklamy také všechny informace, přesvědčování nebo pobídky určené k podpoře předepisování, dodávání, prodeje, výdeje či konzumace humánních léčivých přípravků, a to ve formě: (i) návštěv obchodního zástupce u osob oprávněných předepisovat, dodávat či vydávat humánní léčivé přípravky, (ii) dodávání vzorků léčivých přípravků, (iii) daru, spotřebitelské soutěže a nabídky nebo příslibu jakéhokoliv prospěchu nebo finanční či věcné odměny, (iv) sponzorování setkání konaných za účelem podpory předepisování, prodeje, výdeje nebo spotřeby humánních léčivých přípravků a navštěvovaných odborníky a (v)

Act on Advertising

The Act on Advertising provides general advertising rules applicable to any goods and services, and also contains special regulations for the advertising of pharmaceutical products. Such special provisions of the Act on Advertising are applicable to any advertising (including advertising aimed at healthcare professionals and the general public) of pharmaceuticals, including proprietary as well as generic and homeopathic drugs. In addition, these rules also apply to the advertising of reserved pharmaceuticals, which can be promoted only if duly registered with the Authority, under the Act on Pharmaceuticals. Moreover, regulations of the Act on Advertising are to be considered regarding food products and food additives if advertising statements refer to diagnosis, prevention, removal or alleviation of diseases, conditions or bodily injury in humans.

Since the former provision of the Act on Advertising regarding the advertising of medical devices was deleted from the Act on Advertising as of 26 January 2006, the advertising of medical devices is now only governed by the general provisions of the Act on Advertising and other applicable laws.

The Act on Advertising has been amended to include a new section on the advertising of veterinary medicines, which introduced certain new limitations on the advertising of this category of medicines (see section on “Permitted and prohibited practices” below).

“Advertising” means any announcement, demonstration or other presentation, circulated primarily through communications media, intended to support economic activity; in particular, consumption or sale of goods; construction, lease or sale of real estate; sale or use of rights or obligations; provision of services, or promotion of a trademark.

In addition, the Act on Advertising extends the definition of advertising in relation to pharmaceuticals as follows: “advertising of human pharmaceuticals” means, in addition to the activities included in the definition of advertising, any information, persuasion or incentive provided in order to support the prescription, supply, sale, dispensing or consumption of pharmaceuticals in the form of visits by commercial representatives of persons authorized to prescribe, supply or dispense human pharmaceuticals; supply of samples of pharmaceuticals; a gift, consumer’s lottery or offer of any benefit or financial or other reward; sponsoring of meetings organized for the purpose of support of the prescription, sale, dispensing or

sponzorování vědeckých kongresů s účastí odborníků a úhrady nákladů na cestovné a ubytování souvisejících s jejich účastí.

Koncepce reklamy podle zákona o reklamě také zahrnuje objektivně prezentované faktické informace, jako například odborné publikace, pokud jsou využívány společnostmi k propagaci prodeje, předepisování nebo konzumaci jejich výrobků – humánních léčivých přípravků. Pravidla a omezení stanovená zákonem o reklamě však platí pouze v souvislosti s reklamou na konkrétní nebo identifikovatelné léčivé přípravky. Pokud společnost své výrobky nebo služby propaguje v obecné rovině nebo na základě svého dobrého jména nebo nekonkrétním způsobem zdůrazňuje kvalitu a hodnotu svých výrobků, aniž by upozorňovala (ať již odborníky nebo případně širokou veřejnost) na konkrétní nebo identifikovatelný výrobek, pak se taková reklama neřídí konkrétními ustanoveními zákona o reklamě na humánní léčivé přípravky, ale obecnými ustanoveními tohoto zákona. Totéž se týká i zveřejňování informací ohledně onemocnění, aniž by byl zmíněn konkrétní nebo identifikovatelný léčivý přípravek.

Zákon o reklamě se dále nevztahuje na: (i) označování humánních léčivých přípravků a příbalové informace podle zvláštních právních předpisů, (ii) korespondenci nutnou k zodpovězení specifických dotazů na konkrétní humánní léčivý přípravek a případné doprovodné materiály nereklamní povahy, (iii) prodejní katalogy a ceníky, pokud neobsahují popis vlastností humánních léčivých přípravků, na oznámení, upozornění a poskytnutí informací, týkajících se například změn balení nebo na varování před nežádoucími účinky humánního léčivého přípravku, a (iv) údaje o lidském zdraví nebo onemocněních, pokud neobsahují žádný odkaz, a to ani nepřímý, na humánní léčivý přípravek.

Dále je třeba poznamenat, že dle zákona o reklamě se obecně povoluje srovnávací reklama na humánní léčivé přípravky nebo lékařskou péči, avšak pouze tehdy, jsou-li dodržena zvláštní pravidla uvedená v obchodním zákoníku (viz podrobné informace v ustanovení ohledně povolených a zakázaných činností).

Podle zákona o reklamě je Státní ústav pro kontrolu léčiv (dále jen „úřad") regulatorním orgánem provádějícím dozor v oblasti reklamy na humánní léčivé přípravky, s výjimkou reklamy v rozhlasovém a televizním vysílání, u kterých je dozor prováděn Radou pro rozhlasové a televizní vysílání. V rámci své praxe a dozorčí funkce vydal Státní ústav pro kontrolu léčiv mnoho směrnic a pokynů s výkladem výše uvedených právních předpisů ohledně reklamy na léčivé přípravky.

consumption of human pharmaceuticals and attended by healthcare professionals; and sponsoring of scientific congresses attended by healthcare professionals and reimbursement of travelling and accommodation expenses relating to their attendance.

The concept of advertising under the Act on Advertising also includes objectively presented factual information, such as scientific publications, if used by companies to promote the sale, prescription or consumption of their human pharmaceuticals products. Regulations and restrictions of the Act on Advertising are only applicable, however, with regard to the advertising of certain or identifiable medicinal products. If a company advertises its products or services in general or by its reputation, or emphasizes in a non-specific manner the quality and good value of its products without drawing attention (either to healthcare professionals or, as the case may be, the general public) to a certain or identifiable pharmaceutical product, such advertising is not regulated by the special provisions of the Act on Advertising but is subject only to the general provisions of this law. The same applies to publication of information regarding a disease, without mentioning a particular or identifiable medicinal product.

Moreover, the Act on Advertising does not apply to labeling of medicinal products and information included in patient information leaflets, according to applicable laws; correspondence and documents which do not serve advertising purposes, but are used in order to respond to an individual inquiry regarding a particular medicine; sales catalog and price lists, unless they include a description of the pharmaceuticals' characteristics, announcements, notices and provision of information relating, *inter alia*, to changes in packaging, or to warnings against adverse effects of any human medicine; and information on human health or disease, unless it contains any reference (even a hidden reference) to a human medicinal product.

It should also be noted that, according to the Act on Advertising, comparative advertising of medical products is generally permissible, provided however that special rules included in the Commercial Code are complied with (see section on "Permitted and prohibited practices" for more details).

According to the Act on Advertising, the State Institute for Drug Control ("Authority") is the regulatory authority in the area of advertising medicinal products, with the exception, however, of advertising on radio and television, which is supervised by the Council for Radio and Television Broadcasting.

Pojmy a definice

Vedle pojmů, které jsou již v tomto dokumentu užívány, patří následující pojmy k základním definicím, které odpovídají reklamní činnosti v oblasti farmaceutického průmyslu a mají význam pro analýzu uvedenou v této kapitole:

„odborník" pro účely reklamy na humánní léčivé přípravky znamená jakoukoliv osobu pověřenou předepisovat, vydávat humánní léčivé přípravky. Dle současného výkladu úřadu může být za odborníka považována též osoba právnická (viz níže detailní výklad v odstavci *Dary*).

„humánní léčivé přípravky" znamenají jakýkoliv léčivý přípravek, který je určen k podání lidem. „Léčivý přípravek" znamená jakoukoliv látku či kombinaci látek určenou k léčbě či předcházení nemoci u lidí nebo zvířat, k určení diagnózy nebo k obnově, úpravě či ovlivnění fyziologických funkcí.

„zdravotnický prostředek" znamená jakýkoliv nástroj, přístroj, pomůcku, instrument, zařízení, materiál či jinou věc nebo výrobek užívaný samostatně či kombinovaně, včetně jakéhokoliv příslušného softwaru, který je výrobcem či dovozcem určen k humánnímu užití, tj. k:

a. diagnostice, prevenci, pozorování, léčbě či zmírnění nemoci;
b. diagnostice, pozorování, léčbě, zmírnění následků zranění či zdravotního postižení;
c. vyšetření, náhradě či úpravě anatomické struktury či fyziologického procesu; nebo
d. kontrole početí.

„vyhrazená léčiva" znamenají humánní léčivé přípravky, které mohou být v souladu s rozhodnutím o registraci volně prodejné i mimo lékárny.

In connection with its practice and supervising role, the Authority has issued a number of guidelines and instructions interpreting the abovementioned laws concerning advertising medicinal products.

Terms and Definitions

In addition to the terms already used above, the following basic definitions are relevant to advertising activities in the pharmaceutical industry, and significant to the analysis included in this chapter:

"Healthcare professional," for the purposes of advertising pharmaceuticals, means any person authorized to prescribe or dispense human pharmaceuticals. According to the Authority's current interpretation, "healthcare profession" may also include legal entities (see more detailed discussion in "Gifts" below).

"Human pharmaceutical" means any medicinal substance intended for administration to humans; "medicinal substance" means any substance or combination of substances which is intended for the treatment or prevention of human or veterinary diseases, for making a diagnosis, or for the regeneration or modification of physiological functions.

"Medical device" means any tool, device, instrument, equipment, material or other object or product utilized separately or in combination, including any requisite software, which is intended by its manufacturer or importer for use on humans in connection with: making a diagnosis, or the prevention, monitoring, treatment or moderation of a disease; making a diagnosis, or the monitoring, treatment, moderation of or compensation for injury or health handicap; the examination, replacement or modification of an anatomic structure or physiological process; or contraception.

"Reserved pharmaceuticals" means human pharmaceuticals that can, according to a registration decision, be sold without a medical prescription outside pharmacies.

Competition Law

As of the date of accession of the Czech Republic to the EU, on 1 May 2004, the system of concurrent application of EU competition rules and national rules was put in place. The Community competition rules prevail over national rules (by excluding the application of national rules), provided that the anti-competitive conduct of an undertaking could potentially affect trade between member states and distort competition in the Common Market.

Zákon o hospodářské soutěži

K 1. květnu 2004, kdy Česká republika přistoupila k EU, byl zaveden systém souběžné aplikace pravidel hospodářské soutěže platných v EU a v České republice. Pravidla hospodářské soutěže platná v Evropském společenství mají přednost před pravidly tuzemskými (vyloučením aplikace tuzemských pravidel) s tím, že jednání podniku porušující hospodářskou soutěž by mohlo případně porušit obchodování mezi členskými státy a narušit hospodářskou soutěž na společném trhu.

Vzhledem k tomu, že farmaceutický průmysl představuje vysoce konkurenční, rychle se rozvíjející trh, jehož struktura se mění v závislosti na probíhajícím výzkumu a vývoji nových výrobků a prostředků, a také vzhledem ke slučování mezi soutěžiteli musí být pravidla hospodářské soutěže dodržována jak v souvislosti s marketingem (distribucí), tak v souvislosti s propagací vedenou farmaceutickými společnostmi.

Farmaceutické společnosti by měly především s rozvahou připravit a uplatňovat jakákoliv cenová schémata a systémy slev, které nabízejí svým klientům. To se především vztahuje na situace, kdy výrobek společnosti dosáhne (nebo je velmi blízko[1]) dominantního postavení na relevantním trhu, aby se předešlo porušení ustanovení Smlouvy o založení Evropského společenství a zákona o hospodářské soutěži, kterými se omezuje nezákonné jednání jednoho či více soutěžitelů na úkor spotřebitelů nebo ostatních soutěžitelů. V tomto kontextu je obvykle velmi důležité, aby se za účelem ověření existence dominantního postavení společnosti na trhu správně definoval relevantní trh.[2]

[1] Podle rozhodovací praxe Komise nezaujímají podniky s tržním podílem menším než 25 % dominantní postavení na daném trhu (viz především Úvodní ustanovení 32 Nařízení rady (ES) č. 139/2004 z 20. ledna 2004 o kontrole spojování soutěžitelů). Při zvažování problematiky dominantního postavení je třeba vzít tuto skutečnost na vědomí.

[2] V souladu s rozhodovací praxí Evropské komise (dále jen „Komise" – např. případ č. IV/36, 957/F3 ze dne 8. května 2001 ve věci Glaxo Wellcome, odst. 110) by měl být příslušný trh farmaceutických výrobků definován odkazem na třetí stupeň ATC, ve kterém jsou uvedeny terapeutické/farmakologické podskupiny léčiv. Zastupitelnost výrobků závisí na indikaci, ke které jsou schváleny a užívány.

As the pharmaceutical industry represents a highly competitive market which, at the same time, is quickly evolving, and its structure is also changing due to continuing research and development of new products and devices, as well as mergers between competitors, the competition rules must be observed in connection with both marketing (distribution) as well as promotional activities conducted by pharmaceutical companies.

In particular, pharmaceutical companies should carefully prepare and apply any pricing schemes and discount systems offered to their customers. This applies, in particular, in the situation where a company's product reaches (or is even close to[1]) the threshold of dominance in the relevant market, in order to avoid infringement of the provisions of the EC Treaty and the Competition Act, which restrict abusive behavior to the detriment of consumers or competitors by one or more undertakings in a dominant position. In this context, it is usually of crucial importance for purposes of verifying the existence of a dominant position on the part of a company to correctly define the relevant market.[2]

Where the market share constantly reaches or, even slightly, exceeds the threshold representing dominance, it is necessary to consider whether any discounts provided do not have illegal loyalty-inducing effects and do not foreclose the market to other competitors by tying up the customers.

Furthermore, any interactions between competitors in the pharmaceutical market should be made in strict compliance with the relevant competition rules restricting agreements (whether in written form or otherwise) which result or may result in the distortion of competition (e.g., cartels, fixing of prices or discriminating commercial terms).

[1] Please note that according to the Commission's practice, undertakings with market shares of no more than 25% are not likely to enjoy a single dominant position in the market concerned. When assessing the existence of dominance, it is necessary to take this into account.

[2] Consistently with the decision-making practice of the European Commission, a relevant pharmaceutical product market should be defined by reference to the third ATC level, which reflects the therapeutical/pharmacological subgroups of drugs. Ultimately, however, substitutability of products depends on the indication for which they are approved and used.

V případech, kdy tržní podíl nepřetržitě dosahuje nebo mírně přesahuje limit představující dominantní postavení, je nezbytné zvážit, zda-li poskytované slevy nemají nezákonný účinek vynucené loajality a vázáním spotřebitelů nevylučují ostatní soutěžitele z hospodářské soutěže.

Jakékoliv vzájemné působení mezi soutěžiteli na farmaceutickém trhu, v jehož důsledku dochází nebo může dojít k narušení hospodářské soutěže (např. kartely, určování cen nebo diskriminující obchodní podmínky), by mělo probíhat v přísném souladu se smlouvami vymezujícími příslušná pravidla hospodářské soutěže (ať již v písemné či jiné podobě).

Povolené a zakázané činnosti

Následující článek podává výčet povolených a zakázaných praktik vztahujících se k reklamě na humánní léčivé přípravky v rámci vztahů mezi farmaceutickými společnostmi a distributory na jedné straně a lékařskými zařízeními a jednotlivými odborníky na straně druhé. Toto shrnutí je založeno na analýze zákonů a předpisů odkazujících na výše uvedené a na aplikaci příslušných zákonů úřadem.

Dary, semináře, pohoštění a zábava

Dary

Podle obecného principu stanoveného zákonem o reklamě lze dary nebo jiné výhody přislíbit či poskytnout jednotlivým odborníkům v souvislosti s propagací léčivých přípravků pouze tehdy, pokud jsou tyto dary či jiné výhody nepatrné hodnoty *a* týkají se činnosti odborníka. Na základě rozhodnutí úřadu[3] činí nepatrná hodnota 1.500,- Kč (cca 60,- Eur), včetně všech darů poskytovaných konkrétním dárcem (farmaceutickou firmou, distributorem atd.) jednotlivým odborníkům v rámci konkrétního kalendářního roku.[4] Co se týká požadavku na relevanci daru k činnosti

[3] Úřad není zákonem o reklamě výslovně pověřen, aby vydával jakákoliv nařízení nebo jiné obecně závazné předpisy, kterými by se prováděla ustanovení zákona (včetně pojmu „nepatrná hodnota"). Z přísně technicko-právního hlediska tudíž nejsou obecná rozhodnutí úřadu (na rozdíl od rozhodnutí učiněných v rámci konkrétního správního řízení) právně závazná; jelikož však je úřad pověřen výkonem dozoru nad jakýmikoliv reklamními činnostmi ve farmaceutické oblasti, jsou jeho rozhodnutí a zveřejněná stanoviska obecně respektována a považována za závazná.

[4] Zákazy v tomto odstavci jsou podrobně uvedeny v předpisech řídících propagaci humánních léčivých přípravků, vyhlášených úřadem (regulačním orgánem dohlížejícím na propagaci humánních léčivých přípravků v České republice).

Permitted and Prohibited Practices

The following section outlines permitted and prohibited practices relating to the advertising of human pharmaceuticals in the context of relationships between pharmaceutical companies and distributors on the one hand, and medical facilities and individual healthcare professionals on the other. This summary is based on an analysis of the laws and regulations referred to above, as well as the application of the relevant laws by the Authority.

Gifts

According to the general principle stipulated in the Act on Advertising, gifts or other benefits can be promised or provided to individual healthcare professionals in connection with the advertising of human pharmaceuticals only if the gift or other benefit is of a small nominal value and related to the healthcare professional's expert activities. According to a resolution by the Authority,[3] "small nominal value" means CZK1,500 (approximately EUR60), including all gifts provided by the particular donor (pharmaceutical company, distributor, etc.) to an individual healthcare professional in a particular calendar year.[4] Concerning the requirement for relevance of the gift to the healthcare professional's expert activity, it is generally understood and approved by the Authority that items including, *inter alia*, stationery, diaries or calendars, professional literature or small instruments, are acceptable. These rules also apply to gifts provided in the form of prizes in various competitions or lotteries aimed at or participated in by healthcare professionals.

[3] In general, please note that the Authority is not explicitly authorized in the Act on Advertising to issue any decrees or other generally binding regulations that would implement the provision of the law (including the term "small nominal value"). Thus, from a strictly technical-legal point of view, general resolutions of the Authority (as opposed to decisions adopted in concrete administrative proceedings) are not legally binding; however, since the Authority is vested with the competence to supervise any pharmaceuticals advertising activities, its resolutions and published opinions are commonly respected and viewed as binding.

[4] The prohibitions summarized in this paragraph are implemented in detailed regulations governing the promotion of human pharmaceuticals promulgated by the Authority (the regulatory body supervising the promotion of human pharmaceuticals in the Czech Republic).

odborníka, má se za to a je úřadem schváleno, že předměty jako kancelářské potřeby, diáře nebo kalendáře, odborná literatura nebo drobné nástroje lze akceptovat. Výše uvedené pravidlo se vztahuje také na dary poskytované ve formě ocenění v různých soutěžích nebo spotřebitelských soutěžích, které jsou zaměřeny na odborníky nebo kterých se odborníci přímo účastní.

Ustanovení o darech a jiných výhodách jednotlivým odborníkům (fyzickým osobám) se dle výkladu úřadu vztahují i na dary, příspěvky či jinou podporu (dále jen souhrnně „podpora") poskytnuté nemocnici či jinému zdravotnickému zařízení jako právnické osobě, nicméně tento výklad je předmětem silné kritiky z řad odborné veřejnost a je nutné poznamenat, že se nejedná se o výklad všeobecně závazný, je však nutné upozornit, že úřad za takové porušení již udělil pokutu.

V případě, že by byl pojem odborník vykládán výlučně jako zahrnující pouze fyzické osoby, mohla by být podpora poskytována nemocnicím – právnickým osobám – vlastněným státem a nestátním zdravotnickým zařízením provozujícím svou činnost na základě zák. č. 372/2011 Sb., o zdravotních službách.

Podpora může být poskytována také nestátním zdravotnickým zařízením provozovaným jediným lékařem, aniž by tím došlo k porušení zákona o reklamě. Tento postup je možný, neboť lékař nemůže mít statut nestátního zdravotnického zařízení, může být pouze osobou provozující takové nestátní zdravotnické zařízení a je nahlížen jako osoba oddělená od nestátního zdravotnického zařízení jako takového. V případě nestátní nemocnice provozované jediným lékařem (nebo malou skupinou lékařů) musí dárce zajistit, aby byla podpora skutečně poskytována nestátní nemocnici, nikoliv lékaři/lékařům provozujícímu/provozujícím nemocnici. Je třeba poznamenat, že úřad je v této otázce spíše konzervativní a věnuje podpoře poskytované nestátním nemocnicím provozovaným jedním či více lékaři zvýšenou pozornost.

Provisions of gifts and other benefits to individual healthcare professionals includes, according to the Authority's interpretation of the Act on Advertising, gifts, donations or other support (collectively referred to as "support") provided to a hospital or other medical facility as a legal entity. However, such interpretation is subject to strong criticism by the professional public and it needs to be mentioned that the interpretation is not generally binding. Nonetheless, a sanction has been imposed for such a breach.

If the term "healthcare professional" is construed exclusively as including only natural persons, it would be possible to provide support to hospitals – legal entities – owned by the state or a private medical facility conducting its activity on the basis of Act No. 372/2011 Sb., on healthcare services.

Furthermore, support can also be provided to a private hospital operated by a single physician without breaching the Act on Advertising. This is possible because, although a physician cannot have the status of a private hospital, he or she can be an operator of a private hospital and, therefore, be viewed as separate and distinct from the private hospital itself. Nevertheless, in the case of a private hospital operated by a single physician (or a small group of physicians), the donor must ensure that the support is indeed provided to the private hospital and not to the physician(s) operating the hospital. It should be noted, in this context, that the Authority tends to be more conservative and pays more attention to support provided to private hospitals operated by one physician or a small group of physicians.

Seminars and Promotional Events

For the purposes of the description of allowed activities concerning seminars and other scientific events as well as promotional meetings, it is crucial to define the term "sponsoring." According to the Act on Advertising, "sponsoring" means a contribution which is made in order to support the production or sale of the products of, or the provision of services by, the sponsor. Any legal entity or individual can be a sponsor. According to the interpretation of "sponsoring activities" by the Authority in the pharmaceutical sector, "sponsoring" shall mean the provision of a financial or other contribution to the organizer of: a seminar, scientific congress or symposium; or a meeting organized in order to support the prescription, sale, supply or consumption of human pharmaceuticals, attended by pharmaceutical professionals.

Semináře a propagační akce

Abychom mohli popsat povolené činnosti týkající se seminářů a jiných odborných a propagačních akcí, je nezbytné definovat pojem sponzorství. Podle zákona o reklamě znamená „sponzorství" příspěvek poskytnutý s cílem podporovat výrobu nebo prodej zboží, poskytování služeb nebo jiné výkony sponzora. Sponzorem může být právnická nebo fyzická osoba. Podle toho, jak pojem sponzorství ve farmaceutické oblasti vykládá úřad, znamená sponzorství poskytování finančního nebo jiného příspěvku organizátorovi (i) semináře, vědeckého kongresu nebo sympozia nebo (ii) setkání odborníků za účelem podpory předepisování, prodeje, výdeje nebo užívání humánních léčivých přípravků.

Zákon o reklamě povoluje sponzorování organizace seminářů, vědeckých kongresů nebo sympozií včetně úhrady nákladů odborníků na dopravu, ubytování a zápisné, které jim vznikly v důsledku účasti na takových vědeckých akcích.

Zákon taktéž povoluje sponzorování propagačních setkání za účelem podpory předepisování, prodeje, dodávky či užívání humánních léčivých přípravků. Částka sponzorského příspěvku organizátorovi akce není zákonem omezena. V souvislosti se sponzorstvím propagačních akcí však není povoleno hradit odborníkům náklady na dopravu, ubytování či zápisné nebo jim poskytovat jiné výhody. Sponzor může odborníkovi, který se účastní propagační akce, poskytnout dary nepatrné hodnoty a pohoštění za předpokladu, že jsou dodržena pravidla vztahující se na poskytování výhod.

Farmaceutické společnosti mohou také sponzorovat jiné nezávislé aktivity nebo akce společenského charakteru (tj. kulturní nebo sportovní akce), včetně akcí, kterých se mohou účastnit i odborníci. Takové sponzorství nebo jiná podpora nesmějí být organizované či poskytované způsobem, který by mohl být považován za dar nebo jiný požitek ze strany farmaceutické společnosti odborníkovi v souvislosti s propagací léčivých přípravků.

Vzdělávací granty státním nemocnicím či nestátním zdravotnickým zařízením jsou obecně povoleny pouze tehdy, pokud grant neslouží jako pobídka či nástroj k propagaci předepisování výrobků či prodeji léčivých přípravků konkrétním lékařem nebo jako odměna za totéž. Granty musí být vyplaceny výhradně institucím, nikoliv jednotlivým odborníkům.V souvislosti s výkladem definice odborníka úřadem prozatím není jasné, zda-li je možné takovou podporu poskytovat bez omezení právnickým osobám.

According to the Act on Advertising, it is lawful to sponsor the organization of seminars, scientific congresses or symposia and to reimburse healthcare professionals for the costs of transport, accommodation and admission fees incurred as a result of attending such scientific events.

It is also legally permissible to sponsor promotional meetings organized in order to support the prescription, sale, supply or consumption of pharmaceuticals. The amount of the donor's contribution to the organizer of the meeting is not limited by law. However, in connection with such sponsorship of promotional meetings companies are not allowed to reimburse healthcare professionals for transport, accommodation or admission fees, or provide them with other advantages. A sponsor may provide healthcare professionals attending a promotional event with gifts of a small nominal value as well as refreshments, provided that the rules which apply to the provision of these advantages are met.

In addition, a pharmaceutical company may sponsor other independent activities or events concerning social life (e.g., cultural or sporting events), including events which happen to be attended by healthcare professionals. However, such support must not be provided in such a way that it could be viewed as a gift or other benefit provided by a pharmaceutical company to a healthcare professional in connection with promoting medicine products.

Finally, educational grants to state or privately-owned hospitals are generally permitted if the purpose of the grant is not to serve as an incentive or promotional tool for the prescription of medicinal products by the particular physician, or a reward for the same. Grants may only be paid to institutions only and not to individual healthcare professionals. In relation to the interpretation of the definition of "professional" by the Authority, it is, for now, unclear whether it is possible to provide such support to legal entities without limitation.

Hospitality and Entertainment

Although the Act on Advertising does not specify the term "hospitality," the interpretation generally accepted by the supervising Authority, as well as professional commentators on the law, includes refreshments (i.e., food and drink) and accommodation. Such refreshments and accommodation for individual healthcare professionals provided in connection with promotional meetings organized in order to support the prescription, sale, supply or

Pohoštění a zábava

Ačkoliv zákon o reklamě nedefinuje pojem pohoštění, převládající výklad tohoto pojmu obecně přijímaný úřadem i odbornými vykladači zákona zahrnuje občerstvení (tj. jídlo a pití) a ubytování. Občerstvení a ubytování poskytované jednotlivým odborníkům v souvislosti s (i) propagačními akcemi organizovanými za účelem podpory předepisování, prodeje, výdeje či užívání humánních léčivých přípravků nebo (ii) vědeckými kongresy či sympozii, kterých se odborníci účastní, jsou povoleny ze zákona, pokud jsou přiměřené a s ohledem na hlavní účel setkání vedlejší, a nesmí být rozšířeny na jiné osoby než odborníky (tj. ani na jejich rodiny či partnery). Pokud jsou splněny podmínky tohoto odstavce, neplatí pro rozsah poskytovaného pohoštění limit nepatrné hodnoty ve výši 1.500,- Kč (jak je uvedeno výše).

S výhradou výjimek ohledně darů nepatrné hodnoty je zakázána organizace zábavy (nebo poskytování jiných výhod) odborníkům v souvislosti s reklamou na humánní léčivé přípravky, a to i v rámci propagačních či odborných setkání popsaných výše.

Reklama a jiné propagační činnosti

Obecná omezení

Zákon o reklamě umožňuje reklamu na humánní léčivé přípravky, které jsou registrovány dle zákona o léčivech, tj. léčivé přípravky, které mají platnou marketingovou autorizaci.[5] Reklama na neregistrované výrobky (včetně výrobků v procesu výroby) je zakázána. Toto ustanovení je založeno na úpravě zákona o léčivech, kterým se stanovuje, že s výhradou několika výjimek definovaných zákonem o léčivech (např. zvláštní léčebné programy) mohou být na český trh uvedeny pouze řádně zaregistrované léčivé přípravky a ty pak mohou být předepisovány a poskytovány pacientům v rámci poskytování lékařské péče v České republice.

V souladu se směrnicí EU o humánních léčivých přípravcích rozlišuje zákon o reklamě reklamu na léčivé přípravky pouze na předpis a léčivé přípravky, které si mohou spotřebitelé zakoupit a aplikovat, aniž by potřebovali předpis od příslušného lékaře; léčivé přípravky bez předpisu se nazývají volně prodejné (over-the counter, OTC).

[5] Podle zákona o reklamě mohou být humánní léčivé přípravky registrovány podle tuzemských registračních postupů u úřadu nebo prostřednictvím centralizovaných postupů EU u Evropské agentury pro hodnocení léčivých přípravků (European Agency for the Evaluation of Medicinal Products (EMEA)).

consumption of human pharmaceuticals; or scientific congresses or symposia attended by healthcare professionals, are legally permissible if commensurate with the nature of the meeting, secondary to the main (i.e., scientific or business) purpose of the meeting, and extended only to healthcare professionals (e.g., not to their spouses or families). Provided that these conditions are met, the "small value" threshold of CZK1,500 (specified above) does not apply to the provision of refreshments.

Subject to the exemption concerning gifts of small nominal value, organization of entertainment for (or the provision of other advantages to) healthcare professionals in connection with advertising pharmaceuticals, including during the promotional or scientific meetings described above, is prohibited.

Advertising and Other Promotional Activities

General Limitations

In general, the Act on Advertising allows advertising of medicinal products that have been registered according to the Act on Pharmaceuticals, i.e., medicines with valid marketing authorization.[5] Accordingly, advertising of non-registered products (including products in their manufacturing process) is prohibited. This provision is based on the regulation in the Act on Pharmaceuticals, which stipulates that, subject to a few exceptions (e.g., special treatment programs), only duly registered pharmaceuticals can be placed on the Czech market and prescribed and provided to patients in relation to the provision of healthcare in the Czech Republic.

In line with the EU human medicines directive, the Act on Advertising distinguishes between advertising prescription-only pharmaceuticals and pharmaceuticals that may be bought and applied by consumers without the need to obtain prescription from a physician; the latter being over-the-counter ("OTC") pharmaceuticals.

Prescription-only pharmaceuticals may only be advertised to healthcare professionals (i.e., persons authorized to prescribe or dispense such products) and not to the general public. Such advertising aimed at healthcare

[5] According to the Act on Advertising, human medicines may be registered under the national registration procedure with the Authority or via the EU centralised procedure with the European Medicines Agency ("EMA").

Reklama na přípravky na předpis může být určena pouze odborníkům (tj. osobám oprávněným předepisovat nebo rozšiřovat takové přípravky), a nikoliv široké veřejnosti. Taková reklama zaměřená na odborníky může být šířena prostřednictvím komunikačních prostředků určených převážně pro tyto osoby (tj. odborného tisku, odborných audiovizuálních pořadů apod.). Má-li být reklama šířena prostřednictvím internetu, musí být jasně určeny internetové stránky zaměřené na odborníky, včetně propagačních informací o léčivých přípravcích na předpis.

Reklama na léčivé přípravky pouze na předpis zaměřená na odborníky musí obsahovat (i) přesné, aktuální a prokazatelné informace, na jejichž základě budou odborníci schopni vytvořit si vlastní názor o terapeutické hodnotě nabízeného výrobku, (ii) základní informace podle schváleného souhrnu údajů o přípravku, včetně data schválení nebo poslední revize, (iii) informaci o způsobu výdeje humánního léčivého přípravku podle rozhodnutí o registraci a (iv) informaci o způsobu hrazení z prostředků veřejného zdravotního pojištění.

Obchodní zástupce[6] musí při každé návštěvě provedené za účelem reklamy na humánní léčivý přípravek předat navštívenému odborníkovi souhrn údajů o každém humánním léčivém přípravku, který je předmětem reklamy, a informaci o způsobu hrazení těchto humánních léčivých přípravků.

Jakákoliv reklama na volně prodejné léčivé přípravky zaměřená na širokou veřejnost musí (i) být formulována tak, aby bylo zřejmé, že výrobek je humánním léčivým přípravkem, (ii) obsahovat název humánního léčivého přípravku tak, jak je uveden v rozhodnutí o registraci, (iii) obsahovat informace nezbytné pro správné použití humánního léčivého přípravku a (iv) obsahovat zřetelnou, v případě tištěné reklamy dobře čitelnou, výzvu k pečlivému pročtení příbalové informace.

Volně prodejné léčivé přípravky mohou být propagovány široké veřejnosti za předpokladu, že taková reklama zejména:

- se netýká léčivých přípravků, které obsahují omamné nebo psychotropní látky;

[6] Obchodní zastoupení je definováno v ust. § 652 a násl. zák. č. 513/1991 Sb., obchodní zákoník.

professionals may not be carried out through information channels and communication means other than those dedicated mainly to experts (e.g., professional magazines and professional audiovisual documents). In the case of advertising on the internet, any website intended for healthcare professionals including information about prescription-only pharmaceuticals of a promotional nature must be clearly designated.

The advertising of prescription-only pharmaceuticals aimed at healthcare professionals must include accurate, current and verifiable information enabling the professionals to formulate their own opinion about the therapeutic value of the advertised product; basic information according to the summary of product characteristics ("SPC"), including the date of approval or latest revision; information about the manner of dispensing the product according to the registration; and information about the reimbursement status of the product under the public health insurance system.

In connection with each visit to a healthcare professional made for the purpose of advertising human medicines, a sales representative[6] must provide the visited professional with a summary of the product characteristics and information about the reimbursement status of the product under the public health insurance system.

Any advertising of OTC pharmaceuticals aimed at the general public must be formulated in such a way that it is clear that the product is a human medicine; include the brand name of the product according to the marketing authorization; include information necessary for the proper use of the product; and include clear and visible instructions to read in the patient information leaflet.

OTC pharmaceuticals may be advertised to the general public, provided the such advertising does not:

- concern pharmaceuticals that comprise narcotic or psychotropic substances;
- induce patients to conclude that consultation with a physician or treatment is not necessary, namely, by an offer of remote diagnosis or treatment;

[6] The institute of sales representation is defined in Section 652 and following of Act No. 513/1991 Coll., the Commercial Code.

- nevyvolává dojem, že porada s lékařem, lékařský zákrok nebo léčba nejsou potřebné, zvláště nabídkou stanovení diagnózy nebo nabídkou léčby na dálku;
- není zaměřena výhradně na osoby mladší 15 let;
- nedoporučuje humánní léčivý přípravek s odvoláním na doporučení vědců, zdravotnických odborníků nebo osob, které jimi nejsou, ale které by díky svému skutečnému nebo předpokládanému společenskému postavení mohly podpořit spotřebu humánních léčivých přípravků;
- nenaznačuje, že humánní léčivý přípravek je potravinou nebo kosmetickým přípravkem či jiným spotřebním zbožím.

Jestliže je reklama zaměřená na širokou veřejnost zamýšlena jako připomínka humánního léčivého přípravku, nesmí obsahovat jiné údaje než název humánního léčivého přípravku tak, jak je uveden v rozhodnutí o registraci, nebo jeho mezinárodní nechráněný název (International Nonproprietary Name (INN)), jestliže takový existuje, popřípadě ochrannou známku. Toto pravidlo se vztahuje na připomínky humánního léčivého přípravku na předpis i volně prodejného humánního léčivého přípravku.

Podle zákona o reklamě se zakazuje reklama na zboží, služby nebo jiné výkony či hodnoty, jejichž prodej, poskytování nebo šíření je v rozporu s právními předpisy.[7] Obdobně je zakázána i reklama na zdravotnické prostředky, která nesplňuje požadavky uvedení na trh podle příslušných zákonů.

Zadavatel reklamy je povinen uchovávat ukázku (kopii) každé reklamy (v případě reklamy na léčivé přípravky je zadavatelem nejčastěji farmaceutická společnost) nejméně po dobu 5 let ode dne, kdy byla reklama naposledy šířena, aby tak vyhověl požadavkům ustanovení ohledně dozoru zákona o reklamě.

Zvláštní nabídky a slevy

Farmaceutické společnosti (a také lékárny) mohou využívat různých marketingových nástrojů k propagaci humánních léčivých přípravků a podpoře jejich prodeje, zejména zvláštní nabídky a slevy. V této souvislosti je důležité zmínit skutečnost, že v důsledku přísných opatření ohledně poskytování vzorků humánních léčivých přípravků nesmějí společnosti

[7] Jmenovitě zák. č. 123/2000 Sb., o zdravotnických prostředcích, v platném znění, a zák. č. 22/1997 Sb., o technických požadavcích na výrobky, v platném znění.

- focus solely on persons younger than 15 years of age;
- recommend human pharmaceuticals with reference to recommendations of scientists, healthcare professionals or persons who are not in such position but who could support the consumption of pharmaceuticals due to their actual or presumed social status; or
- indicate that the human pharmaceutical is a food or cosmetic product or other kinds of consumer goods.

If the advertisement of a pharmaceutical product is intended to serve as a reminder of such product, it must not include information other than the brand name of the product approved in the marketing authorization, or its International Nonproprietary Name ("INN"), or a trademark. This rule applies to reminders of prescription-only medicines as well as to OTCs.

According to the Act on Advertising, the advertising of any goods, services or other performance or values whose sale, provision or distribution is in conflict with applicable laws[7] is prohibited. Therefore, the advertising of medical devices which do not meet the requirements for placement on the market according to the relevant laws is prohibited.

In order to comply with the provisions on advertising, the Act on Advertising stipulates that a person who ordered the particular advertising (in case of advertising medicine products, such person would most often be a pharmaceutical company) must store a copy thereof for at least five years following its final distribution.

Special Offers and Discounts

Pharmaceutical companies (and also pharmacies) may use various marketing tools in order to promote human medicines and support their sale, including, *inter alia*, special offers and discounts. In this regard, it is important to mention that, due to the strict regulation of provision of samples of medicines, companies are not allowed to organize special offers in the form of, e.g., 2 + 1 (i.e., if you buy two products, you receive one additional product for free). Such a special offer would contravene the restriction on provision of samples to the general public and, if focused on healthcare professionals, the limitations on provision of samples to healthcare

[7] Namely, Act No. 123/2000 Coll on Medical Devices, as amended, and Act No. 22/1997 Coll on Technical Requirements on Products, as amended.

organizovat zvláštní nabídky např. formou 2 plus 1 (tj. pokud si koupíte dva výrobky, dostanete další výrobek zdarma). Taková zvláštní nabídka by byla v rozporu s omezeními týkajícími se poskytování vzorků široké veřejnosti, a pokud by se zaměřovala na odborníky, v rozporu s omezeními týkajícími se poskytování vzorků odborníkům (viz níže). Na druhou stranu zvláštní nabídka strukturovaná jako „3 výrobky za cenu 2 výrobků" by byla přijatelná, jelikož podle tohoto schématu není žádný výrobek nabízen zadarmo. Všechny tři výrobky jsou se slevou a poskytování slevy je ze zákona přípustné.

Srovnávací reklama

Podle zákona o reklamě je srovnávací reklama na humánní léčivé přípravky nebo zdravotní péči ze zákona přípustná, je-li zaměřena na osoby oprávněné tyto léčivé přípravky předepisovat nebo vydávat anebo tuto zdravotní péči poskytovat, pokud je vedena dle zvláštních ustanovení obchodního zákoníku.

Obchodní zákoník stanovuje všeobecná pravidla srovnávací reklamy, která je definována (spíše nevhodně) v kapitole týkající se nekalé hospodářské soutěže a je za jistých podmínek považována za zvláštní případ nekalé hospodářské soutěže. Podle ust. § 50a obchodního zákoníku znamená srovnávací reklama „*jakoukoliv reklamu, která výslovně nebo i nepřímo identifikuje jiného soutěžitele anebo zboží nebo služby nabízené jiným soutěžitelem*". Ustanovením § 50a obchodního zákoníku se realizují příslušná ustanovení Směrnice rady č. 84/450/EHS, ve znění Směrnice č. 97/55/ES.

Podle obchodního zákonu je srovnávací reklama povolena pouze tehdy, pokud splňuje následující kritéria:

- není klamavá;[8]
- srovnává jen zboží nebo služby uspokojující stejné potřeby nebo určené ke stejnému účelu;
- objektivně srovnává jen takové znaky daného zboží nebo služeb, které jsou pro ně podstatné, relevantní, ověřitelné a reprezentativní; zpravidla musí být srovnání ve více znacích, mezi něž může patřit i

[8] Podle ust. § 45(l) obchodního zákoníku je klamavou reklamou šíření údajů o vlastním nebo cizím podniku, jeho výrobcích či výkonech, které je způsobilé vyvolat klamnou představu a zjednat tím vlastnímu nebo cizímu podniku v hospodářské soutěži prospěch na úkor jiných soutěžitelů či spotřebitelů. Klamavým je i údaj sám o sobě pravdivý, jestliže vzhledem k okolnostem a souvislostem, za nichž byl učiněn, může uvést v omyl.

professionals (see below). In contrast, a special offer structured as "3 products for the price of 2" would be acceptable, as there is no product provided for free under this scheme; all three products are discounted, and the provision of discounts is legally permissible.

Comparative Advertising

According to the Act on Advertising, comparative advertising concerning pharmaceuticals or healthcare is legally permissible if addressed to persons authorized to prescribe or dispense such pharmaceuticals or provide such healthcare, and if conducted in accordance with the special provisions of the Commercial Code.

The Commercial Code sets out the general rules for comparative advertising, which are defined (rather improperly) in the chapter dedicated to unfair competition and are recognized, under certain conditions, as one of the special cases of unfair competition. According to the Commercial Code, comparative advertising is "any advertising which explicitly or by implication identifies a competitor or goods or services offered by a competitor." The Commercial Code implements the relevant provisions of Council Directive 84/450/EEC, as amended by Directive 97/55/EC.

According to the Commercial Code, comparative advertising is permitted only when it meets all of the following criteria:

- It is not misleading.[8]
- It compares only goods or services meeting the same needs or intended for the same purpose.
- It objectively compares only such features of the goods or services which are fundamental (material), relevant, verifiable and representative; as a rule, several features must be compared and these may include the price; only exceptionally may a comparison of one feature be permitted, provided that such comparison fully meets all the stipulated conditions.

[8] According to Section 45(1) of the Commercial Code, "misleading advertising" is the dissemination of information by a competitor about its own or someone else's enterprise, products or services, with the aim of creating misleading perceptions as to the advantage of its own, or someone else's, enterprise at the expense of other competitors or consumers. In addition, the use of a fact which itself is true but which, owing to the circumstances or context in which it is presented, may be misleading, is also considered to be misleading.

cena; jen výjimečně lze připustit srovnání v jediném znaku, splňuje-li takové srovnání v plné míře všechny uvedené podmínky;
- nevede k vyvolání nebezpečí záměny na trhu mezi tím, jehož výrobky nebo služby reklama podporuje, a soutěžitelem nebo mezi jejich podniky, zbožím nebo službami, ochrannými známkami, firmami nebo jinými zvláštními označeními, která se pro jednoho nebo druhého z nich stala příznačnými;
- nezlehčuje[9] nepravdivými údaji podnik, zboží nebo služby soutěžitele ani jeho ochranné známky, firmu či jiná zvláštní označení;
- vztahuje se u výrobků, pro které má soutěžitel oprávnění užívat chráněné označení původu, vždy jenom na výrobky se stejným označením původu;
- nevede k nepoctivému těžení z dobré pověsti spjaté s ochrannou známkou soutěžitele, jeho firmou či jinými zvláštními označeními; a
- nenabízí zboží nebo služby jako napodobení nebo reprodukci zboží nebo služeb označovaných ochrannou známkou nebo obchodním jménem.

S ohledem na výše uvedené musí být srovnávací reklama omezena na objektivně zhodnotitelné rysy, kvalitu či charakteristiky srovnávaných léčivých přípravků a musí být vedena způsobem, který ani potenciálně nesplňuje podmínky nekalé hospodářské soutěže.

Veterinární léčivé přípravky

Podle ust. § 5h zákona o reklamě, ve znění dodatku ze dne 26. ledna 2006, mohou být veterinární léčivé přípravky předmětem reklamy zaměřené na širokou veřejnost, pokud se tato reklama:

(i) netýká veterinárních léčivých přípravků, které mohou být vydávány pouze na lékařský předpis podle rozhodnutí o registraci;
(ii) netýká veterinárních léčivých přípravků obsahujících omamné nebo psychotropní látky.

[9] Podle ust. § 50 obchodního zákoníku je zlehčováním jednání, jímž soutěžitel uvede nebo rozšiřuje o poměrech, výrobcích nebo výkonech jiného soutěžitele nepravdivé údaje způsobilé tomuto soutěžiteli přivodit újmu. Zlehčováním je i uvedení a rozšiřování pravdivých údajů o poměrech, výrobcích či výkonech jiného soutěžitele, pokud jsou způsobilé tomuto soutěžiteli přivodit újmu.

- It does not create confusion in the marketplace between the advertiser and a competitor or between their enterprises, goods or services, or trademarks, commercial names or other distinguishing marks typical of one or the other.
- It is not disparaging[9] with respect to other competitors' enterprises, products, trademarks and/or other designations.
- It relates only to products with the same designation, if the competitor is entitled to use a protected designation of origin.
- It does not take unfair advantage of the reputation of another competitor's trademark, trade name and/or other designation.
- It does not present goods or services as imitations or replicas of goods or services bearing a protected trademark or trade name.

Comparative advertising must therefore be limited to objectively assessable features, qualities or characteristics of the compared pharmaceutical products and must be carried out in a way that does not, even potentially, meet the conditions of other unfair competition conduct.

Veterinary Medicines

According to the Act on Advertising, as amended veterinary medicines may be advertised to the general public, provided however that such advertising does not: concern veterinary medicines that may be dispensed only on the basis of a prescription according to the marketing authorization; or concern veterinary pharmaceuticals that comprise narcotic or psychotropic substances.

Samples

According to the Act on Advertising, free samples of human pharmaceuticals can be distributed exceptionally, in a limited amount, to persons who are authorized to prescribe them[10]. Each sample must represent the smallest

[9] According to the Commercial Code, "disparagement" means conduct whereby one competitor states or disseminates false information about the circumstances, products or services of another competitor; with such false information being likely to be detrimental. Disparagement also involves stating and disseminating truthful information about the circumstances, products or services of another competitor, if such information is capable of causing detriment to that competitor.

[10] Please note that since pharmacists are not generally qualified to prescribe human pharmaceuticals in the Czech Republic, no free samples of human pharmaceuticals may be distributed to them.

Vzorky

Podle zákona o reklamě mohou být vzorky humánních léčivých přípravků výjimečně poskytovány v omezeném množství osobám oprávněným je předepisovat.[10] Každý vzorek musí představovat nejmenší registrované balení dostupné na trhu a musí být označen nápisem „Neprodejný vzorek" nebo „Bezplatný vzorek". Vzorky humánních léčivých přípravků lze bezplatně poskytovat pouze na písemnou žádost osoby oprávněné je předepisovat a vydávat, která je podepsaná a datovaná.

Nelze poskytovat přípravky obsahující omamné a psychotropní látky, a to ani osobám oprávněným je předpisovat.

Vzorky humánních léčivých přípravků nesmí být distribuovány široké veřejnosti či fyzickým osobám, které nejsou oprávněny je předepisovat.

Důsledky porušení povinností

Dle zákona o reklamě může úřad nařídit odstranění nebo ukončení reklamy, která je v rozporu se zákonem. Úřad je oprávněn pozastavit zahájení šíření klamavé reklamy na humánní léčivé přípravky, jestliže by v důsledku jejího šíření mohl být ohrožen život nebo zdraví osob. Pro takový postup je dostatečné podezření úřadu, důkaz o vzniku škody se nevyžaduje.

Úřad může uložit pokutu až 5.000.000,- Kč (cca 200.000,- Eur) jednotlivé fyzické osobě – podnikateli nebo právnické osobě za porušení ustanovení zákona o reklamě týkajících se mimo jiné distribuce zakázané reklamy nebo sponzorské činnosti ve farmaceutickém průmyslu.

Zásady profesionálního jednání

Profesionální etický kodex lékaře

Česká lékařská komora, Česká lékárnická komora a Česká stomatologická komora sdružují v současné době všechny lékaře, lékárníky a stomatology, kteří provozují praxi v České republice. Podle zvláštního zákona, kterým byly tyto komory založeny, musí být každý lékař, lékárník nebo stomatolog provozující praxi nebo poskytující lékařskou péči na území České republiky členem příslušné komory.

[10] Jelikož lékárníci v České republice nejsou obecně oprávněni předepisovat humánní léčivé přípravky, nesmějí jim být bezplatně poskytovány vzorky humánních léčivých přípravků.

registered package available in the market and must be labeled "free sample" or "not for sale." Free samples of pharmaceuticals can only be provided where there is a dated and signed written request from the authorized person. However, distribution of free samples of pharmaceuticals that comprise narcotic or psychotropic substances is prohibited, even to persons authorized to prescribe them.

Distribution of free samples of pharmaceuticals to the general public or to individual persons who are not authorized to prescribe them is prohibited.

Consequences of Breach

According to the Act on Advertising, the Authority may order removal or termination of advertising which contravenes the provisions thereof. In addition, the Authority may specifically suspend commencement of distribution of a misleading pharmaceutical advertising if, in its view, damage could be caused to human health or life by distribution of such advertising. For such measurement, the Authority's suspicion is sufficient and no evidence of occurrence of damage is required.

Furthermore, the Authority can impose a penalty amounting up to CZK5,000,000 (approximately EUR200,000) on an individual entrepreneur or a legal entity for breaches of the provisions of the Act on Advertising relating, *inter alia*, to the distribution of prohibited advertising and to sponsoring activities in the pharmaceutical industry.

Professional Codes of Conduct

Professional Code of Conduct for Physicians

The Czech Medical Chamber, the Czech Chamber of Pharmacists and the Czech Chamber of Dentists are the existing associations for all physicians, pharmacists and dentists, respectively, practicing in the Czech Republic. According to a special law under which the chambers were established, each physician, pharmacist and dentist practicing or providing healthcare services in the territory of the Czech Republic must be a member of the relevant chamber according to his profession ("the Chamber").

By way of illustration, the Czech Medical Chamber has issued a set of rules, including a code of ethics, organizational rules and a disciplinary code, which apply to all its members and which broadly set out the rules for provision of healthcare services.

Česká lékařská komora vydala soubor stavovských předpisů, včetně etického kodexu, organizačního řádu a disciplinárního řádu, které se vztahují na všechny její členy a určují obecná pravidla poskytování lékařských služeb.

Následující pasáže z etického kodexu Komory se týkají použití farmaceutických a diagnostických produktů:

- „Lékař nesmí sám nebo po dohodě s jinými ordinovat neúčelné léčebné, diagnostické a jiné úkony ze zištných motivů."
- „Pokud lékař doporučuje ve své léčebné praxi léky, léčivé přípravky a zdravotní pomůcky, nesmí se řídit komerčními hledisky, ale výhradně svým svědomím a prospěchem pacienta."

Dle organizačního řádu dohlíží Komora nad výkonem činnosti lékařů a v případě, že dojde k porušení příslušné legislativy nebo předpisů a zásad Komory, ukládá sankce v souladu s disciplinárním řádem.

Poruší-li lékař povinnosti, které mu ukládají předpisy Komory nebo jiná příslušná legislativa, může být potrestán peněžitou pokutou, napomenutím nebo vyloučením z Komory (což pro něj v praxi znamená zákaz dalšího výkonu lékařského povolání).

Etický kodex farmaceutických společností

Asociace inovativního farmaceutického průmyslu (dále jen „AIFP") je dobrovolné sdružení výzkumně orientovaných farmaceutických společností a byla v České republice založena v roce 1993 (dříve bylo toto sdružení známé jako Mezinárodní asociace farmaceutických společností). AIFP je členem Evropské federace farmaceutických společností a asociací (European Federation of Pharmaceutical Industry and Associations (EFPIA).

Členové AIFP uvádějí na trh a propagují své léčivé přípravky v souladu s nejpřísnějšími etickými zásadami uvedenými v Etickém kodexu. V této souvislosti se členové AIFP zavazují, že nebudou praktikovat žádné postupy nebo aktivity, které by nutily osoby předepisující léky ke zvyšování počtu předpisů výměnou za pobídky. Odborníkům nesmějí být poskytovány ani nabízeny žádné dary, dotace či jiné výhody nebo pobídky výměnou za předepisování léčivých přípravků za takových podmínek, které by narušily nezávislost rozhodování zdravotnického odborníka při předepisování léčiv.

Etický kodex AIFP se týká reklamy na léčivé přípravky pouze na předpis zaměřené na odborníky (oproti reklamě zaměřené na širokou veřejnost). Propagace, jak je specifikováno v Etickém kodexu AIFP, spočívá v jakékoliv

The following passages from the Chamber's code of ethics deal with the use of pharmaceutical and diagnostic products:

- "A physician may not, on his own or upon agreement with others, prescribe purposeless therapeutic and diagnostic or other treatment for motives of self-interest."
- "If a physician recommends, in his therapeutic practice, drugs, medical remedies or medical aids, he may not pursue commercial goals but only his conscience and the benefit of the patient."

Under the organizational rules, the Chamber supervises the performance of physicians' activities and imposes sanctions in the event of a breach of relevant legislation or of the Chamber's rules and codes under the disciplinary code.

In the event of a breach of obligations under the Chamber's rules, or under other relevant legislation, a physician may face a monetary penalty, reprimand or expulsion from the Chamber (which effectively results in a ban on such physician's further medical practice).

Professional Code of Conduct for Pharmaceutical Companies

Founded in 1993, the Association of the Innovative Pharmaceutical Industry in the Czech Republic ("AIFP") is a voluntary national association of research and development-based pharmaceutical companies (this association was formerly known as International Association of Pharmaceutical Companies). AIFP is a member of the European Federation of Pharmaceutical Industry and Associations ("EFPIA").

Members of the AIFP have committed to market and promote their products in compliance with strict ethical principles that have been embodied in the Code of Conduct. In this context, AIFP members have undertaken in the Code of Conduct not to implement any practice or activity that would lock prescribing physicians into schemes aimed at generating prescriptions in exchange for incentives. In addition, no gifts, donations or other benefits or advantages may be provided or offered to a healthcare professional in exchange for prescribing products or on conditions that would otherwise interfere with the independence of a healthcare professional's prescribing practices.

činnosti realizované, organizované či sponzorované farmaceutickou společností nebo s jejím souhlasem, která propaguje předepisování, poskytování, prodej, podávání nebo užívání léčivých přípravků takové společnosti.

Etický kodex AIFP se ve zvláštních kapitolách zabývá všemi metodami propagace, zejména propagačními aktivitami a komunikací v ústní i písemné podobě, časopisy a zasíláním propagačních materiálů potenciálním zákazníkům (direct mailing), aktivitami prodejců léčivých přípravků, internetem a ostatní elektronickou komunikací, použitím audiovizuálních materiálů, jako jsou filmy, video nahrávky, služby archivace dat a podobně, stejně jako poskytováním vzorků, dárkových předmětů a pohoštění.

Při porovnání obecně závazných právních předpisů a ustanovení Etického kodexu AIFP, jsou pravidla stanovená AIFP v mnoha případech přísnější než obecná právní úprava, jelikož Etický kodex používá zákony jako základ a zaváděním přísnějších pravidel se snaží vytvářet etičtější prostředí v oblasti reklamy na léčivé přípravky.

Například vedle obecného pravidla ohledně limitu 1.500,- Kč za všechny dary poskytované farmaceutickou společností odborníkovi za jeden kalendářní rok stanovil Etický kodex AIFP maximální hodnotu jednoho dárkového předmětu, která činí 200,- Kč.

Dalším příklad může být nové pravidlo 4x2, stanovující přísnější podmínky pro poskytování bezplatných vzorků léků, stanovující, že žádný zdravotnický odborník by neměl ročně dostat více než 4 vzorky konkrétního, nového léčivého přípravku, který je oprávněn předepisovat. Vzorkování konkrétního léčivého přípravku je povoleno pouze po dobu dvou let poté, co první zdravotnický odborník požádal o vzorky daného léčivého přípravku („pravidlo 4x2"). Lhůta dvou let se vztahuje na vzorkování konkrétního léčivého přípravku obecně, tj. na celém trhu, a nikoliv pouze vůči jednotlivým zdravotnickým odborníkům.

Vedle obecných pravidel sponzorství stanovených zákonem o reklamě obsahuje Etický kodex podmínky, za jakých členové AIFP mohou organizovat nebo sponzorovat kongres či jiné odborné setkání za účasti odborníků, a to včetně konkrétních omezení počtu dnů, programu nebo typu místa.

The MAFSAIFP Code of Conduct covers the advertising of prescription-only medicinal products aimed at healthcare professionals (as opposed to the general public). Promotion, as used in the MAFSAIFP Code, includes any activity undertaken, organized or sponsored by a pharmaceutical company, or with its authority, which promotes the prescription, supply, sale, administration or consumption of its medicinal product(s).

The MAFSAIFP Code covers (in special chapters) all methods of promotion including, but not limited to, oral and written promotional activities and communications; journal and direct mail advertising; the activities of medical sales representatives; internet and other electronic communications; the use of audio-visual systems such as films, video recordings, data storage services and the like; and the provision of samples, sponsorships, gifts and hospitality.

In relation to the co-existence of the general legal regulations of advertising and the provisions included in the AIFP Code of Conduct, the rules adopted by AIFP are, in many cases, stricter than the general legislation, as the Code of Conduct takes the laws as a basis and further aspires to create an even more ethical environment in the area of pharmaceutical advertising by implementing more demanding rules.

By way of example, in addition to the general rule concerning the CZK1,500 threshold for any and all gifts provided by a pharmaceutical company to one healthcare professional during a calendar year, the AIFP Code of Conduct further limits the amount of one gift to CZK200.

Another example may be a new 4x2 rule, setting more strict conditions for provision of free samples of medicines, stipulating that no healthcare professional should annually receive more than four samples of a specified, new drug, which he or she is authorized to prescribe. Giving samples of a specified drug is allowed only for two years after the medicals professional's request for the given drug sample. The term of two years applies to samples of a specified drug generally, i.e., on the whole market and not only in relation to individual healthcare professionals.

Also, in addition to the general rule on sponsoring laid down in the Act on Advertising, the Code of Conduct contains a detailed description of the terms under which an AIFP member may organize or sponsor a congress or other scientific meeting attended by healthcare professionals, including specific limitations on the number of days, scope of agenda or types of venues.

Odpovědnost dle trestního a občanského práva

Zákonný rámec

V České republice neexistuje samostatný zákon o úplatkářství a korupčních praktikách jako takových. Ustanovení o jejich zákazu jsou obsažena v řadě zákonů zahrnujících například trestní zákon, obchodní zákoník, zákon o zadávání veřejných zakázek a zákoník práce. Česká republika je také stranou řady mezinárodních úmluv a smluv zaměřených proti úplatkářství a korupci, zejména Úmluvy Organizace pro hospodářskou spolupráci a rozvoj (OECD Convention) o boji proti úplatkářství zahraničních veřejných činitelů v mezinárodních obchodních transakcích (dále jen „Úmluva OECD"),[11] Občanskoprávní úmluvy o korupci (Civil Law Convention on Corruption) (dále jen „ETS č. 174")[12] a Trestněprávní úmluvy o korupci (dále jen „ETS č. 173").[13]

Hlavním cílem uplatňování protikorupčních opatření ve farmaceutickém průmyslu je zajistit objektivitu a profesionální nezaujatost v oblasti prodeje, poskytování a především předepisování léčivých přípravků odborníky a zabránit jakémukoliv ovlivňování činnosti odborníků.

Trestní zákoník

Zákon č. 40/2009 Sb., trestní zákoník, ve znění pozdějších úprav (dále jen „trestní zákon"), úplatky a korupční praktiky obecně zakazuje. Trestní zákon upravuje tři trestné činy související s úplatkářstvím (přijímání úplatku, podplácení a nepřímé úplatkářství ve vztahu k veřejnému činiteli).

Ustanovení § 331 trestního zákona stanoví důsledky v případě přijetí úplatku:

> „Kdo sám nebo prostřednictvím jiného v souvislosti s obstaráváním věcí obecného zájmu pro sebe nebo pro jiného přijme nebo si dá slíbit úplatek, nebo kdo sám nebo prostřednictvím jiného v souvislosti s podnikáním svým nebo jiného pro sebe nebo pro jiného přijme nebo si

[11] Česká republika podepsala Úmluvu OECD dne 17. prosince 1997. Ratifikační listina byla uložena u OECD dne 21. ledna 2000 a v souladu s čl. 15 (1) Úmluvy OECD nabyla účinnosti v České republice ke dni 21. března 2000.
[12] Úmluva byla Českou republikou podepsána v roce 2000, ratifikována o dva roky později a v České republice nabyla účinnosti 1. ledna 2004.
[13] Úmluva byla Českou republikou podepsána v roce 1999, ratifikována o dva roky později a v České republice nabyla účinnosti 1. července 2002.

Liability Under Criminal and Civil Law

The Regulatory Framework

There is no special Act in force which regulates bribery and corruption practices, as such, in the Czech Republic. Czech anti-corruption legislation consists of a number of provisions set out, among others, in the Criminal Code, the Commercial Code, the Act on Procurement of Public Orders and the Labour Code. The Czech Republic is also party to a number of international treaties and conventions aimed at combating bribery and corruption, including, the OECD convention on combating bribery of foreign public officials in international business transactions ("OECD Convention"),[11] the Civil Law Convention on Corruption,[12] and the Criminal Law Convention on Corruption.[13]

In relation to the pharmaceutical industry, the principal objective of the application of anti-corruption provisions is to secure objectivity and professional impartiality concerning the sale, supply and, above all, prescription of medicine products by healthcare professionals, and prevent any influences on the conduct of healthcare professionals.

Criminal Code

Bribery and corrupt practices are generally prohibited under Act No. 40/2009 Coll., Criminal Code, as amended ("Criminal Code"). The Criminal Code regulates three bribery-related criminal offenses (the acceptance of bribes, the offering of bribes and indirect bribery involving public officials).

[11] The Czech Republic signed the OECD convention on 17 December 1997. The instrument of ratification was deposited with the OECD on 21 January 2000 and, in accordance with article 15(1) of the OECD convention, became effective in the Czech Republic as of 21 March 2000.
[12] The Convention was signed by the Czech Republic in 2000, ratified two years later and became effective in the Czech Republic as of 1 January 2004.
[13] The Convention was signed by the Czech Republic in 1999, ratified the next year and became effective in the Czech Republic as of 1 July 2002.

dá slíbit úplatek, bude potrestán odnětím svobody až na čtyři léta nebo zákazem činnosti"

Obdobně ustanovení § 332 trestního zákona stanoví důsledky v případě podplácení:

„Kdo jinému nebo pro jiného v souvislosti s obstaráváním věcí obecného zájmu poskytne, nabídne nebo slíbí úplatek, nebo kdo jinému nebo pro jiného v souvislosti s podnikáním svým nebo jiného poskytne, nabídne nebo slíbí úplatek, bude potrestán odnětím svobody až na dvě léta nebo peněžitým trestem"

Existují tedy tři základní aspekty, jejichž přítomnost musí státní zástupce prokázat pro úspěšné obžalování osoby z porušení ustanovení trestního zákona týkajících se úplatkářství:

1. Nabídnutá nebo přijatá částka (či jiná odměna) musí odpovídat definici „úplatku": podle ust. § 334 odst. 1 trestního zákona se úplatkem rozumí neoprávněná výhoda spočívající v přímém majetkovém obohacení nebo jiném zvýhodnění, kterého se dostává nebo má dostat uplácené osobě nebo s jejím souhlasem jiné osobě a na které není nárok. Úplatek může být v peněžité či nepeněžité formě a jeho hodnota nemusí být vyjádřitelná v penězích. Splňuje-li určitá částka (odměna) definici úplatku dle trestního zákona, nemá dle předchozích rozhodnutí českých soudů na trestní odpovědnost vliv výše takové částky (odměny).
2. Úplatek musí být slíben či přijat v souvislosti s „obstaráváním věcí obecného zájmu": Trestní zákon nevysvětluje pojem „obstarávání věcí obecného zájmu", Nejvyšší soud ČR nicméně judikoval, že činnost lékaře (odborníka) související s ochranou zdraví pacienta spadá pro účely trestního zákona do „věcí obecného zájmu".[14]

   V této souvislosti upozorňujeme, že dle trestního zákona nejsou lékaři z titulu své profese, tj. poskytování zdravotní péče a jiných zdravotnických služeb ve státní nemocnici, v rámci soukromé praxe či jinak, považováni v České republice za úřední osoby. Lékař (odborník)

[14] Rozhodnutí Nejvyššího soudu č. Rt 13/90 4 TZ 45/88, ze dne 16. ledna 1989 (Sb. SC 90, 1:59) vyplacení částky (či poskytnutí jiné výhody) vyplácející (či poskytující) osoba očekávala (nebo zamýšlela), že bude tímto způsobem moci ovlivnit věc obecného zájmu.

The Criminal Code refers to the consequences of the acceptance of a bribe:

> "Whoever, himself or using another one in relation to procurement of the matters of public interest for himself or for another one accepts, allows himself to be promised a bribe, or whoever himself or using another one in relation to a conduct of his business or someone else's for himself or for another one accepts or allows himself to be promised a bribe, will be punished by imprisonment for a term of up to four years or by the banning of his activity."

Similarly, the Criminal Code addresses the consequences of offering a bribe:

> "Whoever, in connection with the procurement of a matter of public interest, affords, offers or promises anyone, or for anyone, a bribe, or whoever affords, offers or promises anyone, or for anyone, in relation to a conduct of business, will be punished by imprisonment of up to two years or with a fine."

There are three basic elements which a prosecutor would need to prove in order to successfully indict an individual under the anti-bribery provisions in the Criminal Code:

1. The payment (or other gratuity) given or accepted must constitute a "bribe": i.e., according to of the Criminal Code, a bribe is an unjust benefit consisting of direct material enrichment or other advantage being provided, or to be provided, to the person being bribed, or, with this person's consent, to another person, to which the person is not entitled. A bribe can be in monetary or non-monetary form and does not necessarily have to have a monetary value attributable to it. According to precedents in the Czech courts, the amount of a payment (or value of gratuity) is irrelevant with respect to the criminal liability once the payment (or gratuity) qualifies as a bribe, according to the definition in the Criminal Code.

2. The bribe must be offered and accepted in connection with the "procurement of a matter of public interest". The Criminal Code is silent on the meaning of the term "procuring a matter of public interest," but the Supreme Court of the Czech Republic has ruled that

se však může stát úřední osobou, je-li zvolen či jmenován do funkce jako např. člen zastupitelstva nebo odpovědný úředník územní samosprávy, orgánu státní správy nebo jiného orgánu veřejné moci apod. (např. ředitel úřadu). Jak je uvedeno níže, lékař (odborník) může navíc nést trestní odpovědnost za korupční praktiky i tehdy, když není pro účely českého práva považován za veřejného činitele, a to v případě, že přijme úplatek v souvislosti s věcí obecného zájmu, kterou se pro účely této analýzy rozumí i poskytování zdravotnických služeb veřejnosti.

3. Slíbení či přijetí úplatku musí být úmyslné (oproti trestným činům z nedbalosti): k tomu, aby nějaká částka nebo jiná výhoda zakládala úplatek dle trestního zákona, je nutné prokázat úmysl na straně příslušné osoby (dárce) za daných okolností. To znamená, že u soudu by bylo nutné prokázat, že v okamžiku

Zákon o trestní odpovědnosti právnických osob

Zákon č. 418/2011 Sb., o trestní odpovědnosti právnických osob a řízení proti nim, (dále jen „zákon o trestní odpovědnosti právnických osob"), stanovuje vybrané skutkové podstaty, pro které může být právnická osoba trestně odpovědná, jedná se o stejné trestné činy, které jsou popsány výše, zákon o trestní odpovědnosti právnických osob na úpravu jejich skutkové podstaty odkazuje. Přijetím tohoto zákona byl prolomen dlouho platící princip českého práva, že trestně odpovědné jsou pouze fyzické osoby.

Právnická osoba může být za spáchání trestných činů souvisejících s úplatkářstvím trestně odpovědná, pokud je spáchání ve jméně, zájmu právnické osoby nebo v rámci její činnosti a pokud je spáchání trestného činu právnické osobě přičitatelné. Přičitatelné je jí zásadně tehdy, pokud byl spáchán (i) jednáním z orgánů právnické osoby, (ii) osobou vykonávající kontrolní činnost, (iii) osobou oprávněnou za právnickou osobu jednat, (iv) osobou vykonávající rozhodující vliv, (v) zaměstnancem nebo osobou v obdobném postavení (osoba pracující na základě dohody o pracích konaných mimo pracovní poměr) při plnění pracovních úkolů, které jim zaměstnavatel zadal, pokud nebyly provedeny povinné nebo potřebné kontroly činnosti zaměstnanců, nebo jim nadřízených osob a nebyly učiněna nezbytná opatření k zamezení nebo odvrácení následků spáchaného trestného činu.

Trestněprávní odpovědnost právnické osoby nevylučuje trestněprávní odpovědnost fyzické osoby.

the activity of a physician (healthcare professional) relating to the protection of a patient's health falls within the purview of a "matter of public interest" for the purposes of the Criminal Code.[14]

In connection, it should be noted that, according to the Criminal Code, physicians are not considered public officials solely by virtue of their profession, i.e., the provision of medical treatment and other health services in a state hospital, private practice or otherwise, in the Czech Republic. Nevertheless, a physician (healthcare professional) can become a public official if he or she is elected or appointed to a function such as a member of the local council or a responsible officer of the local government a member of the body of the civil service or other bodies of public administration (e.g., director of Authority). Furthermore, as indicated below, a physician (healthcare professional) can be held criminally liable for corrupt activities, even if he or she is not deemed to be a public official for the purposes of Czech law, where the physician (healthcare professional) accepts a bribe in connection with a matter of public interest, which, for the purposes of this analysis, would include the provision of healthcare services to the public.

3. The bribe-offering and bribe-taking must be committed intentionally (as opposed to crimes committed by omission): i.e., in order for a payment or other benefit to constitute a bribe under the Criminal Code, it must be demonstrated that there was intent on the part of the individual participant (or donor) under the circumstances. That is, it would have to be proved to the court that, at the moment of making the payment (or providing another benefit) the person making the payment (or conferring the benefit) expected (and intended) that, in doing so, he or she would be able to influence a matter of public interest.

Criminal Liability of Legal Entities Act

Act No. 418/2011 Coll., on Criminal Liability of Legal Entities and Proceedings Against Them ("Criminal Liability of Legal Entities Act"), sets out selected behaviour for which a legal entity may be criminally liable; please note that these are the same criminal acts which are discussed in more

[14] Decision of the Supreme Court no. Rt 13/90 4 TZ 45/88, dated 16 January 1989 (Coll. SC 90,1: 59)

Obchodní zákoník

Ustanovení definující a upravující nekalou soutěž jsou obsažena v zák. č. 513/1991 Sb., obchodním zákoníku (dále jen „obchodní zákoník"). Pojem nekalá soutěž je obchodním zákoníkem definován takto:„Nekalou soutěží je jednání v hospodářské soutěži, které je v rozporu s dobrými mravy soutěže a je způsobilé přivodit újmu jiným soutěžitelům nebo spotřebitelům. Nekalá soutěž se zakazuje."

Obchodní zákoník také obsahuje definici podplácení, tato definice se však vztahuje pouze na nekalou soutěž. Podplácení pro účely obchodního zákoníku tedy nezahrnuje veřejné činitele, věci obecného zájmu či jiné podmínky stanovené trestním zákonem. Upozorňujeme, že podplácení dle obchodního zákoníku nezakládá trestný čin a není stíháno státními orgány.

Obchodní zákoník definuje podplácení takto:

„Podplácením ve smyslu tohoto zákona je jednání, jímž:

(a) soutěžitel osobě, která je členem statutárního nebo jiného orgánu jiného soutěžitele nebo je v pracovním či jiném obdobném poměru k jinému soutěžiteli, přímo nebo nepřímo nabídne, slíbí či poskytne jakýkoliv prospěch za tím účelem, aby jejím nekalým postupem docílil na úkor jiných soutěžitelů pro sebe nebo jiného soutěžitele přednost nebo jinou neoprávněnou výhodu v soutěži, anebo
(b) osoba uvedená v písmenu a) přímo či nepřímo žádá, dá si slíbit nebo přijme za stejným účelem jakýkoliv prospěch."

Povolené a zakázané činnosti

Trestní zákon

Vzhledem k výše uvedenému by peněžitá částka, dar či jiná výhoda poskytnutá odborníkovi distributorem humánních léčivých přípravků či zdravotnických prostředků za okolností, kdy odborník předepisuje či připravuje a vydává produkty dárce pacientům, mohly zakládat trestné činy nabízení anebo přijímání úplatku za předpokladu, že by byly splněny ostatní podmínky uvedené v trestním zákonu (viz rozbor výše).

Obchodní zákoník

Lze argumentovat tím, že poskytnutí určité částky, darů či jiných výhod odborníkovi distributorem humánních léčivých přípravků nebo zdravotnických prostředků, které má takového odborníka přimět, aby dané

detail above. The Criminal Liability of Legal Entities Act refers to facts in the Criminal Code. This law replaced the long-standing principle of Czech law, under to which only natural persons were criminally liable.

A legal entity may be criminally liable for committing criminal acts relating to bribery if the crime is committed in the name, or interest, or in relation to the activity, of the legal entity and if such actions are referable to the legal entity. The actions are referable to the legal entity if the crime was committed by the acting of a body of the legal entity; a person exercising control activities; a person authorized to act on behalf of the legal entity; a person having a controlling influence; or an employee or a person in a similar position (person working on the basis of contracts of work outside of employment) during performance of working tasks ordered by the employer, if the compulsory or necessary checks on the employee's work or their supervisors and precautions for preventing or averting consequences of the committed crime were not made.

Criminal liability of a legal entity does not exclude criminal liability of a natural person.

Commercial Code

The provisions defining and regulating unfair competition are contained in the Commercial Code. The term "unfair competition" is defined as conduct in economic competition which conflicts with ethical competition and which may be detrimental to other competitors or customers. Such unfair competition is prohibited.

The Commercial Code also includes a definition of bribery; however, this definition applies only for the purposes of unfair competition. Accordingly, for the purposes of the Commercial Code, bribery does not involve public officials, matters of public interest, or other conditions stipulated in the Criminal Code. Please note that bribery under the Commercial Code is not a criminal offense and is not prosecuted by public authorities.

The definition of bribery under the Commercial Code means conduct whereby:

- a competitor offers, promises or renders, directly or indirectly, benefits to an individual who is a member of a competitor's statutory body (or similar body), or a competitor's employee (or an individual of a similar

produkty doporučoval či jinak předepisoval svým pacientům (na úkor konkurenčních produktů), by mohlo být považováno za nekalou soutěž dle ustanovení obchodního zákoníku.

Zadávání veřejných zakázek a podvody

Trestní zákon definuje trestný čin ve vztahu k zadávání veřejných zakázek. Ustanovení § 257 trestního zákona zakazuje pletichy v souvislosti se zadáváním veřejné zakázky a při veřejné soutěži. Osoby rozhodující o veřejných soutěžích vyhlašovaných v souvislosti s veřejnými zakázkami navíc bývají v pozici veřejného činitele a jako takové mohou být potrestány na základě ust. § 257 trestního zákona, který stanoví důsledky zneužívání pravomoci úřední osoby. Výše uvedený trestný čin přijímání úplatku by se také vztahoval na úřední osobu, která by přijala neoprávněnou platbu či jinou výhodu v souvislosti se zadáváním veřejné zakázky.

Sankce

Trestní zákon

V případech, kdy neexistuje specifická právní úprava v určité věci, se úplatkářství a korupční praktiky řídí trestním zákonem. Potrestání v případě takovýchto praktik závisí na tom, zda došlo k nabídnutí či přijetí úplatku (viz rozbor výše).

Ve vztahu k trestnému činu podplácení v případě veřejných činitelů stanoví ust. § 333 trestního zákona důsledky nepřímého úplatkářství: „Kdo žádá nebo přijme úplatek za to, že bude svým vlivem nebo prostřednictvím jiného působit na výkon pravomoci úřední osoby, nebo za to, že tak již učinil, bude potrestán odnětím svobody až na tři léta."

Občanské právo

Dle obecných pravidel českého smluvního práva je jakákoliv smlouva uzavřená v rozporu s platným právem či předpisy nebo v rozporu s dobrými mravy neplatná a nevynutitelná dle českého práva.

Obchodní zákoník

Dle obchodního zákoníku může osoba, jejíž práva byla porušena či ohrožena v důsledku nekalé soutěže, požadovat, aby porušující osoba od takového jednání okamžitě upustila. Poškozený se může rovněž domáhat přiměřeného zadostiučinění, které může mít peněžitou formu, formu náhrady škody a navrácení bezdůvodného obohacení.

status) in order to gain, by means of unfair conduct, an advantage for himself or for another person (competitor) to the detriment of another competitor, or an illegal advantage in competition; or

- the individual referred to above directly or indirectly demands, solicits the promise of, or accepts, any type of benefit for the same purpose."

Permitted and Prohibited Practices

Criminal Code

Given the foregoing, a payment, gift or other benefit provided to a healthcare professional by a distributor of human pharmaceuticals or medical devices, under circumstances where the healthcare professional prescribes or dispenses the donor's product to patients, could constitute a criminal offense of bribe-offering and/or acceptance of a bribe, provided that the other conditions specified in the Criminal Code (see the discussion above) are met.

In general, it should be noted that a criminal offense can only be committed by an individual (as opposed to a legal entity, which does not have criminal liability) under the Criminal Code. Thus, a distributor of pharmaceuticals (or medical devices) and a hospital (as an institution) cannot be held liable for bribe-related criminal offenses under the Criminal Code. Only the individual employee (or agent) of a distributor offering a bribe and the particular healthcare professional accepting a bribe would be held liable for criminal prosecution under the Criminal Code.

Commercial Code

An argument can be made that the provision of payments, gifts or other benefits to healthcare professionals by a distributor of human pharmaceuticals or medical devices, for the purpose of inducing the healthcare professional to recommend or otherwise prescribe such products (as distinct from competing products) to patients, could be considered unfair competition under the provisions of the Commercial Code.

Public Procurement and Fraud

There is no special criminal offense defined in the Criminal Code in relation to public procurement. However, section 257 of the Criminal Code prohibits machinations in relation to ordering public procurement and public tendering – which is the prevailing form in which public procurements are organized in the Czech Republic. In addition, persons deciding on tenders organized in

Smlouvy s odborníky a zdravotnickými zařízeními

Odborníci poskytují farmaceutickým firmám různé odborné služby, což je běžnou součástí vztahů mezi těmito dvěma skupinami. Tyto služby mimo jiné zahrnují přednášky a výukovou činnost, odborné konzultace za daným účelem a pomoc při výzkumu. Poskytování takových služeb je v zásadě přípustné. Žádná smlouva o poskytování služeb však nesmí sloužit k nedovolenému ovlivňování odborníků při předepisování nebo vydávání humánních léčivých přípravků.

Platba odměny za referát lékaři na vědeckém kongresu či sympóziu je právně přípustná, pokud se jedná o odměnu *bona fide* za skutečně poskytované služby odborníky v oboru jejich specializace. V této souvislosti je třeba zmínit, že žádná smlouva ohledně odměny za referát nesmí být uzavřena za propagačními účely, jelikož by to bylo chápáno jako skrytá reklama, která je zákonem o reklamě a obchodním zákoníkem zakázána.

Obecná pravidla daná zák. č. 40/1964 Sb., občanský zákoník, ve znění pozdějších předpisů (dále jen „občanský zákoník") nebo případně obchodním zákoníkem, ohledně smluvního práva se budou vztahovat na všechny smlouvy mezi odborníky a farmaceutickými společnostmi a jejich distributory stejným způsobem, jakým se tato obecná pravidla vztahují na smlouvy v jakémkoliv jiném odvětví. Na tyto smlouvy se však vztahují i zásady a zákazy obsažené v další legislativě tak, jak je popsána výše. Obdobně se pravidla představující směrnice pro správnou klinickou praxi budou vztahovat na jakoukoliv smlouvu s odborníkem – zkoušejícím v souvislosti s klinickým hodnocením.

Jakýkoliv smluvní vztah mezi farmaceutickou společností a odborníkem v České republice, jehož účelem je propagovat společnost a její výrobky nebo dokonce přimět určitého odborníka, aby produkty společnosti předepisoval, užíval či vydával pacientům, bude nicméně podléhat výše uvedeným omezením a zákazům. Obdobně by mohla platba (nebo jiná výhoda) uhrazená či poskytnutá odborníkovi výrobcem či distributorem humánních léčivých přípravků či zdravotnických prostředků na základě takové dohody za okolností, kdy odborník předepisuje anebo vydává konkrétní humánní léčivý přípravek nebo zdravotnický prostředek vyrobený či distribuovaný dárcem, zakládat trestný čin podplácení anebo případně přijetí úplatku za předpokladu, že jsou splněny i ostatní podmínky uvedené v trestním zákonu (viz výše).

relation to public procurement usually hold a public official position and, therefore, can be punished according of the Criminal Code for abusing the function of a public official. Also, the criminal offense, defined above, of acceptance of a bribe would apply to a public official accepting an unjust payment or other benefit in relation to public procurement.

Sanctions

Criminal Code

In the absence of specific legislation on the issue, only the Criminal Code governs bribery and corruption practices. The punishment of these practices depends on whether the offer of a bribe, or the acceptance of a bribe, was committed (please see the discussion above).

With respect to the criminal offense of bribery regarding public officials, the Criminal Code describes the consequences of indirect bribery: "Whoever asks for or accepts a bribe to use his influence to affect the exercise of a public official's powers, or for having done so, will be punished by imprisonment of up to three years."

Civil Law

According to the general rules of Czech contract law, any contract that has been concluded unethically or in violation of a valid law or regulation will be void and unenforceable under Czech law.

Commercial Code

Under the Commercial Code, a person whose rights have been violated or threatened as a result of unfair competition may demand that the violator desist from and immediately cease such improper conduct. This person may also demand appropriate remedy, which may be rendered monetarily, as compensation for damages, and by surrendering any unjust enrichment.

Contracts with Healthcare Professionals and Medical Institutions

Rendering various professional services by healthcare professionals to pharmaceutical companies is a standard part of interactions between these two groups which include, *inter alia*, lecturing and proctorships, ad hoc expert's advice and assistance with research. Provision of such services is, in

Platba odměny lékařům za provádění klinických nebo neklinických hodnocení je ze zákona přípustná, pokud klinická studie splňuje podmínky rozsáhlých ustanovení zákona o léčivých přípravcích a zásady správné klinické praxe. Klinické hodnocení musí být předem schváleno úřadem, etickou komisí pro multicentrická hodnocení a etickou komisí pro příslušnou nemocnici (místo, kde hodnocení probíhá). Lékaři (zkoušející) mají nárok na odměnu, musí však být uzavřena písemná dohoda mezi zadavatelem studie a zkoušejícím nebo nemocnicí. Příslušná etická komise (etické komise) by měla zkontrolovat výši odměny.

Platba uhrazená (či jiná výhoda poskytnutá) odborníkovi výrobcem či distributorem humánních léčivých přípravků či zdravotnických prostředků s cílem přesvědčit odborníka, aby doporučoval nebo jinak předepisoval tyto výrobky svým pacientům (na úkor konkurenčních výrobků) by mohla být považována za projev nekalé soutěže dle ustanovení obchodního zákoníku a také za porušení předpisů Komory či jiné příslušné legislativy.

Doporučení

Pokud není jisté, jaké budou právní důsledky jakékoliv navržené či právě probíhající reklamy, sponzorování, darů či dohod s odborníky nebo reklamní činnosti zaměřené na odborníky v České republice, doporučujeme, aby byla taková reklama přezkoumána z hlediska souladu s příslušnými zákony a předpisy anebo aby byla předem zkonzultována s příslušným odborem úřadu.

Z výše uvedeného vyplývá, že omezení a zákazy týkající se propagačních aktivit zahrnujících poskytování darů a dalších výhod odborníkům neplatí, pokud jsou takové dary a výhody poskytovány nemocnicím a ostatním zdravotnickým zařízením jako právnickým osobám, zde nicméně odkazujeme na výklad definice odborníka úřadem, který, pokud byl závazný, by poskytování darů a výhod odborníkům – právnickým osobám, omezil.

Doporučujeme, aby farmaceutické společnosti (a jejich případní distributoři) vedly přesné a podrobné záznamy o výdajích na reklamu a aby vedení těchto společností zavedlo opatření, která zajistí, že společnosti budou obeznámeny se všemi navrhovanými případy sponzorování, darů či dohod s jednotlivými odborníky.

principle, permissible. However, any such agreement on provision of services must not serve as an undue influence of healthcare professionals when prescribing or dispensing human pharmaceuticals.

Further payment of speaker fees to physicians or administrators at scientific congresses or symposia is legally permissible if the compensation is *bona fide* for the actual services rendered by healthcare professionals competent in their field. In this regard, it is important to mention that no such agreements on speaker fees should be awarded for promotional purposes, as such agreements would be viewed as hidden advertising, prohibited by the Act on Advertising and the Commercial Code.

The general rules of Act No. 40/1964 Coll Civil Code, as amended ("Civil Code") or, as the case may be, of the Commercial Code, regarding contractual law, will apply to all agreements between healthcare professionals and pharmaceutical companies and their distributors in the same way as those general rules apply to contracts in any other industry. However, the principles and prohibitions contained in the additional legislation, described above, also apply to such agreements. Accordingly, the rules representing good clinical practice will apply to any agreement with a healthcare professional in relation to the activities of an investigator in a clinical trial.

However, any contractual relationship between a pharmaceutical company and a healthcare professional in the Czech Republic, the purpose of which is to promote the company and its products or even to induce a particular healthcare professional to prescribe, use, or dispense its products, will be subject to the restrictions and prohibitions mentioned above. Accordingly, a payment (or other benefit) provided to a healthcare professional by a producer or distributor of pharmaceuticals or medical devices on the basis of such an agreement, under circumstances where the pharmaceutical professional prescribes and/or dispenses to patients the particular pharmaceutical or medical device manufactured or distributed by the donor, could constitute a criminal offense of bribe-offering and/or acceptance of a bribe, as the case may be, provided that the other conditions specified in the Criminal Code (see the discussion above) are met.

Payment of compensation to physicians for the conduct of clinical or non-clinical studies is lawful if the clinical study complies with the extensive provisions in the Act on Pharmaceuticals and regulation of good clinical practice. Clinical studies must be pre-approved by the Authority, the ethics

committee for multi-centric studies, and the ethics committee of the relevant trial site (hospital), and written consent must be obtained from the subjects of the study. Physicians (investigators) may be compensated, but a written agreement should be entered into between the sponsor of the study and the investigator or hospital, and the relevant ethics committee(s) should review the amount of compensation.

In addition, payments made (or other benefits provided) to healthcare professionals by a manufacturer or distributor of human pharmaceuticals or medical devices, for the purpose of inducing the healthcare professional to recommend or otherwise prescribe such products (as distinct from competing products) to patients, could be considered unfair competition under the provisions of the Commercial Code and also a breach of the Chamber rules or other relevant legislation.

Recommendations

In the event of uncertainty about the legal consequences of any proposed or ongoing advertisement, sponsorship, donation or agreement with healthcare professionals, or any promotional activity directed at healthcare professionals in the Czech Republic, it is strongly recommended that the advertisement be reviewed for compliance with applicable laws and regulations and/or that appropriate, prior consultation be undertaken with the relevant department of the Authority.

As highlighted above, the restrictions and prohibitions regarding promotional activities consisting of the provision of gifts and other benefits to healthcare professionals do not apply when such gifts or benefits are provided to hospitals or other medical facilities as legal entities. However, please see the discussion on the term “healthcare profession” by the Authority, which, if binding, would restrict provision of gifts and benefits to legal entities.

It is strongly recommended that pharmaceutical companies (and their distributors, if applicable) keep accurate and detailed records and accounts of promotional expenditures, and that management should institute measures to ensure that they are advised and kept informed of any proposed sponsorship, donation or agreement with an individual healthcare professional.

France

Thomas Devred

Les relations entre les professionnels de sante et l'industrie

Dans le cadre de la promotion des médicaments auprès des personnes habilitées à les prescrire ou à les délivrer, il est interdit d'octroyer, d'offrir ou de promettre à ces personnes une prime, un avantage pécuniaire ou un avantage en nature à moins que ceux-ci ne soient de valeur négligeable et n'aient trait à l'exercice de la médecine ou de la pharmacie. Ce principe, repris aujourd'hui par l'article 94 du Code communautaire sur les médicaments [1], est issu initialement de la directive n° 92/28/CEE sur la publicité en faveur des médicaments.

La transposition en France de la directive 92/28/CEE a été opérée par la loi du 18 janvier 1994 [2], dont les dispositions ont été codifiées dans le Code de la Santé Publique (ci-après le « CSP ») au sein du Livre V consacré à la pharmacie.

Toutefois, le cadre juridique français était déjà pourvu d'un dispositif légal encadrant les relations entre les professionnels de santé et l'industrie des produits de santé, avec les dispositions de la loi du 27 janvier 1993[3] qui, elles, étaient codifiées dans le CSP au sein de Livre IV dédié aux professions médicales et aux auxiliaires médicaux.

Ainsi, préalablement à la transposition de la directive 92/28/CEE, il existait déjà en France un principe général d'interdiction des avantages pécuniaires ou en nature bénéficiant aux professionnels de santé.

[1] Directive 2001/83/CE du Parlement européen et du Conseil, en date du 6 novembre 2001, instituant un code communautaire relatif aux médicaments à usage humain, JOCE l L-311 du 28 novembre 2001, (ancien article 9 de la directive n° 92/28/CEE du Conseil du 31 Mars 1992 sur la publicité en faveur des médicaments à usage humain).
[2] Loi n° 94-43 du 18 janvier 1994 relative à la santé publique et à la protection sociale, JORF du 19 janvier 1994.
[3] Loi n° 93-121 du 27 janvier 1993, JORF du 30 janvier 1993.

France

Thomas Devred

Interactions Between the Industry and Healthcare Professionals

Within the framework of promoting medicinal products among persons authorized to prescribe or deliver them, it is forbidden to grant, offer or promise a bonus, a pecuniary advantage or a benefit in kind to such persons unless it is of negligible value and relates to the practice of medicine or of pharmacy. This principle, which is now included in Article 94 of the Community Medicines Code,[1] results from Directive n° 92/28/EEC concerning advertising for medicinal products.

Directive 92/28/EEC was implemented in France by the law of 18 January 1994,[2] the provisions of which were codified in the French Code of Public Health (namely, the *Code de la Santé Publique*, the "FCPH") in Book V on pharmacy.

However, the French legal framework already contained a legal provision regulating the relationships between health professionals and the pharmaceutical industry in the provisions of the law of 27 January 1993[3] which were codified in the FCPH in Book IV, dedicated to the medical professions and medical auxiliaries.

Thus, prior to the implementation of Directive 92/28/EEC, there was already in France a general principle of prohibition of pecuniary advantages or benefits in kind to health professionals.

The so-called Anti-Gift (*anti-cadeaux*) Law of 27 January 1993 was codified in FCPH Article L.4113-6. Moreover, this article complements the provisions of FCPH Article L.4113-8 which state, in essence, that health professionals

[1] Directive 2001/83/EC of the European Parliament and Council, dated 6 November 2001, creating a community code relating to medical products for human use, JOCE 1L 311 dated 28 November 2001 (formerly Article 9 of Directive 92/28/EEC of the Council dated 31 March 1992 concerning advertising for medicinal products for human use).
[2] Law n° 94-43 dated 18 January 1994 relating to public health and social protection, JORF dated 19 January 1994.
[3] Law n° 93-121 dated 27 January 1993 JORF dated 30 January 1993.

La loi du 27 janvier 1993, dite loi « Anti-Cadeaux », a été codifiée au sein de l'article L.4113-6 du CSP. Cet article s'inscrit par ailleurs à titre de complément des dispositions de l'article 4113-8 du CSP, qui énoncent en substance qu'est interdit le fait, pour les professionnels de santé, de recevoir, sous quelque forme que ce soit, de manière directe ou indirecte, des intérêts ou ristournes proportionnelles au nombre d'unités prescrites ou vendues, qu'il s'agisse de médicaments ou d'appareils de quelque nature que ce soit.

Une circulaire du 9 juillet 1993[4] est venue préciser le contenu de l'article L.4113-6 du CSP, en énonçant notamment que les dispositions de la loi Anti-Cadeaux devaient être interprétées à la lumière des dispositions de la directive 92/28/CEE.

L'approche de la directive 92/28/CEE et celle de la loi du 27 janvier 1993 étaient cependant distinctes. En effet, là où le texte communautaire interdisait aux entreprises pharmaceutiques de procurer des avantages aux professionnels de santé, la loi française préexistante interdisait aux professionnels de santé de recevoir ces avantages de la part de l'industrie des produits de santé.

La loi du 4 mars 2002 sur le droit des malades[5] a modifié les dispositions de la loi Anti-Cadeaux. Dorénavant le dispositif de l'article L.4113-6 du CSP interdit également aux entreprises de procurer des avantages aux professionnels de santé.

La loi du 4 mars 2002 a également introduit un principe de transparence avec l'article L.4113-13 du CSP, qui prévoit l'obligation suivante à la charge des professionnels de santé:

« Les membres des professions médicales qui ont des liens avec des entreprises et établissements produisant ou exploitant des produits de santé ou des organismes de conseil intervenant sur ces produits sont tenus de les faire connaître au public lorsqu'ils s'expriment lors d'une manifestation publique ou dans la presse écrite ou audiovisuelle sur de tels produits. »

Le non respect de cette obligation entraîne pour le professionnel de santé concerné des sanctions disciplinaires prononcées par l'ordre professionnel

[4] Circulaire du 9 juillet 1993 relative à l'application de l'article L.365-1 du code de la santé publique, JORF du 6 août 1993.
[5] Loi n° 2002-303 du 4 mars 2002 relative aux droits des malades et à la qualité du système de santé, JORF du 5 Mars 2002.

are prohibited from receiving, in any form whatsoever, directly or indirectly, interests or rebates proportional to the number of units prescribed or sold, whether it be a question of medicinal products or of devices of any nature.

A circular dated 9 July 1993[4] spelled out the content of Article L.4113-6, providing that the provisions of the Anti-Gift Law have to be interpreted in the light of Directive 92/28/EEC.

The approach of directive 92/28/CEE and that of the law of 27 January 1993 were, however, distinct. In effect, where the European text forbade pharmaceutical companies from giving benefits to health professionals, the pre-existing French law forbade health professionals from receiving these benefits from pharmaceutical companies.

The Patients' Rights Law of 4 March 2002[5] modified the provisions of the Anti-Gift Law. Henceforth, the provisions of Article L.4113-6 also forbid health product companies from procuring advantages for health professionals.

The 4 March 2002 law also introduced a new principle for transparency which, together with Article L.4113-13, provides for the following obligation for healthcare professionals:

The members of the medical profession who have connections with business and establishments which produce or develop health products or counseling organizations involved with these products are required to make such connections known to the public if they make statements on such products in public or in the written or audio-visual press.

Non-compliance with this obligation gives rise to disciplinary sanctions declared by the relevant professional body for the health professional concerned. According to the implementing decree of the law of 4 March 2002, the public shall be informed via the presentation of the professional concerned, either in writing at the beginning of articles published by the

[4] Circular dated 9 July 1993 relating to the enforcement of Article L.365-1 of the French Code of Public Health, JORF dated 6 August 1993.
[5] Law n° 2002-303 dated 4 March 2002 relating to patients' rights and quality of the health system, JORF dated 5 March 2002.

compétent. Le décret d'application de la loi du 4 mars 2002 prévoit que l'information du public devra être faite dans le cadre de la présentation du professionnel concerné, soit de façon écrite en début d'article en cas d'article diffusé par la presse écrite ou sur l'internet, soit oralement en début d'intervention en cas de manifestation publique ou d'intervention par la presse audiovisuelle.[6]

La question de la promotion des produits de santé au travers des relations entre les professionnels de santé et l'industrie des produits de santé doit donc être abordée en premier lieu sous l'angle d'une analyse de la loi Anti-Cadeaux, cette analyse devant le cas échéant être complétée par une référence à la réglementation de la publicité en faveur des médicaments.

Ces relations sont donc régies par un principe général d'interdiction mettant un terme à des pratiques abusives d'incitation à la prescription. Ce principe est toutefois assorti de dérogations permettant à l'industrie des produits de santé de continuer son rôle en matière de diffusion des connaissances scientifiques sur les médicaments et de recherche fondamentale, et est atténué par certaines règles en matière de publicité. Au delà de ces dérogations, l'article L.4113-6 du CSP précise in fine que les règles qu'il instaure n'ont pas vocation à s'appliquer aux « relations normales de travail », notion sur laquelle il convient de revenir tant elle est discutée en pratique. Enfin, le non respect des règles encadrant les avantages consentis aux membres des professions médicales entraîne l'application de sanctions pénales et disciplinaires.

La transparence dans les relations entre l'industrie des produits de santé et les professionnels de santé a été renforcée avec la loi "Bertrand" du 29 décembre 2011.[7] Cette loi a introduit dans le CSP un nouvel article L.1453-1 qui oblige les industries des produits de santé à rendre public l'ensemble des conventions conclues avec les professionnels de santé ainsi que les avantages qu'elles leur ont octroyés. A la date de rédaction de cet ouvrage (20 juillet2012), le décret d'application qui doit détailler les modalités de cette nouvelle obligation n'est pas publié.

[6] Décret n° 2007-454 du 25 Mars 2007 relatif aux conventions et aux liens unissant les membres de certaines professions médicales et certaines entreprises et modifiant le code de la santé publique, (insertion d'un nouvel article R.4113-110 du CSP).
[7] Loi n° 2011-2012 du 29 décembre 2011 relative au renforcement de la sécurité sanitaire du médicament et des produits de santé, JORF du 30 décembre 2011.

written press or on the internet, or orally at the beginning of public events or speeches by the audiovisual press.[6]

The question of promoting health products by way of relationships between health professionals and the health products industry must be dealt with, in the first place, from the viewpoint of an analysis of the Anti-Gift Law. This analysis should be supplemented, if appropriate, by a reference to regulations concerning advertising for medicinal products.

Hence, these relationships are governed by a general principle of prohibition which puts an end to improper practices that tend to be an incentive to prescription. However, this principle is subject to exceptions enabling the health products industry to continue its role in the dissemination of scientific knowledge concerning medicinal products and in fundamental research, and it is mitigated by certain rules concerning advertising. Beyond such exceptions, Article L.4113-6 *in fine* specifies that its particular rules do not apply to the notion of "normal working relations," which is subject to discussion in practice and which must thus be clarified. Finally, non-compliance with the rules governing the advantages granted to medical professionals triggers the application of criminal and disciplinary sanctions.

Transparency in interactions between the health products industry and healthcare professionals has been intensified with the Bertrand Law of 29 December 2011 (the "Bertrand Law").[7] This law adds Article L.1453-1 — which requires that the health product companies disclose to the public all the contracts entered into with healthcare professionals, as well as any benefit granted to such healthcare professionals — to the FCPH. As of the drafting date of this chapter, the implementing decree which is to detail the provisions of this new disclosure obligation has not yet been published.

The Bertrand Law has also reorganized the French Authority for the Safety of Health Products ("AFSSAPS"), reinforcing its power and changing its name. The AFSSAPS is now called the National Agency for the Safety of Medicinal Products and Other Health Products ("ANSM").

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[6] Decree n° 2007-454 dated 25 March 2007, relating to the agreements and relations between the members of certain medical professions and certain companies and modifying the French Code of Public Health (inclusion of a new Article R.4113-110 of the FCPH).

[7] Law n° 2011-2012 of 29 December 2011 for the reinforcement of the safety of medicinal products and health products, JORF 30 December 2011.

La loi “Bertrand” a par ailleurs changé l’organisation de l’Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS), a renforcé ses pouvoirs, et a changé son nom. L’AFSSAPS est en effet désormais appelée “ANSM” (Agence Nationale de Sécurité des Médicaments et des produits de santé).

Principe général d’interdiction des avantages consentis par l’industrie des produits de santé aux professionnels de santé

Le principe est formulé au sein de l’article L.4113-6 alinéa 1 du CSP, qui dispose :

« Est interdit le fait, pour les étudiants se destinant aux professions relevant de la quatrième partie du présent code et pour les membres des professions médicales visées au présent Livre, ainsi que les associations les représentant, de recevoir des avantages en nature ou en espèces, sous quelque forme que ce soit, d’une façon directe ou indirecte, procurés par des entreprises assurant des prestations, produisant ou commercialisant des produits pris en charge par les régimes obligatoires de sécurité sociale. Est également interdit le fait, pour ces entreprises, de proposer ou de procurer ces avantages ».

L’article 24 du Code de Déontologie Médicale[8] reprend ce principe d’interdiction, et précise en outre qu’il est interdit aux médecins de solliciter de tels avantages.

Les avantages considérés sont frappés d’une interdiction qui ainsi vise notamment les membres des professions médicales, dès lors qu’ils sont consentis par des entreprises précisément définies.

Notion d’avantage

Notion

Le champ d’application de l’article L.4113-6 du CSP est large. Sont en effet visés les avantages en nature ou en espèces, sous quelque forme que ce soit, d’une façon directe ou indirecte. L’article L.4133-6 du CSP ne fournit cependant aucune définition légale de la notion d’avantage.

[8] Décret n° 95-1000 du 6 septembre 1995 portant code de déontologie médicale, codifié aux R.4127-1 à R.4127-112 du CSP.

General Principle of Prohibition of Advantages Granted by the Industry to Healthcare Professionals

The principle is formulated in FCPH Article L.4113-6, paragraph 1, which provides:

> The members of the medical professions mentioned in the present book, as well as students preparing a diploma to practice the same medical professions, and their associations, are prohibited from receiving pecuniary advantages or benefits in kind, in any form whatsoever, directly or indirectly, provided by companies which provide services, produce or market products reimbursed by the mandatory social security regimes. These businesses are also prohibited from offering or procuring such advantages.

Article 24 of the Medical Code of Ethics[8] incorporates this prohibition principle, and also specifies that physicians are prohibited from requesting such advantages.

The advantages in question are subject to a prohibition that thus principally targets medical professionals, in so far as they are granted by precisely defined companies.

Definition of Advantage

Definition

The scope of FCPH Article L.4113-6 is quite broad. In effect, it targets pecuniary advantages or benefits in kind, in any form whatsoever, given directly or indirectly. Such article does not provide for a legal definition of the notion of advantage.

The prohibited advantage must be understood as being that which is paid or allocated to healthcare professionals, without any reciprocal benefit on their part (such as in the form of scientific collaboration or expertise), or when the said reciprocity is out of proportion to what is allocated or paid. This

[8] Decree n° 95-1000 dated 6 September 1995 relating to the Medical Code of Ethics, as codified in Articles R.4127-1 to R.4127-112 of the FCPH.

L'avantage interdit doit s'entendre de ce qui est versé ou alloué au professionnel de santé, sans contrepartie directe de sa part (sous forme de collaboration scientifique, d'expertise…) ou bien lorsque cette contrepartie est sans proportion avec ce qui est alloué ou versé. Cette approche emporte la conséquence, notamment, qu'une rémunération injustifiée doit être considérée comme un avantage illicite. Il en va ainsi par exemple de la rémunération de chirurgiens pour le résultat d'une enquête n'impliquant aucun travail de recherche et dont les résultats se réduisent à une simple synthèse de commentaires sur le suivi de patients, dont le montant atteint en moyenne 220 EUR par patients alors qu'il est acquis que, en pratique, ce type d'enquête est rémunéré à hauteur de 75 EUR par patients (condamnation de chacun des chirurgiens concernés à 2875 EUR d'amende).[9]

Avantages en nature ou en espèce

L'interdiction couvre tant les avantages en nature que les avantages en espèce.

A titre d'exemple, il faut considérer que les voyages d'agrément, les invitations à des manifestations culturelles et sportives, les cadeaux sous forme de matériels ou d'objets, ou le prêt d'objet sont des avantages en nature; et que la remise d'une somme d'argent, notamment sous la forme d'une commission, ou encore le paiement par une entreprise, pour le compte du professionnel, de ses frais professionnels (par exemple la location de biens immobiliers ou de matériels) constituent des avantages en espèces au sens de l'article L.4113-6 du CSP.

Un médecin a pu ainsi être condamné à une amende de 1220 EUR pour avoir bénéficié de la prise en charge d'un forfait touristique en complément des frais attachés à son déplacement à Cuba pour participer à un congrès scientifique.[10]

La circulaire du 9 juillet 1993 précise par ailleurs qu'il est indifférent que les avantages considérés aient un rapport exclusivement avec des produits ou services non pris en charge par les organismes de la sécurité sociale dès lors que l'entreprise qui les verse commercialise d'autres produits ou assure d'autres prestations qui sont pris en charge par les organismes de sécurité sociale.

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[9] Cour d'appel de Montpellier, 3ème Ch. Correctionnelle, 3 décembre 1998, arrêt n° 1538.
[10] TGI de Brest, 16 février 1999, jugement n° 464/99.

approach entails the consequence, in particular, that unjustified compensation must be considered as an illegal advantage.

This was the case for surgeons who were remunerated for the performance of a study which did not involve any research effort and the results of which were limited to a very simple synthesis of comments on the surgeons' monitoring of patients. In this case, the surgeons were remunerated EUR220 per patient on average, whereas this kind of study is in practice generally paid EUR75 per patient (the surgeons were therefore sentenced to a EUR2,875 fine)[9].

Pecuniary Advantages or Benefits in Kind

The prohibition covers both pecuniary advantages and benefits in kind.

For example, trips for leisure, invitations to cultural and sporting events, gifts in the form of equipment or objects, and putting items at disposal are considered benefits in kind. The payment of an amount of money, particularly in the form of a commission or payment by the company of professional expenses on the professional's behalf (e.g., expenses of renting of real properties or equipment) constitute pecuniary advantages in the meaning of Article L.4113-6.

A physician was sentenced to a fine of EUR1,220 for having taken advantage of a fixed-price tourism package in addition to the costs related to his business trip in Cuba.[10]

Moreover, the circular of 9 July 1993 specifies that it makes no difference whether the advantages in question are related solely to products or services not reimbursed by social security organizations as long as the company that provides such advantages markets other products or provides other services that are reimbursed by social security organizations.

Direct or Indirect Advantages

Finally, said advantages may be granted directly or indirectly.

This detail is important as it extends the application of the principle of prohibition to advantages given to third parties when said advantages benefit

[9] Court of Appeal of Montpellier, 3rd correctional chamber, 3 December 1998 case n° 1538.
[10] TGI of Brest, 16 February 1999, case n° 464/99.

Avantages directs ou indirects

Enfin, ces avantages peuvent être consentis directement ou indirectement.

Cette précision est importante dans la mesure où elle entraîne l'application du principe d'interdiction à des avantages procurés à des tiers, lorsque ces avantages bénéficient finalement à un professionnel de santé de manière individuelle.

Les tiers sont dans cette hypothèse des intermédiaires comme par exemple les associations de médecins qui reçoivent des dons de la part des entreprises du secteur des produits de santé. Les fonds donnés à ces associations ne sauraient bénéficier à un médecin, qu'il soit membre ou non de l'association bénéficiaire.

La Cour d'appel d'Angers a précisé le notion d'avantage indirect dans un arrêt du 25 mars 1999 par lequel un médecin, Président Directeur Général d'une Société Anonyme propriétaire d'une clinique, a été condamné à une amende de 3050 EUR. Le médecin possédait 23% des actions de la Société Anonyme, elle-même était propriétaire à 60% de la clinique. Ce médecin, en sa qualité de Président Directeur Général, avait accepté de la part de différents fabricants de dispositifs médicaux différents matériels (par exemple des équipements pour vidéo opératoire) d'une valeur totale d'environ 56400 EUR. La Cour d'appel d'Angers a estimé que la fourniture gratuite de matériel par le fabricant avait comme contrepartie l'achat d'autres produits commercialisés par ce fabricant et devait être dès lors qualifiée d'avantage prohibé au sens de l'article L.4113-6 du CSP. La Cour a ainsi jugé que cet article était applicable en l'espèce car *« l'avantage consenti à une société, par laquelle des médecins s'associent pour exercer leur art, constitue un avantage indirect qui est de nature à les inciter à choisir un matériel, non pas en fonction de ses qualités exclusivement médicales mais en raison également de l'intérêt qu'ils peuvent tirer des conditions de vente de ce matériel, non seulement en qualité d'utilisateurs des biens obtenus mais également en qualité d'associés ».*[11]

La jurisprudence de la Cour d'appel d'Angers, confirmée par la Chambre criminelle de la Cour de cassation dans un arrêt du 29 septembre 1999,[12] ne doit cependant pas vider de tout contenu les dispositions du CSP relatives à la

[11] Cour d'appel d'Angers, Ch. Correctionnelle, 25 mars 1999, arrêt n° 245.
[12] Cass., Crim., 29 septembre 1999, pourvoi n° 99.83300.

a health professional individually in the end. In such a case, the third parties are intermediaries, as, for instance, when the physicians' associations receive gifts from health product companies. The funds given to such associations may or may not benefit the physician, whether or not he is a member of the association which receives such funds.

The Court of Appeal of Angers spelled out the notion of indirect advantage in a decision issued on 25 March 1999 in which a physician who was simultaneously the president and chief executive officer of a corporation that owned a clinic was sentenced to a fine of EUR3,050. The physician held 23 percent of the shares of the corporation, which in turn was the 60 percent owner of the clinic. The physician, as president and chief executive officer, had accepted various items from various medical device manufacturers (e.g., video operating equipment) with a total value of around EUR56,400. The Court of Appeal of Angers considered that the free supply of equipment by the manufacturer was reciprocated by the purchase of other products marketed by that manufacturer and hence was to be characterized as a prohibited advantage under Article L.4113-6. Thus, the Court of Appeal ruled that said article was applicable to that case since:

> the advantage granted to a company through which physicians exercise in common their art, constitutes an indirect advantage that is of such nature as to lead them to choose equipment, not strictly in the light of its medical characteristics, but also because of the advantage that they may derive from the sales terms of the said equipment, not only as users of the goods obtained, but also as partners.[11]

The precedent set by the Court of Appeal of Angers, which was confirmed by the Criminal Chamber of the Supreme Court (*Cour de Cassation*) in a decision dated 29 September 1999,[12] must not, however, be taken as voiding the provisions of the FCPH related to advertising for pharmaceutical companies, which authorize, under specific conditions, gifts made by the pharmaceutical companies to legal entities.

[11] Court of Appeal of Angers, correctional chamber, 25 March 1999 case n° 245.
[12] Cass. Crim., 29 September 1999 case n° 99.83300.

publicité en faveur des entreprises pharmaceutiques, qui autorisent dans des conditions strictes les dons faits par les laboratoires aux personnes morales.

Personnes visées par l'interdiction de recevoir des avantages

L'article L.4113-6 du CSP renvoie aux membres des professions médicales visés au « *présent Livre* ». Il s'agit Livre 1er de la quatrième partie du CSP relatives aux professions de santé. Ce livre couvre la catégorie des professions médicales, parmi lesquelles on trouve les médecins, les sages-femmes et les chirurgiens dentistes.

A la catégorie des professions médicales il faut ajouter les infirmiers,[13] les masseurs – kinésithérapeutes,[14] les orthophonistes ainsi que les orthoptistes[15] qui, s'ils font partie de la catégorie des auxiliaires médicaux et non de celle des professions médicales, sont visés également par le principe d'interdiction, ainsi que les pharmaciens.[16]

En effet, les articles L.4343-1 et L.4311-28 du CSP prévoient expressément que l'article L.4113-6 s'applique aux membres de ces professions. Les tribunaux ont par ailleurs déjà appliqué l'article L.4113-6 du CSP aux infirmiers (amende de 3050 EUR) pour avoir reçu la somme de 1070 EUR d'un laboratoire dans le but de s'équiper en matériel médical.[17]

Il en va de même pour les pharmaciens. La loi du 23 décembre 1998 de financement de la sécurité sociale pour 1999 a en effet inséré dans le CSP l'article L.4221-17 qui renvoie aux dispositions de l'article L.4113-6 du CSP. En pratique, sont visés par ce texte les pharmaciens d'officine et les pharmaciens hospitaliers.

La loi du 4 mars 2002 a étendu le champ d'application de l'interdiction de recevoir des avantages notamment aux membres des commissions consultatives placées auprès des ministres chargés de la santé et de la sécurité sociale et aux personnes qui collaborent occasionnellement aux travaux de

[13] Article L.4311-28 du CSP.
[14] Article L.4321-19 du CSP.
[15] Article L.4343-1 du CSP.
[16] Article L.4221-17 du CSP.
[17] Tribunal de Grande Instance d'Albi, jugement du 27 mai 1999, cité par T. Pléan, « La loi anti- cadeaux, premiers éléments de jurisprudence », Contrats, Concurrence, Consommations, n° 116, juillet-août 2000.

Healthcare Professionals Targeted by the Prohibition

FCPH Article L.4113-6 refers to the members of the medical professions identified in the "Present Book." The book in question is Book 1 of the fourth part of the FCPH relating to the health professions. The book covers the category of the medical professions, which includes physicians, midwives and dental surgeons.

Nurses,[13] masseur-physiotherapists,[14] speech therapists and orthoptists[15] are also subject to the prohibition principle even if they are part of the category of medical auxiliaries and not of the medical professions. The same holds true for pharmacists.[16]

Articles L.4343-1 and L.4311-28 of the FCPH explicitly provide that Article L.4113-6 applies to members of these professions. Moreover, the courts have already applied FCPH Article L.4113-6 by sentencing a nurse to pay a fine of EUR3,050 for having received EUR1,070 from a pharmaceutical company for the purpose of purchasing medical equipment for herself.[17]

The same applies to pharmacists (chemists). The law of 23 December 1998 concerning social security financing for the year 1999 in fact added Article L.4221-17 to the FCPH, referring to the provisions of FCPH Article L.4113-6. In practice, that text affects dispensing pharmacists and hospital pharmacists.

The law of 4 March 2002 extended the scope of the application of the prohibition on receiving advantages, particularly to members of consulting committees advising ministers in charge of health and social security and to persons who occasionally participate in the work of these committees. Members of the Transparency Commission (*Commission de la Transparence*), who are responsible for giving a prior opinion on the inscription of a medicine on the list of reimbursable medications, are especially targeted here.

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[13] Article L.4311-28 of the FCPH.
[14] Article L.4321-19 of the FCPH.
[15] Article L.4321-1 of the FCPH.
[16] Article L.4221-17 of the FCPH.
[17] Tribunal de Grande Instance of Albi, judgment dated 27 May 1999 quoted by T. Pléan, "*La loi anti-cadeaux, premiers éléments de jurisprudence* [first cases relating to the Anti-Gift Law]", Contracts, Competition, Consumptions, n° 116, July-August 2000.

ces commissions. Sont visés ici, par exemple, les membres de la Commission de la Transparence (en charge de rendre un avis préalable sur l'inscription d'un médicament sur la liste des médicaments remboursables).

En dernier lieu, la loi "Bertrand" du 29 décembre 2011 est venue ajouter les étudiants préparant un diplôme pour exercer l'une des professions de santé visées ci-dessus, ainsi que les associations de professionnels de santé et les associations d'étudiants.

Entreprises visées par l'interdiction de procurer des avantages

L'article L.4113-6 du CSP vise les avantages consentis par les entreprises « *assurant des prestations, produisant ou commercialisant des produits pris en charge par les régimes obligatoires de sécurité sociale* ».

Entreprises visées et entreprises échappant au principe d'interdiction

A l'évidence sont visés ici les entreprises assurant l'exploitation de médicaments remboursables, ainsi que les entreprises qui exploitent des dispositifs médicaux pris en charge par les organismes de sécurité sociale.

Celles des entreprises qui n'assurent l'exploitation d'aucun produit remboursable ne sont par contre pas concernées par l'article L.4113-6 du CSP. Mais cet article trouve cependant son écho parmi les règles relatives à la publicité en faveur des médicaments. L'article L.5122-10 *in fine* du CSP[18] dispose en effet que :

« *Dans le cadre de la promotion des médicaments auprès des personnes habilitées à les prescrire ou à les délivrer, il est interdit d'octroyer, d'offrir ou de promettre à ces personnes une prime, un avantage pécuniaire ou un avantage en nature …* ».

Cette interdiction, exprimée ici à l'encontre des entreprises pharmaceutiques (à l'exclusion des fabricants de dispositifs médicaux), n'opère aucune distinction entre les entreprises exploitant des médicaments remboursables et les entreprises n'exploitant que des médicaments non remboursables. L'interdiction s'applique à l'ensemble des entreprises pharmaceutiques et répond par là-même à l'objectif assigné par la réglementation communautaire d'assurer l'indépendance professionnelle des médecins en élaborant un corps

[18] L'article L.5122-10 du CSP transpose l'article 9 de la directive 92/28/CEE (article 94 du Code communautaire sur les médicaments).

Finally, the Bertrand Law has included students preparing to practice any of the medical professions mentioned above, as well as associations of healthcare professionals and associations of students.

Companies Targeted by the Prohibition to Receive Advantages

FCPH Article L.4113-6 deals with the advantages granted by companies "providing services or producing or marketing products reimbursed by the mandatory social security regimes."

Companies Subject to and Companies Exempt from the Principle of Prohibition

Companies which market reimbursed products are obviously affected here, as are companies which market medical devices paid for by social security entities. Companies which do not market any reimbursed products are not affected.

However, Article L.4113-6 is echoed in the rules relating to advertising for medicinal products. FCPH Article L.5122-10 *in fine*[18] provides as follows:

> Within the framework of promotion of medicinal products among persons authorised to prescribe or to deliver them, it is forbidden to grant, offer or promise, to such persons a bonus, a pecuniary advantage or a benefit in kind…

The prohibition, expressed here in terms of pharmaceutical companies (to the exclusion of medical device manufacturers), does not distinguish between companies marketing reimbursed medicinal products and companies marketing only medicinal products that are not reimbursable. The prohibition applies to all pharmaceutical companies, and thereby meets the objective laid down in the Community Regulation of ensuring healthcare professionals' independence by developing a set of rules guaranteeing that the persons authorized to prescribe or deliver medicinal products are in a position to carry out that task with complete objectivity, without being influenced by direct or indirect incentives.

[18] Article L.5122-10 of the FCPH implements Article 9 of directive 92/28/EEC (Article 94 of the Community code on medical products)

de règles garantissant que les personnes habilitées à prescrire des médicaments soient à même d'exercer ces tâches en toute objectivité, sans être influencées par des incitations directes ou indirectes.

Personnes intermédiaires

La notion d'avantage indirect, telle qu'elle a été interprétée par la Cour d'appel d'Angers dans l'hypothèse où l'intermédiaire est le bénéficiaire de l'avantage considéré (une Société Anonyme dans laquelle les médecins possèdent des parts, voir ci-dessus), doit couvrir également le schéma par lequel l'industriel procurerait indirectement l'avantage au travers d'une société ou d'une association « écran ». La circulaire du 9 juillet 1993 précise à cet effet qu'entrent dans le champ d'application de l'article L.4113-6 du CSP les sociétés de communication ou toute autre structure agissant pour le compte d'entreprises elles-mêmes concernées par son application.

Le raisonnement est le même concernant les avantages émanant d'entreprises étrangères; le principe d'interdiction devrait recevoir application, si par ailleurs il était établi que ces entreprises étrangères faisaient partie d'un groupe comprenant d'autres entreprises répondant aux critères de l'article L.4113-6 du CSP.

Les notions d'avantage, de membre des professions médicales et d'entreprise ont donc un champ d'application très large. Le principe d'interdiction des avantages souffre cependant d'exceptions.

Exceptions au principe d'interdiction

Le principe d'interdiction des avantages consentis par les entreprises produisant ou commercialisant des produits remboursables aux professionnels de santé est écarté dans deux séries d'hypothèses.

L'article L.4113-6 du CSP prévoit tout d'abord lui-même deux dérogations relatives aux contrats de recherche et à l'hospitalité offerte lors de manifestations à caractère scientifique ou promotionnel. Par ailleurs, la réglementation sur la publicité des médicaments autorise expressément, mais sous certaines conditions, les entreprises pharmaceutiques à délivrer gratuitement à certains professionnels de santé des échantillons de médicaments, à leur procurer des avantages dès lors que lesdits avantages ont une valeur négligeable, et à faire des dons.

Intermediaries

The notion of indirect advantage, as construed by the Court of Appeal of Angers on the assumption that the intermediary (a corporation in which the physicians hold shares) is the beneficiary of the advantage in question, must also cover the situation where a company would offer the advantage indirectly through a company or a "screen" association. The circular of 9 July 1993 specifies in effect, that the scope of Article L.4113-6 includes communication companies or any other structure acting on behalf of companies that, themselves, are affected by its application.

The reasoning is the same with respect to advantages emanating from foreign companies. The principle of prohibition should apply, if moreover it were established that the said foreign companies are part of a group which includes other companies meeting the criteria laid down in Article L.4113-6.

Hence, the notions of advantage of members of the medical profession and of companies have a very broad scope. However, the principle prohibiting advantages is subject to exceptions.

The Exceptions to the Prohibition Principle

The principle of prohibition of advantages granted to healthcare professionals by companies manufacturing or commercializing health products admitted to reimbursement does not apply on two sets of cases.

Article L.4113-6 itself provides, first of all, for two exceptions relating to research contracts and to hospitality offered during events of a scientific or promotional nature. Moreover, the regulations on advertising of medicinal products explicitly authorize, subject to certain conditions, the pharmaceutical industry to deliver medicinal product samples free of charge to certain health professionals, provide them with advantages when the said advantages are of negligible value, and make financial grants.

The Exceptions Provided for by FCPH Article L.4113-6

Article L.4113-6 is aimed at ensuring greater transparency in the relationship between health professionals and the health products industry. However, such an objective must not prevent research activities or actions which promote medical training.

Two exceptions are explicitly provided for in Article L.4113-6: one for contracts concerning research or scientific evaluations concluded between

Dérogations prévues par l'article L.4113-6 du CSP

L'article L.4113-6 du CSP a pour objet d'assurer une plus grande transparence dans les relations entre les professionnels de la santé et l'industrie des produits de santé. Cet objectif ne doit cependant pas empêcher les activités de recherche ni les actions favorisant la formation médicale.

Deux dérogations sont expressément prévues par l'article L.4113-6 du CSP, l'une pour les contrats relatifs à la recherche ou à l'évaluation scientifique conclus entre les industriels et les professionnels de santé, et l'autre pour l'hospitalité offerte à ces professionnels à l'occasion de manifestations à caractère scientifique ou promotionnel. Ces deux dérogations ne sont recevables qu'à condition de respecter la procédure de demande d'avis préalable auprès des instances ordinales compétentes.

Conventions passées entre les professionnels de santé et les entreprises ayant pour objet des activités de recherche ou d'évaluation scientifique

L'article L.4113-6 alinéa 2 du CSP dispose:

« Toutefois, l'alinéa précédent [principe d'interdiction des avantages] ne s'applique pas aux avantages prévus par conventions passées entre les membres de ces professions médicales et des entreprises, dès lors que ces conventions ont pour objet explicite et but réel des activités de recherche ou d'évaluation scientifique, qu'elles sont, avant leur mise en application, soumises pour avis au Conseil départemental de l'Ordre compétent et notifiées, lorsque les activités de recherches sont effectuées, même partiellement, dans un établissement de santé au responsable de l'établissement, et que les rémunérations ne sont pas calculées de manière proportionnelle au nombre de prestations ou produits prescrits, commercialisés ou assurés. Il ne s'applique pas également aux avantages prévus par conventions passées entre des étudiants se destinant aux professions relevant de la quatrième partie du présent code et des entreprises lorsque ces conventions ont pour objet des activités de recherche dans le cadre de la préparation d'un diplôme ».

Sont visés ici les contrats avec les investigateurs dans le cadre des essais cliniques soumis aux articles L.1121-1 et suivants du CSP, ainsi que les contrats ayant pour objet d'autres activités de recherche ou d'évaluation scientifique dites "non interventionnelles", telles que par exemple les études épidémiologiques, les études de pharmacovigilance, les enquêtes ou encore les essais sur des dispositifs médicaux.

manufacturers and healthcare professionals; and the other for hospitality offered to such persons during events of a scientific or promotional nature. These two exceptions are admissible only if the procedure for requesting a prior opinion from the competent professional associations is observed.

Agreements Concluded Between Healthcare Professionals and Companies which have Research or Scientific Evaluation Activities as their Purpose

Article L.4113-6, paragraph 2, provides as follows:

> However, the foregoing paragraph [principle of prohibition of advantages] does not apply to the advantages provided for in agreements concluded between the members of the said medical professions and companies if the said agreements have the explicit object and real purpose of research or of scientific evaluation activities, if before their implementation they are submitted for an opinion to the departmental board of the relevant professional association, and duly notified, when the research activities are carried out, even in part, in a health establishment, to the person in charge of such establishment, and as long as the remuneration is not calculated in a way that is proportional to the number of services or products that are prescribed, marketed or assured. It does not apply to the advantages provided for in agreements concluded between companies and students preparing a diploma to practice a health care profession if the purpose of such agreements relates to research activities in the framework of the preparation of their diploma.

This relates to research contracts with investigators in the framework of clinical trials, as well as contracts dealing with non-interventional studies such as epidemiological studies, pharmacovigilance studies, surveys, or even tests of medical equipment.

Clinical Trials

With respect, first of all, to the clinical trial agreements, all stages in research are covered.

Clinical trials are ranked in the first category of research on the human being, pursuant to the new classification provided for by the Law of 5 March

Essais cliniques

S'agissant tout d'abord des contrats avec les investigateurs dans le cadre des essais cliniques, il convient de rappeler que tous les stades de la recherche sont concernés.

Les essais cliniques correspondent à la première des catégories de recherches impliquant la personne humaine, dans le cadre de la nouvelle classification opérée par la loi du 5 mars 2012.[19] Cette catégorie est celle des recherches interventionnelles, définies comme les recherches *« qui comportent une intervention sur la personne non justifiée par sa prise en charge habituelle».*[20] Ces recherches peuvent avoir pour objet des essais sur des médicaments ou des essais sur des dispositifs médicaux. Sont ainsi concernés l'ensemble des essais cliniques de la phase 1 à la phase 4.

En application de la loi relative aux recherches sur la personne humaine, les essais cliniques doivent être, avant d'être lancés, soumis pour avis au Comité de Protection des Personnes (« CPP ») et autorisés par l'ANSM. Dès lors que l'ANSM a délivré son autorisation sur la base d'un avis favorable du CPP, la condition selon laquelle le contrat doit avoir pour but réel une activité de recherche ou d'évaluation scientifique semble être remplie, et il convient dès lors de s'assurer que la rémunération allouée au professionnel de santé en vertu du contrat est en adéquation par rapport à la prestation demandée.

En effet, l'autorisation de l'ANSM n'exclut pas pour autant que les contrats d'essais cliniques concernés aient par ailleurs des conséquences pour les investigateurs en terme de promotion ou d'incitation à prescrire.

La rémunération du professionnel de la santé doit ainsi être proportionnée à la charge de travail qui lui est demandée. Cette charge de travail se mesure par le nombre d'observations qui doivent être effectuées dans le cadre de l'essai, de l'étendue de la mission du professionnel pour chacune de ses observations, et des autres obligations pouvant résulter de la conduite de l'essai considéré. De manière générale, les dérives peuvent éventuellement survenir pour les essais cliniques de phase 4, le médicament étant déjà commercialisé et la frontière pouvant être difficile à établir entre recherches médicales *stricto sensu* et études visant à démontrer l'intérêt du médicament et occultant par là- même une démarche promotionnelle ou une incitation à

[19] Loi n° 2012-300 du 5 mars 2012 relative aux recherches impliquant la personne humaine, JORF du 6 mars 2012.
[20] Article L.1121-1 du CSP.

2012.[19] This category encompasses interventional trials defined as research which "include[s] for the persons interventions which are not justified by their usual medical treatment."[20] Such researches may pertain to medicinal products or medical devices. All clinical trials from phase 1 to phase 4 are concerned.

Pursuant to the law regarding research on the human being, clinical trials, prior to their launch, must be submitted to the Committee for Protection of Persons (*Comité de Protection des Personnes*, the "CPP") for a prior opinion, and then authorized by the ANSM. Once the ANSM delivers its authorization based on a favorable opinion of the CPP, the condition that the contract must have research or scientific evaluation activity as its real purpose is assumed to be met, and companies must then ensure that the compensation paid to the health professional according to the contract is commensurate with the requested services.

The fact is that the ANSM authorization does not, at the same time, exclude the possibility that the clinical trial agreements concerned may also have consequences for investigators in terms of promotion or of incentives to prescribe.

Thus the health professional's remuneration must be in proportion to the assignment and work load requested from him/her. That work load is measured by the number of observations to be made in connection with the trial, the extent of the professional's assignment for each of his/her observations, and the other obligations that might result from carrying out the trial in question. In general, abuses could potentially occur in connection with phase 4 of clinical trials, when the medicinal product is already being marketed and when it may be difficult to determine the borderline between clinical trial *per se* and studies aimed at demonstrating the interest of the medicinal product and thus masking, *ipso facto*, a promotional approach or an incentive to prescribe. When investigators conducting research are remunerated each time a patient is included in such research, the National Board of Physicians' Association requires in practice that the research protocols or the related agreements must determine the maximum number of patients to be included for the purpose of the research. In absence of such a limit, the National Board considers that investigators are incentivized to

[19] Law n° 2012-300 of 5 March 2012 regarding researches on the human being, JORF of 6 March 2012.
[20] Article L.1121-1 of the FCPH.

prescrire. A cet effet, lorsque les investigateurs participant à une recherche sont rémunérés sur la base d'un tarif par patient recruté, le Conseil National de l'Ordre des Médecins exige en pratique que les protocoles de recherche ou les contrats afférents déterminent le nombre maximum de patients qui doivent être recrutés pour les besoins de la recherche concernée. En l'absence d'un tel seuil, l'Ordre estime en effet que les investigateurs sont encouragés à recruter le plus grand nombre de patients dans le seul but d'accroître leur rémunération, ce qui porterait atteinte à leur indépendance.

Il doit être rappelé ici que l'article 15 du Code de Déontologie Médicale énonce pareillement que « le médecin ne peut participer à des recherches biomédicales sur les personnes que dans les conditions prévues par la loi; il doit s'assurer de la régularité et de la pertinence de ces recherches ainsi que de l'objectivité de leurs conclusions ».[21]

Autres recherches ou évaluations scientifiques

Il s'agit notamment des essais « non interventionnels »,[22] ou encore d'essais non cliniques (en pharmacologie ou en toxicologie par exemple). Depuis la loi du 5 mars 2012, les essais non interventionnels tombent dans le champ d'application de la règlementation relative aux recherches sur la personne humaine. A partir du 1er juillet 2014,[23] ces essais seront notamment soumis à l'avis préalable d'un CPP, conformément au nouvel article L.1123-6 tel que modifié par la loi du 5 mars 2012.

Par conséquent, de même que pour les essais cliniques, il pourra être considéré à l'avenir que l'avis favorable d'un CPP justifiera le caractère réel de l'activité de recherche ou d'évaluation scientifique en ce qui concerne les essais non interventionnels, et qu'il appartiendra au conseil compétent de l'Ordre des Médecins de vérifier simplement la proportionnalité de la rémunération au travail demandé aux médecins conduisant de tels essais.

[21] Article R.4127-1 du CSP.
[22] Les recherches non interventionnelles sont définies par l'article L.1121-1 du CSP comme les recherches "dans lesquelles tous les actes sont pratiqués et les produits utilisés de manière habituelle, sans procédure supplémentaire ou inhabituelle de diagnostic, de traitement ou de surveillance" (nouvelle définition introduite par la loi du 5 mars 2012).
[23] Article 1 § I-9°-b) de la loi du 5 mars 2012.

include the greatest number of patients in the research only to increase their remuneration. Such situation would affect their independence.

It must be noted here that Article 15 of the Code of Medical Ethics states similarly that "the physician may take part in biomedical research on persons only under the conditions laid down under the law. He must make sure of the regular nature and of the relevance of such research as well as of the objectivity of its conclusions."[21]

Other Research or Scientific Evaluations

This refers in particular to "non-interventional" trials[22] or non-clinical tests (e.g., in pharmacology or in toxicology). Since the Law of 5 March 2012, non-interventional trials fall under the scope of the regulations governing research on the human being. As from 1 July 2014,[23] these trials will have to be submitted to the CPP for prior opinion, as provided for by FCPH Article L.1123-6 amended by the Law of 5 March 2012.

This means that for clinical trial agreements, it will be possible in the future to consider for non-interventional trial agreements that the favorable opinion of the CPP justifies the real nature of the research or of the scientific evaluation, and that the competent professional association merely has to control the proportionality of the compensation to the work requested from the healthcare professional.

The examination of the conformity of the research contracts to the requirements of Article L.4113-6 is carried out by the competent association of the profession of which the researching professional is a member, within the framework of the prior notification procedure with the competent professional association.

Hospitality Offered for Promotional Events or for Events of a Strictly Professional and Scientific Nature

Article L.4113-6, paragraph 3 provides as follows:

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[21] Article L.1121-1 of the FCPH.

[22] Non-interventional trials are defined by FCPH Article L.1121-1 as research in which "all medical care are practiced and products used as usual, without any additional diagnostic, treatment or monitoring procedures" (new definition provided for by the Law of 5 March 2012).

[23] Article 1 § I-9°-b) of the Law of 5 March 2012.

L'examen de la conformité des contrats de recherche avec les exigences de l'article L.4113-6 du CSP est effectué par l'instance ordinale compétente de la profession dont est membre le professionnel qui effectue la recherche, dans le cadre de la procédure de notification préalable auprès de l'instance ordinale compétente.

Hospitalité offerte lors de manifestations de promotion ou lors de manifestations à caractère exclusivement professionnel et scientifique

L'article 4113-6 alinéa 3 du CSP dispose:

« Il ne s'applique pas non plus [le principe d'interdiction] à l'hospitalité offerte, de manière directe ou indirecte, lors de manifestations de promotion ou lors de manifestations à caractère exclusivement professionnel et scientifique lorsqu'elle est prévue par convention passée entre l'entreprise et le professionnel de santé et soumise pour avis au conseil départemental de l'ordre compétent avant sa mise en application, et que cette hospitalité est d'un niveau raisonnable, reste accessoire par rapport à l'objectif principal de la réunion et n'est pas étendue à des personnes autres que les professionnels directement concernés. Il en va de même, en ce qui concerne les étudiants se destinant aux professions relevant de la quatrième partie du présent code, pour l'hospitalité offerte, de manière directe ou indirecte, aux manifestations à caractère scientifique auxquelles ceux-ci participent, dès lors que cette hospitalité est d'un niveau raisonnable et limitée à l'objectif scientifique principal de la manifestation ».

Le principe d'interdiction ne doit pas empêcher l'industrie des produits de santé de contribuer au financement de colloques, séminaires ou journées d'études ayant pour objet de faire le point des connaissances, des recherches ou des pratiques dans des domaines scientifiques déterminés. Il ne doit pas non plus empêcher les industriels de lancer des actions de formation médicale continue.

Ainsi, les invitations à des congrès ou des réunions d'information ou de promotion organisées par les industriels ou les aides matérielles consenties par ces industriels aux professionnels de santé ou aux étudiants pour participer à des congrès ou réunions scientifiques organisées notamment par des sociétés savantes, constituent l'un des aspects les plus importants des relations entre les professionnels de santé et les industriels.

Les entreprises du secteur des produits de santé gardent donc la possibilité d'organiser des manifestations promotionnelles, à l'occasion par exemple du lancement d'un nouveau produit par exemple; et de contribuer

> It [the principle of prohibition] also does not apply to the hospitality offered, directly or indirectly for promotional events or for events of a strictly professional and scientific nature when it is provided for under an agreement concluded between the company and the health professional and is submitted for its opinion to the departmental board of the competent professional association before its application, and as long as said hospitality is on a reasonable level, remains of secondary importance in comparison with the principal objective of the meeting, and is not extended to persons other than the professionals directly concerned. The same applies to students preparing a diploma to practice a medical profession, for hospitality offered, directly or indirectly, to scientific events if such hospitality is reasonable in level and limited to the scientific purpose of the event.

The principle of prohibition should not prevent the health products industry from contributing to the financing of symposia, seminars or study days aimed at updating knowledge, research or practices in given scientific domains. Nor should it prevent companies from launching continuing medical training actions.

Thus, invitations to informational or promotional meetings organized by the industry or the material assistance granted by the industry to healthcare professionals or students to take part in conferences or scientific meetings organized, in particular, by "scientific societies," constitute one of the most important aspects of the relationship between healthcare professionals and the health products industry.

Hence, companies retain the option of organizing promotional events on the occasion of the launch of a new product for example, and of contributing financially to health professionals' participation in meetings, seminars or conferences, whether such events are held in France or abroad.

Promotional Meetings Organized by Companies

Healthcare professionals may be invited to take part in promotional meetings organized by companies, particularly in connection with the launch of a new product.

financièrement à la participation de professionnels de la santé à des réunions, séminaires ou congrès, que ces manifestations se déroulent en France ou à l'étranger.

Réunions de promotion organisées par les entreprises

Les professionnels de santé et les étudiants peuvent être invités à participer à des réunions à caractère promotionnel organisées par les entreprises des produits de santé, notamment dans le cadre du lancement d'un nouveau produit.

Le caractère promotionnel de ces réunions déclenche l'application des règles relatives à la publicité en faveur des produits de santé, et peut plus particulièrement entraîner l'intervention de la Commission chargée du contrôle de la publicité au sein de l'ANSM.

La présentation des produits doit être objective, limitée à un discours scientifique et être guidée par l'objectif de favoriser leur bon usage.

La prise en charge des frais de déplacement, de restauration et, le cas échéant, d'hébergement des professionnels invités doit répondre aux mêmes conditions que celles qui s'appliquent aux séminaires et congrès scientifiques, telles qu'elles sont détaillées ci-après.

Hospitalité offerte lors de réunions, séminaires ou congrès organisés par des tiers

Cette aide se concrétisera en général par la prise en charge des frais d'inscription à la manifestation, de restauration, d'hébergement ou de transport. Elle sera acceptable sous réserve du respect des règles qui conditionnent cette dérogation.

L'hospitalité doit être d'un niveau raisonnable. Les invitations proposées aux professionnels de la santé ne doivent pas revêtir un caractère ostentatoire et doivent simplement lui permettre d'assister dans des conditions normales à des réunions qui présentent un intérêt pour lui.

Sur ce point, les entreprises ne sauraient prendre en charge les frais occasionnés par la venue du conjoint ou de la famille du professionnel bénéficiant de l'invitation. Lorsque le professionnel souhaite être accompagné d'un proche, il doit en assurer seul le coût supplémentaire. Dans un arrêt du 10 juin 1998, la Cour d'appel de Pau a ainsi condamné un médecin qui, invité par une entreprise pharmaceutique à un congrès se

The promotional nature of such meetings triggers the application of the rules governing advertising for health products and, more particularly, may entail intervention by the commission responsible within ANSM for checking on advertising and information on proper use of health products.

Introduction of the products must be objective, limited to scientific presentation, and guided by the goal of promoting their proper use.

Payment of travel and meal expenses and, if the case arises, of lodging for the invited professionals must comply with the same conditions as those that apply to scientific seminars and conferences, as specified hereinafter.

Hospitality Offered in Connection with Third Parties' Meetings, Seminars or Conferences

This assistance generally takes the form of payment of registration expenses for the event, as well as meals, lodging or transportation. It is acceptable, subject to observance of the rules governing the said exception.

The hospitality must be of a reasonable level. Invitations offered to health professionals must not be ostentatious and must simply enable such persons to attend meetings of interest to them, under normal conditions.

On this point, companies may not cover the expenses of the accompanying spouse or family of the professional benefiting from the invitation. If the professional would like to be accompanied by someone close to him, he must pay for the additional cost. Thus the Court of Appeal of Pau, in a decision issued on 10 June 1998, sentenced a physician who had been invited by a pharmaceutical company to a conference in San Francisco and who had accepted a downgrade of his airline ticket to allow his spouse to accompany him without increasing the expenses paid by the company. In ruling on the appeal lodged by the physician against said decision, the *Cour de Cassation* confirmed the decision, stating that even if the hospitality offered to a physician in connection with events of a professional or scientific nature is not covered, under certain conditions, by the prohibition laid down in Article L.4113-6, "it may not be extended to persons other than the professionals directly concerned"[24] (reference can also be made to the Tribunal of Grasse

[24] Court of Appeal of Pau, 10 June 1998, and Cass. Crim. 7 December 1999 quoted by T. Pléan, "*La loi anti-cadeaux, premiers éléments de jurisprudence* [first cases relating to the anti-gift law]", Agreements, Competition, Consumptions, n° 116, July-August 2000.

déroulant à San Francisco, avait accepté un déclassement de son billet d'avion pour permettre à son épouse de l'accompagner sans pour autant augmenté les frais pris en charge par l'entreprise. En statuant sur le pourvoi formé par le médecin à l'encontre de cet arrêt, la Cour de cassation a confirmé cet arrêt en énonçant que, si l'hospitalité offerte à des médecins lors de manifestations à caractère professionnel ou scientifique échappe, sous certaines conditions, à la prohibition prévue à l'article L.4113-6 du CSP, *« elle ne saurait être étendue à des personnes autres que les professionnels directement concernés »*[24] (dans ce sens également : TGI de Grasse, 26 février 1999: condamnation d'un médecin à 2290 EUR pour avoir bénéficié de la prise en charge d'un séjour aux Antilles en compagnie de son épouse et de ses enfants;[25] TGI de Clermond Ferrand, 15 mars 2010: condamnation d'un laboratoire pharmaceutique à 20 000 EUR d'amende).[26]

Doivent être exclues du champ de la dérogation toutes les prestations sans rapport avec la réunion envisagée (notamment les activités culturelles, touristiques ou sportives), les agréments proposés en complément de la manifestation devant restés à la charge du professionnel.

Les thèmes qui sont développés lors de ces réunions doivent répondre à l'intérêt pratique du professionnel qui est invité à y participer. N'entreraient pas dans le champ d'application de la dérogation des réunions ou séminaires dont l'ordre du jour ou le programme serait imprécis ou contiendrait des thèmes banals.

Les repas qui accompagnent ou clôturent les manifestations doivent conserver un caractère accessoire et nécessaire. L'organisation d'un dîner dans un restaurant à l'occasion duquel les professionnels de santé sont invités pour suivre une conférence tomberait sous le coup du principe d'interdiction, s'il s'avérait que le temps dévolu au repas excédait le temps consacré au développement des thèmes scientifiques ou professionnels.

L'hébergement offert par l'entreprise à l'occasion de séminaires ou de congrès doit de même être nécessaire et accessoire. S'il est loisible à l'entreprise d'organiser un séminaire ou un congrès dans un lieu agréable, les activités de loisir doivent rester secondaires. Le Conseil National de l'Ordre

[24] Cour d'appel de Pau, 10 juin 1998, et Cass., Crim., 7 décembre 1999, cité par T. Pléan, « La loi anti-cadeaux, premiers éléments de jurisprudence », Contrats, Concurrence, Consommations, n° 116, juillet-août 2000.
[25] TGI de Grasse, 26 février 1999, jugement n° 99/895.
[26] TGI Clermond Ferrand, Chambre Correctionnelle, 15 mars 2010.

judgment dated 26 February 1999 in which a physician was sentenced to a fine of EUR2,290 for having taken advantage of a tourism trip in the West Indies, accompanied by his wife and children[25] ; and the Tribunal of Clermond Ferrand judgment dated 15 March 2010 in which a pharmaceutical company was sentenced to a fine of EUR20,000[26]).

All services that are not related to the planned meeting must be excluded from the scope of the exception (particularly cultural, tourist or sports activities), and the entertainment proposed as a complement to the event must be paid for by the professional.

Topics addressed at such meetings must correspond to the practical interest of the professional invited to take part therein. The scope of the exception does not cover meetings or seminars for which the agenda or the program is imprecise or contains common and unimportant subjects.

Meals accompanying the events must remain incidental and necessary. A dinner organized in a restaurant to allow health professionals to listen to a lecture on scientific or professional topics would fall under the scope of the principle of prohibition if the time devoted to the meal exceeded the time devoted to the lecture.

Lodging offered by a company for seminars or conferences must, similarly, be necessary and incidental. If it is permissible for the company to organize a seminar or a conference in a pleasant place, leisure activities must remain secondary. The National Board of Physicians' Association specifies, as an indication, that free time must not exceed one-third of the total time of the event. It also notes that the expenses resulting from leisure-time activities must be paid for by the health professionals, in addition to the expenses due to an extension of the stay beyond the time of the scientific program of the event. Such approach has been confirmed by case law. A health professional has been sentenced to pay a fine of EUR720 for having stayed in Marbella on the occasion of a scientific seminar, with the time spent for purposes other than the seminar having exceeded one-third of the total duration of the stay in Marbella.[27]

[25] TGI of Grasse, 26 February 1999, case n° 99/895.
[26] TGI of Clermond Ferrand, Criminal Section, 15 March 2010.
[27] Court of Appeal of Rennes, 3rd correctional chamber, 21 July 1998 case n° 1249/98.

des Médecins précise à titre d'indication que le temps libre ne doit pas excéder le tiers de la durée totale de la manifestation, et rappelle que les frais induits par les activités de loisir doivent rester à la charge des professionnels de santé, ainsi les frais occasionnés par un prolongement du séjour au delà du déroulement du programme scientifique de la manifestation. Cette approche a été confirmée par la jurisprudence. Un professionnel de santé a pu en effet être condamné à une amende de 720 EUR pour avoir séjourné à Marbella à l'occasion d'un séminaire scientifique, le temps passé sur place en dehors du temps du séminaire ayant été supérieur au tiers de la durée totale du séjour.[27]

La question lieu dans lequel se déroule la manifestation est par ailleurs régie par les codes d'autorégulation adoptés par l'industrie.

S'agissant de l'industrie pharmaceutique, le guide commun adopté en 2007 par le Leem, le SNITEM et le CNOM[28] renvoie à l'article 9 du code adopté à l'échelle européenne par l'EFPIA (fédération européenne des entreprises et des syndicats nationaux de l'industrie pharmaceutique).[29] De manière générale, les principes essentiels de l'article 9 du code EFPIA rappellent que l'hospitalité offerte pour des manifestations à l'étranger doit être justifiée par des impératifs logistiques ou par le caractère international de la manifestation, et que les emplacements réputés pour leurs activités de loisir doivent être évités.

Enfin, les frais de déplacement peuvent également être pris en charge par les industriels. Le montant de ces frais doit rester raisonnable, notamment lorsque la manifestation se déroule à l'étranger. Afin d'éviter toute difficulté sur ce point, le caractère raisonnable de ces frais sera toutefois apprécié au cas par cas, notamment pour la réservation de billets d'avion, en considération des négociations entre les industriels et les agences de voyages avec qui ils traitent (réduction de prix en cas de réservation antérieure) et pour la durée du trajet (il est recommandé en pratique de réserver des billets d'avion en classe "économique", la classe "affaires" ne pouvant être qu'exceptionnellement justifiée par un très long trajet.

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[27] Cour d'appel de Rennes, 3ème Ch. Correctionnelle, 21 juillet 1998, arrêt n° 1249/98.

[28] Document d'Orientation d'Interprétation et d'Application de l'article L.4113-6 du code de la santé publique, 21 juin 2007, adopté conjointement par le Leem (Syndicat des entreprises pharmaceutiques), le SNITEM (Syndicat des fabricants de dispositifs médicaux) et le CNOM (Conseil National de l'Ordre des Médecins).

[29] Code EFPIA sur la promotion des médicaments soumis à prescription et sur les relations avec les professionnels de santé, 14 juin 2011.

The determination of the place where the event takes place is currently governed by the guidelines jointly adopted in 2007 by the French Association of Pharmaceuticals Manufacturers ("Leem"), the French Association of Medical Devices Manufacturers ("SNITEM") and the National Council of the Professional Association of Physicians ("CNOM")[28] , which refer to Article 9 of the European Federation of Pharmaceutical Industries and Associations ("EFPIA") Code[29] . The main principle of Article 9 of the EFPIA Code provides that hospitality offered for events organized abroad must be justified by logistic organization or the international nature of the event, and that venues that are reputed for their entertainment facilities should be avoided.

Finally, travel expenses may also be paid by the company. The amount of said expenses must remain reasonable, particularly when the event takes place abroad. However, the reasonable level of these expenses shall be analyzed on a case-by-case basis, particularly with respect to reserving air tickets, in light of negotiations between the company and the travel agencies with which they deal (e.g., any price reduction for reservation booked far in advance of the event date and group rates) and of the duration of the flight (e.g., tickets in tourist class are advisable, business class should be justified only for very long flights).

Submission Procedure for Prior Opinion of Professional Associations

Pursuant to FCPH Article L.4113-6, for the purpose of benefiting from the exception to the general principle of prohibition on advantages, the proposed research contract or the proposed invitation to a scientific event must be submitted ahead of time to the appropriate professional association. The said notification is incumbent upon the health products company, which must request an opinion.

The professional associations for medical professions (namely, physicians, midwives and dental surgeons), as well as the professional association for pharmacists, are already organized for the examination of the requests for prior opinion submitted by companies.

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[28] Document for the interpretation and implementation of FCPH Article L.4113-6, 21 June 2007, jointly adopted by Leem , SNITEM and CNOM.

[29] EFPIA Code of Practice on the promotion of prescription-only medicines to, and interactions with, healthcare professionals (Amended following Statutory General Assembly approval of 14 June 2011).

Procédure de demande d'avis préalable aux Ordres professionnels

Aux termes de l'article L.4113-6, le bénéfice de la dérogation au principe général d'interdiction des avantages est conditionné par la notification préalable à l'ordre professionnel compétent du projet de contrat de recherche ou du projet d'invitation à une manifestation scientifique. Cette obligation de notification incombe aux entreprises des produits de santé, qui doit demander un avis.

Les ordres professionnels pour les professions médicales (médecins, sages-femmes et chirurgiens dentistes) ainsi que l'ordre professionnel des pharmaciens sont organisés pour examiner les demandes d'avis préalables.

Pour les auxiliaires médicaux, la loi du 4 mars 2002 avait prévu la création d'un Conseil Professionnel regroupant notamment les infirmiers, les masseurs – kinésithérapeutes, les orthophonistes et les orthoptistes. Ce Conseil Professionnel devait avoir vocation à rendre les avis préalables sur les projets soumis par les entreprises conformément à la loi Anti-Cadeaux. Mais la création de ce Conseil a été annulée. Une loi de 2006[30] a prévu la création d'un ordre pour les infirmiers,[31] et une loi de 2004[32] a prévu la création d'un ordre pour les masseurs-kinésithérapeutes.[33] A ce jour, les ordres des infirmiers et des masseurs-kinésithérapeutes semblent s'organiser pour recevoir les demandes d'avis préalables, mais des difficultés subsistent car le décret d'application de l'article L.4113-6 ne s'applique qu'aux membres de professions médicales, à l'exclusion des auxiliaires médicaux.[34]

Seuls les orthophonistes et les orthoptistes ne sont pas représentés par un ordre professionnel et il faut dès lors considérer que le procédure de notification pour avis préalable n'est pas applicable aux contrats ou à l'hospitalité convenus avec ces professionnels de santé.

[30] Loi n° 2006-1668 du 21 décembre 2006 portant création d'un ordre national des infirmiers, JORF du 27 décembre 2006.
[31] Article L.4312-1 du CSP,
[32] Loi n° 2004-806 du 9 août 2004 relative à la politique de santé publique, JORF du 11 août 2004.
[33] Article L.4321-14 du CSP.
[34] L'article R. 4113-104 du CSP ne vise en effet que les conventions conclues avec les professions médicales.

As far as medical auxiliaries are concerned, the law of 4 March 2002 had created a professional council grouping, in particular for nurses, masseur-physiotherapists, speech therapists and orthoptists. It had been anticipated to have this professional council give prior opinion on proposals submitted by companies in compliance with the Anti-Gift Law. However, the creation of this professional council has been cancelled. A Law of 2006[30] has created a professional association for nurses[31] and a Law of 2004[32] has created a professional association for masseur-physiotherapists.[33] Today, the professional associations for nurses and for masseur-physiotherapists are elaborating their process to examine requests for prior opinion submitted by companies, but issues are still arising as the implementing decree of FCPH Article L.4113-6 is limited in scope to medical professions, to the exclusion of medical auxiliaries.[34]

Request for Advice by the Company

Article L.4113-6, paragraph 4, of the FCPH provides as follows:

> All the agreements between members of medical professions or students and companies [contracts and invitations to meetings, seminars or conferences] are, before their application, submitted for opinion to the district board of the competent professional association or, if their scope is national or covers more than one district, to the national board of the competent professional association. A decree determines the methods of submission of these agreements as well as the time periods in which the professional associations must issue their opinion. If the latter give a negative opinion, the company must forward this opinion to the health professionals, before the implementation of the agreement. If there is no response from the association within the applicable time period, the opinion is

[30] Law n° 2006-1668 of 21 December 2006 creating a professional association for nurses, JORF of 27 December 2006.
[31] FCPH Article L.4312-1.
[32] Law n° 2004-806 of 9 August 2004 regarding public health, JORF of 11 August 2004.
[33] FCPH Article L.4321-14.
[34] FCPH R. 4113-104 only refers indeed to contracts and hospitality with members of the medical professions.

Demande d'avis par l'entreprise

L'article L.4113-6 alinéa 4 du CSP dispose :

« Toutes les conventions passées entre les membres des professions médicales ou les étudiants se destinant aux professions relevant de la quatrième partie du présent code et les entreprises susvisées sont, avant leur mise en application, soumises pour avis au conseil départemental de l'ordre compétent ou, lorsque leur champ d'application est interdépartemental ou national, au conseil national de l'ordre compétent. Un décret en Conseil d'Etat détermine les modalités de la transmission de ces conventions ainsi que les délais impartis aux ordres des professions médicales pour se prononcer. Si ceux-ci émettent un avis défavorable, l'entreprise transmet cet avis aux professionnels de santé, avant la mise en œuvre de la convention. A défaut de réponse des instances ordinales dans les délais impartis, l'avis est réputé favorable. L'entreprise est tenue de faire connaître à l'instance ordinale compétente si la convention a été mise en application. ».

Le décret visé ci-dessus a été adopté en mars 2007[35] et prévoit un délai d'un mois pour les avis concernant l'hospitalité offerte pour des manifestions scientifiques et un délai de deux mois pour les contrats de recherche ou d'évaluation scientifique ou, dans les situations d'urgence, un délai unique de trois semaines.[36]

Si le dossier soumis à l'ordre professionnel n'est pas complet, l'ordre doit le notifier à l'entreprise concernée et le délai est alors suspendu jusqu'à la communication du dossier complet.[37] Toutefois, en ce qui concerne l'hospitalité offerte aux médecins pour leur participation à des congrès, le CNOM a convenu avec Leem et le SNITEM que la modification de la liste des médecins invités après la soumission du dossier ne suspendait pas le délai d'un mois.[38]

[35] Décret n° 2007-454 en date du 25 mars 2007, relatif aux conventions et aux liens unissant les membres de certaines professions médicales et certaines professions de santé aux entreprises et modifiant le code de la santé publique, JORF du 28 mars 2007.
[36] Article R.4113-107 du CSP.
[37] Article R.4113-106 du CSP.
[38] Document d'Orientation d'Interprétation et d'Application de l'article L.4113-6 du code de la santé publique, 21 juin 2007, adopté conjointement par le Leem (Syndicat des entreprises pharmaceutiques), le SNITEM (Syndicat des fabricants de dispositifs médicaux) et le CNOM (Conseil National de l'Ordre des Médecins).

considered positive. The company must inform the competent professional association when the convention is implemented.

The decree mentioned above was adopted in March 2007[35] and provides for a period of one month for opinions concerning hospitality offered during scientific events and a period of two months for research or scientific assessment agreements or, in case of urgency, a unique period of three weeks[36]. If the file submitted to the professional association is not complete, the professional association must notify the company, after which the clock stops until the submission of the complete file.[37] However, as far as hospitality is concerned, CNOM has agreed with Leem and SNITEM that the modification of the list of invited physicians after the submission of the file does not suspend the one-month period[38].

When the request for an opinion concerns a research or scientific evaluation contract, the company must submit a dossier containing:

- the draft agreement identifying the company;
- the amount of compensation, terms and conditions of the determination of compensation, and the advantages granted to the professional;
- the names of the professionals concerned, with their title, specialty and professional address;
- the document of collection of data relating to the research or scientific assessment activities; and
- the summary of the research or assessment protocol in French.

If the request for an opinion concerns the hospitality offered to a professional on the occasion of a scientific or promotional event, the dossier presented by the company shall include:

- the invitation to the event;
- the nature of the paid services on the occasion of the event in question and the amount of the accommodation, food and registration fees;

[35] Decree n° 2007-454 of 25 March 2007, regarding conventions and interactions between health product companies and healthcare professionals and modifying the French Code of Public Health, JORF of 28 March 2007.
[36] FCPH Article R.4113-107.
[37] FCPH Article R.4113-106.
[38] Document for the interpretation and implementation of FCPH Article L.4113-6, 21 June 2007, jointly adopted by Leem, SNITEM and CNOM.

Un décret devrait être adopté prochainement pour définir la procédure pour définir l'organisme compétent et la procédure applicable en ce qui concerne les étudiants.

S'agissant des professionnels de santé, le cadre réglementaire prévoit les obligations suivantes.

Lorsque la demande d'avis concerne un contrat de recherche ou d'évaluation scientifique, l'entreprise doit constituer un dossier comprenant:

- le projet de convention identifiant l'entreprise,
- le montant et les modalités de détermination de la rémunération et avantages consentis au professionnel,
- la liste nominative des professionnels concernés mentionnant leur qualité, leur spécialité et leur adresse professionnelle,
- le document de recueil des données relatives aux activités de recherche ou d'évaluation scientifique,
- le résumé du protocole de recherche ou d'évaluation rédigé en français.

Lorsque la demande d'avis porte sur l'hospitalité offerte à un professionnel à l'occasion d'une manifestation scientifique ou promotionnelle, le dossier présenté par l'entreprise doit comprendre:

- l'invitation à la manifestation,
- la nature des prestations prises en charge à l'occasion de la manifestation considérée ainsi que le montant de l'hébergement, de la restauration et des frais d'inscription,
- le programme prévisionnel détaillé de la manifestation,
- la liste des membres de professions médicales auxquels l'invitation a été adressée, mentionnant leur spécialité et leur adresse professionnelle.[39]

En dernier lieu, il convient de rappeler que cette procédure de notification est destinée à obtenir un simple avis préalable de l'Ordre professionnel compétent. Cet avis ne lie pas l'entreprise qui le demande. Par conséquent, en cas d'avis défavorable, l'entreprise pourrait décider d'exécuter quand même le contrat de recherche ou de maintenir son invitation à la manifestation scientifique. Une telle décision devra être prise par l'entreprise après un

[39] Article R.4113-105 du CSP.

- the contemplated detailed program of the event; and
- the list of members of medical professions to whom the invitation was sent, with their specialties and professional addresses.[39]

Finally, it should be noted that this notification procedure is aimed at obtaining a simple prior opinion from the competent professional association. Such opinion does not bind the company requesting it. Hence, in case of a negative opinion, the company can still decide to perform the research contract, or to maintain its hospitality to the scientific event. Such a decision shall be made by the company after having considered each situation on a case-by-case basis. The evaluation of risks is very important since, in case of subsequent investigations of the French Authority for Consumption, Unfair Competition and Fraud Affairs (namely the *Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes*, the "DGCCRF"), criminal proceedings could be triggered.

Compliance with Article L.4113-6 is subject, finally, to the review by the courts. In a decision dated 29 June 1999, the Court of Appeal of Paris ruled, regarding the hospitality offered to physicians for a conference, that the opinion issued by the professional association was strictly advisory, and that Article L.4113-6 does not in any way require physicians to make sure that the professional association's opinion has been requested in advance by the company and that the said opinion is positive. In that case, the association's opinion was negative, but since the physicians might have thought that the procedures relating to the said hospitality complied with the requirements laid down in Article L.4113-6 and that the association's opinion was positive, neither the pharmaceutical company nor the physicians were sentenced.[40]

This precedent in French case law is important since it specifies that the opinion given by the professional association is only advisory. However, it is no longer applicable since the law of 4 March 2002, which modified Article L.4113-6 to provide for the obligation for companies to forward negative opinions to health professionals before the execution of the agreements or hospitality.

The opinion of the competent professional association is only advisory; it must be reiterated that if the professional association gives its approval, such

[39] FCPH Article R.4113-105.
[40] Court of Appeal of Paris, 11th correctional chamber, A, 29 June 1999 case n° 98/03995.

examen attentif de chaque situation au cas pas cas. L'appréciation des risques est ici importante étant rappelé que, à l'occasion d'inspections ultérieures, notamment de la Direction Générale de la Concurrence, de la Consommation, et de la Répression des Fraudes (la « DGCCRF »), le dispositif pénal de la loi Anti-Cadeaux pourrait être déclenché.

La compatibilité de tels agissements avec l'article L.4113-6 du CSP ressort en dernier lieu de l'appréciation souveraine des juges du fond. Dans un arrêt du 29 juin 1999, la Cour d'appel de Paris a ainsi rappelé, à propos de l'hospitalité offerte à des médecins pour un congrès, que l'avis rendu par le Conseil National de l'Ordre des Médecins était purement consultatif, et que l'article L.4113-6 du CSP n'oblige aucunement les médecins à s'assurer que l'avis de l'Ordre a été préalablement sollicité par l'entreprise et que cet avis est positif. En l'espèce, l'avis de l'Ordre était négatif, mais les médecins ayant pu considérer que les modalités de cette hospitalité étaient conformes aux exigences de l'article L.4113-6 du CSP et penser que l'avis de l'Ordre était positif, ni les médecins, ni l'entreprise pharmaceutique n'ont été condamnés.[40]

Cette jurisprudence demeure importante en ce qu'elle précise que l'avis délivré par un ordre professionnel est consultatif. Elle a toutefois perdu de son intérêt depuis la loi du 4 mars 2002, qui a modifié l'article L.4113-6 du CSP pour y insérer l'obligation à la charge des entreprises de transmettre les avis défavorables aux professionnels de santé avant l'exécution des conventions ou de l'hospitalité.

L'avis ordinal étant consultatif, il faut enfin rappeler par ailleurs que si celui-ci est positif, il n'écarte pas pour autant la possibilité d'une constatation ultérieure d'une infraction à l'article L.4113-6 du CSP.[41]

On notera enfin que la loi du 29 décembre 2011 est venu compléter le dispositif de l'article L.4113-6 du CSP par une nouvelle obligation à la charge des entreprises. Depuis le 30 décembre 2011, les entreprises sont en effet tenues de notifier à l'ordre professionnel qui a préalablement rendu un avis la date à laquelle le contrat ou l'hospitalité à propos desquels l'avis a été

[40] Cour d'appel de Paris, 11ème Ch. Correctionnelle, A, 29 juin 1999, arrêt n° 98/03995.
[41] Notamment à l'occasion d'une inspection de la DGCCRF : Cour d'Appel de Montpellier, 3ème Ch. Correctionnelle, 3 décembre 1998, arrêt n° 1538 ; Cour d'Appel de Montpelier, 3ème Ch. Correctionnelle, 12 février 2009, n° 224 ; TGI Clermond Ferrand, Chambre Correctionnelle, 15 mars 2010.

approval does not avoid the proof of subsequent violation of Article L.4113-6.[41]

Lastly, it must be highlighted that the Law of 29 December 2011 has amended Article L.4113-6 providing for a new obligation incumbent on companies. Since 30 December 2011, companies are obliged to notify the professional association which has issued a prior opinion of the date when the contract is effective or the date when the hospitality is offered.

Since Article L.4113-6 does not provide any further details, it should be considered that this new obligation applies whether the prior opinion of the professional association is positive or negative. In the absence of any time period, it is advisable for companies to address such notification as soon as possible.

Communication of the Contracts by the Professionals

Pursuant to Article L.4113-9 of the FCPH, physicians and dental surgeons must communicate to the departmental board of their professional association the contracts relating to the practice of their professions, as well as the contracts assuring them of the use of equipment or premises if they do not own the equipment they use or the premises where they practice their profession.

This communication must take place, at the latest, one month after the signing of the contract so as to enable the relevant association to ascertain compliance with the principles of morality, probity and dedication that are essential to the practice of the profession.

Failure or refusal to communicate contracts constitutes a disciplinary fault that may be sanctioned by the relevant professional association.

The verification is for professional ethics purposes. The departmental board of the competent professional association shall ensure that the concerned practitioner does not expose himself to any alienation of his professional independence, and the opinion that is issued, if any, is also merely advisory.

[41] In particular, upon an inspection by DGCCRF: Court of Appeal of Montpellier, 3rd Criminal Section, 3 December 1998 case n° 1538; Court of Appeal of Montpellier, 3rd Criminal Section, 9 February 2009, case n° 224; TGI of Clermond Ferrand, Criminal Section, 15 March 2010.

rendu ont été mis en application (i.e. la date d'effet pour les contrats ou la date du congrès ou autre évènement pour l'hospitalité).

Sans autre précision dans l'article L.4113-6 du CSP, il faut considérer que cette obligation s'applique aussi bien lorsque l'avis de l'ordre est négatif que quand il est positif. Et en l'absence de délai, il est recommandé aux entreprises de procéder à cette notification dès que possible.

Communication des contrats par les professionnels

En vertu de l'article L.4113-9 du CSP, les médecins et les chirurgiens-dentistes doivent communiquer au conseil départemental de l'ordre professionnel dont ils relèvent les contrats ayant pour objet l'exercice de leurs professions ainsi que, s'ils ne sont pas propriétaires de leur matériel et du local dans lequel ils exercent leur profession, les contrats leur assurant l'usage de ce matériel ou de ce local.

Cette communication doit être faite au plus tard un mois après la signature du contrat de manière à permettre à l'instance ordinale compétente de veiller au maintien des principes de moralité, de probité, et de dévouement qui sont indispensables à l'exercice de la profession.

Le défaut ou le refus de communication des contrats constitue une faute disciplinaire que l'ordre professionnel compétent peut sanctionner.

Le contrôle est ici d'ordre déontologique. Le conseil départemental de l'ordre compétent veillera à ce que le professionnel concerné ne s'expose pas à une quelconque aliénation de son indépendance professionnelle et l'avis qui sera rendu le cas échéant est également simplement consultatif.

Communication des contrats relatifs à des activités de recherches ou d'évaluation scientifique au responsable de l'établissement de santé dans lequel sont conduites les activités

En dernier lieu, l'article L.4113-6 du CSP exige également que les contrats relatifs à une activité de recherche ou d'évaluation scientifique soient, lorsque l'activité concernée est conduite au sein d'un établissement de santé, notifiés au responsable de cet établissement.

Il convient en effet de s'assurer que le responsable de l'établissement de santé ne soit pas opposé à ce qu'une activité de recherche ou d'évaluation scientifique soit organisée au sein de l'établissement.

Notification of the Contracts Relating to Research or Scientific Evaluations to the Manager of the Health Establishment in which the Activities are Conducted

Finally, Article L.4113-6 provides that contracts relating to research or scientific evaluation must, when the concerned activity is conducted within a health establishment, be notified to the manager of such establishment.

It must be ascertained that the person responsible for the establishment has agreed to the organization of research activities or scientific evaluations in the establishment.

Article L.4113-6 does not specify who is responsible for such notification. As such obligation of notification follows the obligation for the companies to refer the contracts to the competent professional association in order to obtain its opinion, it seems that it is the duty of the companies to notify the manager of the establishment of such contracts.

For clinical trials, this obligation is clearly incumbent on the company since the regulations on clinical trials provide that the "sponsor" of the clinical trial must inform the manager of the health establishment when the trial is performed within the facilities of such establishment.[42]

For non-interventional trials, as the law does not make any provision on this point, the research agreement or the contract relating to a scientific evaluation may stipulate that the health professional is responsible for informing the person in charge of the health establishment.

Practices Authorized by Regulations on Advertising

Like Article L.4113-6, which applies, above all, to health professionals, the regulations on advertising for medical products explicitly authorize pharmaceutical companies to provide such health professionals with free medical product samples and to offer them advantages of negligible value. The possibility of offering advantages of negligible value is incorporated into the provisions of the FCPH which relate to advertising for pharmaceutical establishments, and those provisions also allow pharmaceutical companies to make gifts to encourage research or training of health professionals.

[42] FCPH Article L.1123-13.

L'article L.4113-6 du CSP ne précise pas à qui cette notification incombe. Puisque cette obligation de notification s'inscrit à la suite de l'obligation faite aux entreprises de saisir l'ordre professionnel compétent pour demande d'avis, il apparaît logique de considérer que l'obligation de notifier au directeur de l'établissement de santé soit également rattachée à ces entreprises.

Pour les essais cliniques, cette obligation incombe clairement aux entreprises car l'article L.4113-6 du CSP est relayé par la réglementation sur les essais cliniques, qui prévoit que le promoteur de l'essai informe préalablement le directeur de l'établissement de santé lorsque l'essai est conduit dans l'établissement.[42]

Pour les autres recherches de type non interventionnelles, dans le silence du texte, rien ne s'oppose à ce que le contrat de recherche ou d'évaluation scientifique stipule au contraire que le professionnel de santé concerné ait la charge d'informer le responsable de l'établissement de santé.

Pratiques autorisées par la réglementation sur la publicité

Parallèlement à l'article L.4113-6 du CSP, qui s'applique avant tout aux membres des professions de santé, la réglementation sur la publicité en faveur des médicaments autorise expressément les entreprises pharmaceutiques à remettre gratuitement à ces professionnels des échantillons de médicaments et à leur procurer des avantages de valeur négligeable. La possibilité de procurer des avantages de valeur négligeable est reprise par les dispositions du CSP relatives à la publicité en faveur des établissements pharmaceutiques, qui admettent par ailleurs que les entreprises pharmaceutiques peuvent faire des dons pour encourager la recherche ou la formation des professionnels de santé.

Remise d'échantillons gratuits

L'article L.5122-10 du CSP autorise la remise d'échantillons gratuits aux « personnes habilitées à prescrire ou à dispenser des médicaments dans le cadre des pharmacies à usage intérieur ».

Ainsi, les entreprises pharmaceutiques ne peuvent donner des échantillons gratuits qu'aux médecins et aux pharmaciens hospitaliers, à l'exclusion de tout autre membre des professions médicales ou paramédicales.

[42] Article L.1123-13 du CSP.

Delivery of Free Samples

Article L.5122-10 of the FCPH authorizes the supply of free samples to "persons authorized to prescribe or to deliver drugs within the framework of pharmacies for internal use."

This means that pharmaceutical companies may give free samples only to physicians and to hospital pharmacists, to the exclusion of any other member of the medical or paramedical professions.

The delivery of free samples may occur only at the request of the physicians or of the hospital pharmacists. Hence, pharmaceutical companies may not make such deliveries spontaneously since the initiative is not theirs.

Furthermore, Article L.5122-10 of the FCPH prohibits such deliveries on facilities accessible to the public during medical or pharmaceutical conferences.

With respect to the samples themselves, it should be emphasized that delivery is prohibited for samples of medicinal products containing substances classified as psychotropic drugs or narcotics, or to which all or part of the regulations concerning narcotics apply.

When delivery thereof is authorized, these samples must be identical to the medicinal products concerned and bear the indication "free sample."

Article R.5122-17 of the FCPH incorporates these rules, spelling them out as follows:

- Each supply of free samples must be in response to a written request, dated and signed, from the addressee.
- For each medicinal product, only a limited number of samples may be provided, with a limit of 10 per year and per addressee, determined in consideration with the nature of the medicinal product and of the need for the prescriber to familiarize himself/herself with it; each sample must be in the smallest packaging marketed.
- When a medicinal product is subject to limited prescription conditions, the samples may be delivered only to hospital pharmacists and to prescribers authorized to write a prescription.
- Each pharmaceutical company providing samples must set up tracking procedures for checking such deliveries and monitoring the samples.
- Each sample must be accompanied by a summary of the characteristics of the product.

La remise d'échantillons gratuits ne peut être faite que sur demande des médecins ou des pharmaciens hospitaliers. Les industriels ne peuvent donc pas procéder à de telles remises spontanément car l'initiative ne leur appartient pas.

En outre, l'article L.5122-10 du CSP interdit une telle remise dans les enceintes accessibles au public à l'occasion des congrès médicaux ou pharmaceutiques.

S'agissant des échantillons mêmes, on soulignera que leur remise est interdite lorsqu'il s'agit d'échantillons de médicaments contenant des substances classées comme psychotropes ou stupéfiants, ou auxquels la réglementation des stupéfiants est appliquée en tout ou partie.

Lorsque leur remise est admise, ces échantillons doivent être identiques aux médicaments concernés et porter la mention « échantillon gratuit ».

L'article R.5122-17 du CSP reprend ces règles en les précisant :

- chaque fourniture d'échantillons gratuits doit répondre à une demande écrite, datée et signée, émanant du destinataire;
- pour chaque médicament, il ne peut être remis qu'un nombre restreint d'échantillons, dans la limite de dix par an et par destinataire, déterminé en fonction de la nature du médicament et de la nécessité pour le prescripteur de se familiariser avec celui-ci; chaque échantillon doit être identique au plus petit conditionnement commercialisé;
- lorsqu'un médicament est soumis à des conditions de prescription restreinte, les échantillons ne peuvent être remis qu'aux pharmaciens hospitaliers et aux prescripteurs habilités à établir la prescription ;
- chaque établissement pharmaceutique remettant des échantillons doit organiser en son sein le contrôle de cette remise et le suivi des échantillons;
- chaque échantillon doit être accompagné du résumé des caractéristiques des produits.

L'article R.5122-17 du CSP disposant que la remise d'échantillons ne peut être faite qu'en réponse à une demande écrite des médecins, la Charte sur la visite médicale signée entre le Leem et le Comité Economique des Produits

Article L.5122-17 provides that samples must be delivered in reply to written requests from physicians only. As a result, the charter relating to the medical representation as signed between Leem and the Economic Committee of Health Products (*Comité Economique des Produits de Santé*) specifies that medical representatives may not deliver samples.[43]

It must also be highlighted that Article R.5122-17 has been amended in 2012[44] and now provides that free samples are only authorized during the first two years following the first commercialization in France:

- of a medicinal product covered by a first registration or marketing authorization; or
- of a medicinal product already covered by a registration or a marketing authorization but with a new dosage or a new pharmaceutical form, if the related registration or marketing authorization has been extended accordingly.

Free samples are also authorized during the two years following a change in the prescription status of the medicinal product.

Beyond delivery of free samples, pharmaceutical companies are also authorized to give health professionals advantages of negligible value.

Advantages of Negligible Value

The possibility for health product companies to provide health professionals with advantages of negligible value is not provided for in Article L.4113-6 of the FCPH.

As far as pharmaceutical companies are concerned, the provisions of Article L.5122-10 *in fine* of the FCPH concerning advertising for medicinal products and R.5124-65 of the FCPH concerning advertising for pharmaceutical establishments state that it is forbidden to grant, offer or promise to healthcare professionals a bonus, a pecuniary advantage or a benefit in kind unless they are of negligible value and, as required by Article 94-1 of the

[43] Charter on sales medical representatives as signed between Leem and the Economic Committee of Health Products (*Comité Economique des Produits de Santé*) dated 21 July 2005, Article 2-d.
[44] Decree n° 2012-741 of 9 May 2012 regarding regulations on advertising for medicinal products for human use, JORF of 10 May 2012.

de Santé est venue préciser qu'il est interdit aux visiteurs médicaux de délivrer de tels échantillons.[43]

Il faut également souligné que l'article R.5122-17 du CSP a été modifié en 2012[44] pour préciser dorénavant que la remise d'échantillons gratuits n'est admise que pendant les deux années suivant la première commercialisation effective en France :

- d'un médicament bénéficiant d'un premier enregistrement ou d'une première autorisation de mise sur le marché ; ou
- d'un médicament déjà enregistré ou autorisé ayant obtenu un enregistrement ou une autorisation de mise sur le marché pour un nouveau dosage ou une nouvelle forme pharmaceutique, si l'enregistrement ou l'autorisation est assorti d'une extension d'indication.

Elle est également admise pendant les deux années suivant une modification du classement du médicament en matière de prescription.

Au delà de la remise d'échantillons gratuits, les entreprises pharmaceutiques sont également autorisées à procurer aux professionnels de santé des avantages de valeur négligeable.

Avantages de valeur négligeable

La possibilité laissée aux entreprises de procurer aux professionnels de santé des avantages de valeur négligeable n'est pas envisagée par l'article L.4113-6 du CSP.

Pour le secteur des médicaments, ce sont les dispositions combinées des article L.5122-10 *in fine* du CSP sur la publicité qui prévoient que l'interdiction d'octroyer, d'offrir ou de promettre à ces personnes une prime, un avantage pécuniaire ou un avantage en nature n'est pas applicable aux avantages de valeur négligeable qui, selon les exigences de l' article 94 § 1

[43] Charte sur la visite médicale signée entre le Leem et le Comité Economique des Produits de Santé du 22 décembre 2004 (dernières modifications le 21 juillet 2008), article 2-d.
[44] Décret n° 2012-741 du 9 mai 2012 portant dispositions relatives à la publicité pour les médicaments à usage humain, JORF du 10 mai 2012.

Community Code on Medicinal Products,[45] relate to the practice of the medical or the pharmaceutical profession.

Although the abovementioned provisions are limited in scope to pharmaceutical companies, it is admitted in practice that medical device manufacturers can also grant advantages of negligible value.

The guidelines jointly adopted by Leem, SNITEM and CNOM on 21 June 2007 provide for an annual threshold of EUR30 (tax excluded) per healthcare professional and per company.[46]

In practice, this possibility is now very limited since the charter on sales medical representatives as signed between Leem and the Economic Committee of Health Products prevents medical representatives from delivering small gifts to professionals.[47]

Grants by Pharmaceutical Companies

Finally, among the rules governing advertising for pharmaceutical establishments, we mention Article R.5124-66 of the FCPH, which authorizes pharmaceutical companies to offer grants, subject to compliance with the following three conditions:

- The recipient of the grant must necessarily be a legal entity. Any donation to an individual healthcare professional would be subject to the prohibition of advantages provided for in Article L.4113-6.
- The grant must only aim at encouraging research or continuing medical education and Article R.5124-66 provides that the grant must not have the actual purpose of providing a healthcare professional with an individual advantage.
- The grant must be declared in advance to the Regional Health Agency ("ARS") of the region where the beneficiary entity's registered office

[45] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use, OJEU L–311/67 of 28 November 2001.
[46] Document for the interpretation and implementation of FCPH Article L.4113-6, 21 June 2007, jointly adopted by Leem, SNITEM and CNOM.
[47] Charter on sales medical representatives as signed between Leem and the Economic Committee of Health Products (*Comité Economique des Produits de Santé*) dated 21 July 2005, Article 2-d.

du Code communautaire sur les médicaments,[45] sont rattachés à l'exercice de la médecine ou de la pharmacie.

Même si les textes visés ci-dessus ont un champ d'application limité aux entreprises pharmaceutiques, il est admis en pratique que les entreprises du secteur des dispositifs médicaux peuvent également octroyer des avantages de valeur négligeable.

En ce sens, le guide d'application de l'article L.4113-6 du CSP adopté conjointement par le Leem, le SNITEM et le CNOM le 21 juin 2007 prévoit un seuil annuel de 30 EUR HT par professionnel et par entreprise.[46]

Dans le secteur pharmaceutique, cette possibilité est aujourd'hui très restreinte en pratique, puisque la Charte sur la visite médicale signée entre le Leem et le Comité Economique des Produits de Santé interdit aux visiteurs médicaux de remettre eux-mêmes aux professionnels de santé des petits cadeaux[47].

Dons faits par les entreprises pharmaceutiques

Parmi les règles gouvernant la publicité en faveur des établissements pharmaceutiques, il convient de citer en dernier lieu l'article R.5124-66 du CSP qui autorise les entreprises pharmaceutiques à faire des dons, sous réserve du respect des trois conditions suivantes.

Le bénéficiaire du don doit obligatoirement être une personne morale. Toute donation à un professionnel de la santé, personne physique, tomberait sous le coup de l'interdiction des avantages prévue à l'article L.4113-6 du CSP.

Le don doit avoir pour objectif exclusif d'encourager la recherche ou la formation des professionnels de santé, et l'article R.5124-66 de rappeler ici que le don ne doit pas avoir pour objet réel de procurer un avantage individuel à un professionnel de la santé.

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[45] Directive 2001/83/CE du Parlement European et du Conseil instituant un Code communautaire relatif aux médicaments à usage humain, JOCE L-311/67 du 28 novembre 2001.

[46] Document d'Orientation d'Interprétation et d'Application de l'article L.4113-6 du code de la santé publique, 21 juin 2007, adopté conjointement par le Leem (Syndicat des entreprises pharmaceutiques), le SNITEM (Syndicat des fabricants de dispositifs médicaux) et le CNOM (Conseil National de l'Ordre des Médecins).

[47] Charte sur la visite médicale signée entre le Leem et le Comité Economique des Produits de Santé du 21 juillet 2005, article 2-d.

is located. In practice, that declaration must include the following information:

- The designation of the donor as well as of the nature of its activity and address
- The designation of the beneficiary as well as of the nature of its activity and address
- The nature and amount of the grant
- The purpose of the grant

Although grants are authorized in these circumstances, it is recommended to check each case with scrutiny, particularly if the beneficiary entity is a physicians' association. The notion of indirect advantage, as construed in the precedents, requires pharmaceutical companies to make sure that their grants do not, in the end, benefit a practitioner in an individual way and thus become subject to the prohibition of advantages set forth in Article L.4113-6.

In practice, pharmaceutical companies ask the beneficiary entity for a copy of its articles of association to verify the actual corporate purpose of the said entity, as well as for an affidavit issued by the person in charge of said entity containing an undertaking to use the amounts given in accordance with the corporate purpose described in the articles, and not to use them for the personal expenditures of a member of the entity. These two documents are attached to the file transmitted in advance to the ARS.

Indeed, the circular of 9 December 1996 on advertising for pharmaceutical companies[48] specifies that it is up to the ARS to verify that the articles of association of the beneficiary entity do allow it to receive grants.

It must be noted that, in practice, this legal framework is voluntarily applied by medical device manufacturers.

Finally, it must be emphasized that the Bertrand Law of has inadvertently modified FCPH Article L.4113-6 in a way that leads to consider that grants to associations of healthcare professionals are now prohibited. The industry, the professional associations, and even the administration, agree to state that this prohibition results from a wrong drafting of Article L.4113-6 and the Parliament did not intend to forbid grants to associations of healthcare professionals.

[48] Circular DGS n° 96-741 dated 9 December 1996 relating to advertising in favor of pharmaceutical entities, BOMTAS 96/51.

Enfin, le don doit être déclaré préalablement à l'Agence Régionale de Santé du lieu où est situé le siège de l'organisme bénéficiaire. Cette déclaration doit en pratique comporter les éléments suivants :

- la désignation du donateur ainsi que la nature de son activité et son adresse
- la désignation du bénéficiaire ainsi que la nature de son activité et son adresse
- la nature et le montant du don
- l'objet du don

L'autorisation des dons dans ces circonstances n'empêche pas de recommander la plus grande prudence lorsque, par exemple, l'organisme bénéficiaire est une association de médecins. En effet, la notion d'avantage indirect, telle qu'interprétée par la jurisprudence, commande aux entreprises pharmaceutiques de s'assurer que le don qu'elles accordent ne puisse pas bénéficier finalement à un praticien de manière individuelle et tomber ainsi sous le coup de l'interdiction des avantages prévue à l'article L.4113-6 du CSP.

En pratique, les entreprises pharmaceutiques demandent à l'organisme bénéficiaire une copie de ses statuts pour vérifier l'objet réel dudit organisme, ainsi qu'une attestation de la personne responsable de cet organisme contenant l'engagement d'utiliser les sommes données conformément à l'objet statutaire et de ne pas les affecter à des dépenses personnelles d'un membre de l'organisme. Ces deux documents sont joints au dossier transmis préalablement à l'Agence Régionale de Santé.

En effet, la circulaire du 9 décembre 1996 relative à la publicité en faveur des entreprises pharmaceutiques[48] précise qu'il appartient à l'administration de vérifier que les statuts de l'organisme bénéficiaire lui permettent bien de recevoir des dons.

Il convient de noter que, en pratique, ce cadre réglementaire est appliqué spontanément par les entreprises du secteur des dispositifs médicaux.

On soulignera enfin que la loi "Bertrand" du 21 décembre 2011 a malencontreusement modifié l'article L.4113-6 du CSP en ce sens que les dons aux associations de professionnels de santé sont désormais interdits. Les

[48] Circulaire DGS n° 96-741 du 9 décembre 1996 relative à la publicité en faveur des établissements pharmaceutiques, BOMTAS 96/51.

As from the 30 December 2011 (the publication date of the Bertrand Law), and as long as this drafting is not corrected by a new law, parties to financial grant agreements are in a grey zone and must assess the risks to enter into such agreements. The issue can be summarized in the three situations, as follows:

- The company willing to make a financial grant and the association which would benefit from such grant agree to consider that the amendment of FPCH Article L.4113-6 results from a wrong drafting of the Parliament and that, therefore, violation of this new prohibition would likely not be sanctioned. The concerned parties thus enter into the financial grant agreement.
- In contrast, the company willing to make a financial grant and/or the association which would benefit from such grant consider that, even if this prohibition results from a wrong drafting, the prohibition is clearly stated in the provisions of FCPH Article L.4113-6 and can trigger criminal sanctions. The concerned parties thus do not enter into the financial grant agreement.
- Lastly, the companies can update their compliance policies referring to FCPH Article L.4113-6 *in fine*, which provides that the funding of continuing medical education remains out of the scope of the prohibition provided by said article. Companies can therefore consider that financial grants made to associations of healthcare professionals for the purpose of supporting continuing medical education are still authorized (as opposed to financial grants aimed at encouraging research).

It must finally be noted that this new prohibition appears to be limited in scope to grants which are made only to the benefit of associations. Financial support granted to other legal entities such as private clinics or hospitals seem to still be authorized.

Scope of the Prohibition of Advantages, Scope of the Preliminary Submission Procedure and Notion of "Normal Working Relations"

Article L.4113-6, *in fine*, of the FCPH provides that:

> The provisions of such article would not either subject to agreement the normal working relations nor prohibit the financing of continuing medical training.

The notion of "normal working relations" as mentioned above is not defined and leads to various interpretations in practice.

représentants de l'industrie, les ordres professionnels, et même l'administration, s'accordent pour considérer qu'il s'agit là d'une erreur dans la nouvelle rédaction de l'article L.4113-6 du CSP et que le législateur n'avait nullement l'intention d'interdire les dons aux associations de professionnels de santé.

Ainsi, depuis l'entrée en vigueur de la loi "Bertrand" le 30 décembre 2011, et dans l'attente d'une nouvelle loi pour corriger ce point, les parties à un contrat de donation se trouvent dans une zone d'incertitude juridique et doivent apprécier les risques ensemble pour consentir ou non à un tel contrat. La problématique peut être circonscrite aux trois situations suivantes:

- L'entreprise souhaitant octroyer un don et l'association qui en bénéficierait sont d'accord pour considérer que la modification de l'article L.4113-6 du CSP résulte d'une erreur de plume du législateur et qu'il est dès lors peu probable que la violation de ce nouveau principe d'interdiction des dons soit sanctionnée en pratique. Les parties concernées concluent dès lors le contrat de donation.
- Au contraire, l'entreprise souhaitant octroyer un don ou l'association qui en bénéficierait considèrent que, même s'il s'agit d'une erreur de plume du législateur, l'interdiction est clairement exprimée et sa violation peut entraîner en principe des sanctions pénales. Les parties concernées ne concluent pas le contrat de donation.
- Enfin, les entreprises pourront adopter leurs chartes "compliance" en optant pour une solution médiane en référence au dernier alinéa de l'article L.4113-6 du CSP, qui dispose que les principes énoncés par cet article n'interdisent pas le financement des formations médicales continues. En ce sens, les entreprises de produits de santé pourront considérer que les donations consenties à des associations de médecins dans le but de financer la formation médicale continue demeurent autorisées (contrairement aux dons destinés à encourager la recherche).

On soulignera enfin que cette nouvelle interdiction est limités au dons consentis au seul bénéfices des associations. Les dons octroyés à d'autres personnes morales, comme notamment les sociétés exploitant les cliniques ou les hôpitaux, semblent être toujours autorisés.

The circular dated 9 July 1993[49] had specified that "normal working relations" would include, for example, "the missions, employment contracts or participation in scientific advices" and that such relations would not fall within the scope of Article L.4113-6 to the extent that the payment made to the health professionals is not disproportionate with regard to the service rendered.

In principle, it could be considered that certain interactions between companies and healthcare professionals do not lead to any advantage in favor of such professionals and therefore do not fall under the general prohibition as provided for in Article L.4113-6, or at least, do not need to be submitted for prior opinion to the competent professional association.

However, in 2001, the DGCCRF published a restrictive interpretation of the notion of "normal working relations" in response to a request for interpretation presented by the CNOM:

> Except for the employment contract between a physician and a company providing for precise duties, various particular situations such as health professionals' participations as speaker in a symposium organised by companies, writing of articles for manufacturers, participation to scientific committees of pharmaceutical companies, training sessions by health professionals upon request of companies on the occasion of implementation of new techniques or new materials, can be analysed as particular cases which relate to the very broad notion of "clinical research and/or scientific evaluation," and as the case may be, relate to the principle of hospitality, in connection with "promotional events or events of a strictly professional and scientific nature…

According to the DGCCRF, "these situations, subject to the appreciation of the Courts, should fall in the scope of Article L.4113-6 except for agreements without financial counterpart or if the financial counterpart is of 'negligible value' (including working meals with a representative of the Industry, delivery of samples of products or demonstration equipment of a negligible value)."

[49] Circular dated 9 July 1993 relating to the enforcement of Article L. 365-1 of the French code of public health, JORF dated 6 August 1993.

Etendue de l'interdiction des avantages, champ de la procédure de soumission préalable, et notion de « relations normales de travail ».

L'article L.4113-6 *in fine* du CSP dispose que:

« Les dispositions du présent article ne sauraient ni soumettre à convention les relations normales de travail ni interdire le financement des actions de formation médicale continue ».

La notion de « relations normales de travail » visée ci-dessus n'est pas définie et fait l'objet d'interprétations divergentes dans la pratique.

La circulaire du 9 juillet 1993[49] avait précisé que les « relations normales de travail » pouvaient s'entendre comme celles résultant par exemple de « missions, contrats de travail ou participation à des conseils scientifiques » et que de telles relations n'entraient pas dans le champ d'application de l'articleL.4113-6 du CSP à condition que la rémunération des professionnels de santé ne soit pas disproportionnée par rapport aux prestations rendues.

En principe, il était dès lors permis de considérer que certaines relations entre entreprises et professionnels de santé n'emportaient pas d'avantages au bénéfice de ces derniers et ne tombaient dès lors sous le coup de l'interdiction générale de l'article L.4113-6 du CSP ou, à tout le moins, n'étaient pas soumises à la procédure préalable de notification aux instances ordinales pour avis prévue par cet article.

Mais en 2001, la DGCCRF avait toutefois pris position plus restrictive de la notion de « relations normales de travail » en réponse à une demande d'interprétation présentée par le Conseil National de l'Ordre des Médecins : .

« En dehors du salariat d'un médecin par une entreprise pour des fonctions précises, les différentes situations particulières telles que les participations de médecins en tant qu'orateur à un symposium organisé par un laboratoire, la rédaction d'article pour le compte d'industriels, la participation à des comités scientifiques d'industrie biomédicale, des fonctions de formateurs assurées par des médecins à la demande d'entreprises dans le cadre de la mise en place de techniques ou matériels nouveaux peuvent être considérées comme des cas particuliers se rattachant à la notion très large de «

[49] Circulaire du 9 juillet 1993 relative à l'application de l'article L.365-1 du code de la santé publique, JORF du 6 août 1993.

The DGCCRF appeared to consider that the activities relating to research or scientific evaluation, and the activities pertaining to the hospitality offered during promotional or scientific events as mentioned in paragraphs 2° and 3° of Article L.4113-6 had to be interpreted as broadly as possible in order to comply with the notification procedure before the professional associations the most attractive scope as possible. The scope of activities, which can be considered as part of "normal working relations" and, as such, excluded from such procedure, became therefore very limited in practice.

Then, with the guidelines jointly adopted by Leem, SNITEM and CNOM in June 2007,[50] the issues raised by the scope of the notification of contracts to professional associations were clarified.

According to these guidelines (which contain no reference to the notion of "normal work relations"), certain contracts relate to activities other than for which the related contracts must be submitted for prior opinion. Such contracts remain subject in the scope of FCPH Article L.4113-9.[51]

Therefore, the guidelines provide that the contracts which remain out of the scope of the notification by companies to professional associations for prior opinion are the contracts relating to the following activities:

- Training sessions organized by physicians for other physicians (e.g., learning surgery protocols)
- Drafting of publications which do not pertain to research activities performed for companies
- Attendance for companies to advisory boards which are not linked with research
- General presentations in congresses (excluding the presentation of research results)
- Bibliography researches
- Training for companies' staff (in particular, sales medical representatives)

Before their publication, these guidelines were reviewed by the DGCCRF, and it did not raise any issues regarding the above position.

[50] Document for the interpretation and implementation of FCPH Article L.4113-6, 21 June 2007, jointly adopted by Leem, SNITEM and CNOM.
[51] Notification of contracts by physicians themselves to their professional association at the latest one month after their effective date.

recherche clinique et/ou évaluation scientifique », tout comme le cas échéant, au principe d'hospitalité lié à des « manifestations de promotion ou manifestations à caractère exclusivement professionnel et scientifique… ».

Dès lors, pour la DGCCRF, « sous réserve de l'appréciation souveraine des tribunaux, ces situations devraient entrer dans le champ d'application de l'article L.4113-6 sauf pour des accords sans contrepartie financière ou dans le cadre d'accord où la contrepartie financière est de « valeur négligeable » (incluant également déjeuner de travail avec un représentant de l'industrie biomédicale, remise d'échantillon de produit ou de matériel de démonstration de valeur modique). »

Selon la DGCCRF, les activités rattachées à la recherche ou à l'évaluation scientifique, ainsi que les activités liées à l'hospitalité offert à l'occasion de manifestations promotionnelles ou scientifiques visées aux paragraphes 2° et 3° de l'article L.4113-6 du CSP devaient être entendues le plus largement possible, de manière à conférer un champ d'application qui soit le plus attractif possible à la procédure de notification préalable pour avis auprès des organismes professionnels. L'étendue des activités pouvant être considérées comme faisant partie des « relations normales de travail » et échappant dès lors à cette procédure s'en trouvait d'autant plus réduite.

Depuis l'adoption par le Leem, le SNITEM et le CNOM en 2007 d'un guide commun pour l'application de l'article L.4113-6 du CSP,[50] la question du champ d'application de la procédure de notification des contrats pour avis des organismes professionnels s'était stabilisée.

En effet, sans toutefois faire référence à la notion de "relation normale de travail", ce guide considérait que certains contrats entre les entreprises et les médecins étaient relatifs à des activités qui pouvaient être dissociées de celles devant faire l'objet d'une notification préalable. De tels contrats demeuraient néanmoins dans le champ d'application de l'article L.4113-9 du CSP.[51]

[50] Document d'Orientation d'Interprétation et d'Application de l'article L.4113-6 du code de la santé publique, 21 juin 2007, adopté conjointement par le Leem (Syndicat des entreprises pharmaceutiques), le SNITEM (Syndicat des fabricants de dispositifs médicaux) et le CNOM (Conseil National de l'Ordre des Médecins).
[51] Notification des contrats par les médecins à leur ordre au plus tard 1 mois après leur date d'effet.

Therefore, since 2007, the abovementioned contracts were no longer submitted to professional associations for prior opinion.

However, the position of the guidelines has become invalid since the Bertrand Law came into force. Indeed, FCPH Article L.4113-6 as amended by this law provides now that all contracts between health product companies and healthcare professionals must be submitted to the competent professional associations for prior opinion. The guidelines jointly adopted in 2007 should thus be updated accordingly in the future to remove this position as it leads now to discrepancies with the law.

Today, it appears that the notion of "normal work relations" can be useful only for lunches offered in the day-to-day relationship with healthcare professionals and out of the "hospitality" offered during scientific events. Such lunches remains out of the scope of the notification procedure for prior opinion, but is still subject to the general prohibition of advantages. Payments made by companies to cover such lunches must thus be reasonable in level. The national board of the professional association for pharmacists ("CNOP") refers to a threshold of EUR54 under which a lunch can reasonably be offered to a pharmacist.[52]

Transparency: The "French Sunshine Act"

In addition to the general principle prohibiting any advantage and providing for the ethical control of contracts and hospitality by associations of healthcare professionals, the Bertrand Law[53] provides for a new transparency regime regarding interactions between health product companies and healthcare professionals. This new regime is called the "French Sunshine Act," referencing the US Sunshine Act that France has followed.

France has indeed adopted a new disclosure obligation incumbent on health product companies, which must make available to the public any contracts they entered into with healthcare professionals, any hospitality for scientific events and any advantage they offer to healthcare professionals.

[52] CNOP: anti-gift procedure, http://www.ordre.pharmacien.fr/Nos-missions/Le-role-de-l-Ordre-dans-les-missions-de-sante-publique/Dispositif-anti-cadeaux.
[53] Law n° 2011-2012 of 29 December 2011 for the reinforcement of the safety of medicinal products and health products, JORF 30 December 2011.

Aux termes de ce guide, les contrats exclus du champ d'application de la procédure de notification préalable étaient les contrats qui se rapportaient aux activités suivantes :

- Les activités de formation réalisées par des médecins au bénéfice d'autres médecins (apprentissage de techniques opératoires…),
- Les rédactions d'articles ne relatant pas des activités de recherche réalisées pour le compte de l'entreprise,
- La participation à des groupes de réflexion (boards) scientifiques ou stratégiques d'entreprises, déconnectés de la réalisation d'une recherche spécifique,
- Les interventions dans des congrès sur des thèmes généraux (hors présentation de résultats de recherche),
- Les activités de recherches bibliographiques,
- Les activités de formation réalisées pour le personnel des entreprises (visiteurs médicaux par exemple).

Il doit être rappelé que, préalablement à sa publication, le guide avait été soumis à la revue de la DGCCRF et que cette dernière n'avait pas fait de commentaires sur cette approche. Ainsi en pratique, depuis juin 2007, l'ensemble des contrats visés ci-dessus n'était plus soumis aux instances ordinales pour avis préalable, sans que cela n'ait fait difficulté en pratique.

L'approche du guide n'est cependant plus valable depuis l'entrée en vigueur le 30 décembre 2011 de la loi "Bertrand".

En effet, cette loi a modifié les dispositions de l'article L.4113-6 du CSP, qui prévoient dorénavant que tous les contrats entre les entreprises des produits de santé et les professionnels de santé doivent être soumis à l'ordre professionnel compétent pour avis préalable.

Ainsi le guide adopté en 2007 devrait être modifié à l'avenir pour se conformer aux nouvelles dispositions de l'article L.4113-6 du CSP.

Aujourd'hui, il semble que la notion de "relation normale de travail" ne conserve qu'une utilité restreinte aux seules invitations à déjeuner dans le cadre des relations courantes avec les professionnels de santé et en dehors de "l'hospitalité" offerte à l'occasion des congrès. Ce type de déjeuner demeure en dehors de la procédure de notification préalable, mais reste bien sûr soumis au principe général d'interdiction des avantages. Les coûts supportés par les entreprises pour ce type de déjeuner doivent en conséquence être raisonnables. Le CNOP (Conseil National de l'Ordre des Pharmaciens) se

The French Sunshine Act also increases the regime for the declarations of interests for the experts involved in the various decision-making processes regarding health products in France.[54]

As of the date of drafting of this chapter (20 July 2012), the implementing decree which details the disclosure obligation has not yet been published.

Disclosure Obligation Incumbent on Companies

The new transparency regime for interactions with healthcare professionals is codified under new FCPH Article L.1453-1, as follows:

Companies manufacturing or commercializing products that are listed by FCPH Article L.5311-1-II or providing services in connection with such products are obliged to make available to the public the existence of any contracts entered into with:

- healthcare professionals whose practice is governed by Title IV of the FCPH;
- associations (i.e., non-profit organizations) of healthcare professionals;
- associations of students;
- associations of health system users (i.e., patients' associations);
- health establishments (i.e., both public hospitals and private clinics);
- foundations, medical societies and advisory societies or bodies operating in the health products sector;
- press publishing companies, broadcasters of radio or television services and publishers of public online communications services;
- publishers of product prescription and delivery aid software; and
- legal entities providing training sessions for the healthcare professionals mentioned above.

The same disclosure obligation applies, beyond a threshold that must be determined by the implementing decree, to any benefits in cash or in kind offered by companies, even indirectly, to healthcare professionals and other entities mentioned above.

The implementing decree must detail the conditions for the enforcement of this disclosure obligation, the information which must be made available to the public, particularly the purpose of the contracts and their date, as well as

[54] FCPH new Articles L.1451-1 *et seq*.

réfère à un seuil de 54 EUR, en dessous duquel un repas peut être raisonnablement offert à un pharmacien.[52]

Transparence: le "Sunshine Act" à la française

En complément du principe d'interdiction des avantages et du contrôle par les ordres professionnels des contrats et de l'hospitalité, la loi "Bertrand" du29 décembre 2011[53] instaure un nouveau régime de transparence dans les relations entre les entreprises des produits de santé et les professionnels de santé appelé "Sunshine Act à la française", en référence au "Sunshine Act" adopté aux Etats-Unis, dont la France s'est inspirée.

La France a en effet adopté le principe d'une nouvelle obligation incombant aux entreprises de devoir divulguer au public les contrats qu'elles concluent avec les professionnels de santé, ainsi que l'hospitalité aux manifestations scientifique et les avantages divers qu'elles leurs offrent.

Le Sunshine Act à la française renforce également le régime des déclarations d'intérêts des experts siégeant au sein des commissions et divers groupes impliqués en France dans le processus décisionnel relatif aux produits de santé.[54]

A la date de rédaction de la présente publication (20 juillet 2012), le décret d'application qui doit détailler les règles de mise en œuvre de cette nouvelle obligation n'a pas été publié.

Obligation de divulgation incombant aux entreprises

Le nouveau régime de transparence dans les liens avec les professionnels de santé est inscrit sous le nouvel article L.1453-1 du CSP, dans les termes suivants :

[52] CNOP, Procédure applicable au dispositif "anti-cadeaux", http://www.ordre.pharmacien.fr/Nos-missions/Le-role-de-l-Ordre-dans-les-missions-de-sante-publique/Dispositif-anti-cadeaux.
[53] Loi "Bertrand" n° 2011-2012 du 29 décembre 2011 relative au renforcement de la sécurité sanitaire du médicament et des produits de santé, JORF du 30 décembre 2011.
[54] Nouveaux articles L.1451-1 et suivants du CSP.

the process for disclosure and the updating of the information disclosed. This implementing decree must also provide for the conditions under which the associations of healthcare professionals shall be involved in this regard.

Companies Bound by the Disclosure Obligation

FCPH Article L.1453-1 refers to "companies manufacturing or commercializing products that are listed by FCPH Article L.5311-1-II or providing services in connection with such products."

The French Sunshine Act is much broader in scope than the Anti-Gift Law (FCPH Article L.4113-6).

The Anti-Gift Law indeed only covers companies manufacturing or commercializing products that are admitted to reimbursement in France (i.e., pharmaceuticals and medical device manufacturers), whereas the French Sunshine Act refers to FCPH Article L.5311-1 which draws upon the list of all the health products for which the ANSM is competent, with no reference to their reimbursement status.

Therefore, various medical device manufacturers, whose devices are not admitted to reimbursement and thus remain out of the scope of the Anti-Gift Law, fall under the scope of the French Sunshine Act (in particular, manufacturer of medical or hospital equipment).

The same applies to the pharmaceutical sector, in particular, for biotechnology companies manufacturing medicinal products which are not yet marketed and thus not yet admitted to reimbursement.

Lastly, players on other health product markets are covered by the French Sunshine Act as the products they market are listed under FCPH Article L.5311-1. This is, in particular, the case for companies of the cosmetics sector.

Healthcare Professionals and Other Entities Targeted by the Disclosure Obligation

The notion of healthcare professionals in the framework of the French Sunshine Act is broader in scope than the same notion under the Anti-Gift Law. FCPH Article L.1453-1 refers to all professionals whose practice is

“I. - Les entreprises produisant ou commercialisant des produits mentionnés au II de l’article L.5311-1 ou assurant des prestations associées à ces produits sont tenues de rendre publique l’existence des conventions qu’elles concluent avec :

1° Les professionnels de santé relevant de la quatrième partie du présent code 2° Les associations de professionnels de santé ;

3° Les étudiants se destinant aux professions relevant de la quatrième partie du présent code ainsi que les associations et groupements les représentant ;

4° Les associations d’usagers du système de santé ;

5° Les établissements de santé relevant de la sixième partie du présent code ;

6° Les fondations, les sociétés savantes et les sociétés ou organismes de conseil intervenant dans le secteur des produits ou prestations mentionnés au premier alinéa ;

7° Les entreprises éditrices de presse, les éditeurs de services de radio ou de télévision et les éditeurs de services de communication au public en ligne ;

8° Les éditeurs de logiciels d’aide à la prescription et à la délivrance ;

9° Les personnes morales assurant la formation initiale des professionnels de santé mentionnés au 1° ou participant à cette formation.

II. - La même obligation s’applique, au-delà d’un seuil fixé par décret, à tous les avantages en nature ou en espèces que les mêmes entreprises procurent, directement ou indirectement, aux personnes, associations, établissements, fondations, sociétés, organismes et organes mentionnés au I.

III. - Un décret en Conseil d’Etat fixe les conditions d’application du présent article, la nature des informations qui doivent être rendues publiques, notamment l’objet et la date des conventions mentionnées au I, ainsi que les délais et modalités de publication et d’actualisation de ces informations. Il précise également les modalités suivant lesquelles les ordres des professions de santé sont associés à cette publication.”

regulated by Part IV of the FCPH, in particular opticians,[55] and also to those entities which are listed above, in particular associations of healthcare professionals and associations of patients.

Information to Disclose

FCPH Article L.1453-1 provides that companies must make available to the public the existence of contracts, as well as advantages.

The Law of 29 December 2011 specifies that this obligation applies to contracts which are effective as of 1 January 2012 or which become effective after that date, as well as advantages granted after that date.[56]

The implementing decree is to detail the nature of the information to disclose regarding the contracts, the existence of which must be made available to the public, as well as the information regarding the hospitality and advantages offered to the healthcare professionals and the other entities targeted by FCPH Article L.1453-1.

The decree also determines the value threshold under which the advantages of "negligible value" will not fall within the scope of the disclosure obligation.

Process for Disclosure

It will also be up to the government to detail in the implementing decree the support for disclosure to the public (likely the internet) and the time periods for successive disclosures and updating.

[55] In addition to the HCPs already covered by FCPH Article L.4113-6 (physicians, midwives, dental surgeons, nurses, masseur-physiotherapists, speech therapists, orthoptists, and pharmacists), FCPH Article L.1453-1 also covers the following health practitioners: assistants who assist pharmacists within pharmacies in town or hospitals' pharmacies; podiatrists; occupational therapists; psycho motorists; technicians of medical imaging centers; technicians of biological analysis laboratories; opticians, specialists for hearing aid prosthesis; specialists of prosthesis for disabled persons; dieticians; assistants for patients care; assistants for children care; ambulance drivers; and students preparing to enter the professions covered by the Part n° IV of FCPH.

[56] Article 41-II of the Law of 29 December 2011.

Entreprises soumises à l'obligation de divulgation

L'article L.1453-1 du CSP vise " *Les entreprises produisant ou commercialisant des produits mentionnés au II de l'article L.5311-1 ou assurant des prestations associées à ces produits*".

Le champ d'application est ici beaucoup plus large que celui de la loi Anti-Cadeaux.

En effet, là où l'article L.4113-6 du CSP les entreprises produisant ou commercialisant des produits pris en charge par la sécurité sociale, à savoir les entreprises pharmaceutiques et celles du secteur des dispositifs médicaux, l'article L.1453-1 du CSP renvoie à l'article L.5311-1 du même Code qui liste l'ensemble des produits de santé pour lesquelles l'ANSM est compétente, sans référence à leur statut de produit remboursable.

Ainsi de nombreuses entreprises du secteur des dispositifs médicaux qui n'étaient pas soumises à la loi Anti-Cadeaux sont soumises au Sunshine Act (notamment les entreprises commercialisant des dispositifs médicaux destinés à l'équipement hospitalier).

Il en va de même dans le secteur pharmaceutique, notamment en ce qui concerne les sociétés de biotechnologie qui produisent des médicaments non encore autorisés, donc non remboursés.

Enfin de nouvelles entreprises actives sur d'autres marchés que celui des médicaments ou des dispositifs médicaux tombent dans le champ d'application du Sunshine Act car leurs produits sont listés sous l'article L.5311-1. On notera plus particulièrement ici les entreprises du secteur des produits cosmétiques.

Professionnels de santé et autres organismes visés par l'obligation de divulgation

La notion de professionnel de santé est également beaucoup plus large sous l'empire de l'article L.1453-1 que sous celui de l'article L.4113-6 du CSP, puisque l'article L.1453-1 vise, non seulement tous les professionnels de

Enforcement

The Law of 29 December 2011 provides that the disclosure obligation shall be enforceable at the date of the publication of the implementing decree or, in the absence of the decree, on 1 August 2012 at the latest. [57]

Since the application of the disclosure obligation appears to be impossible in practice without the implementing decree, it would be appreciated that, in the event that this decree is not yet adopted on 1 August 2012, the French Ministry of Health publishes a moratorium to secure these companies which may decide not to disclose any information, as non-compliance with FCPH Article L.1453-1 can trigger criminal sanctions.

Sanctions

Non-compliance with the provisions of Article L.4113-6 may entail the application of disciplinary and criminal sanctions. Moreover, the regulations on advertising are combined with administrative sanctions and may also give rise to criminal proceedings.

First of all, it shall be mentioned that the breach by a company of the provisions of Article L.4113-6 can be considered by a competitor as unfair competition detrimental to its interests. Moreover, violation of such article may also lead to litigation before the commercial courts between competitors.[58]

Violation of the Provisions of FCPH Article L.4113-6

Non-compliance with the principle of prohibition of advantages may be analyzed as an alienation of the independence of the professional who has benefited from the prohibited advantage, and thus allows the professional association to decide disciplinary sanctions. Independent of these professional sanctions, Article L.4113-6 includes criminal sanctions, and disregard thereof may trigger proceedings filed by the *Parquet* (public prosecutor's office).

[57] Article 41-II of the Law of 29 December 2011.
[58] For an enforcement: Court of Appeal of Versailles, 12 ch. 6 May 2003 Pharmacia v/ Alcon, case n° 260.

santé régis par le Livre IV du CSP, dont notamment les opticiens,[55] mais également certains organismes dont la liste est visée ci-dessus, dont notamment les associations de professionnels de santé et les associations de patients.

Information à divulguer

L'article L.1453-1 du CSP dispose que les entreprises doivent rendre publique "*l'existence des conventions*" ainsi que les "*avantages*".

Selon les précisions apportées par la loi du 29 décembre 2011, sont visées ici les contrats en cours au 1er janvier 2012 ou produisant leurs effets après cette date, ainsi que tout avantage offert après cette date.[56]

Le décret d'application devra détailler la nature des informations relatives aux contrats dont l'existence doit être divulguée par les entreprises, ainsi que les informations relatives à l'hospitalité offerte par ces dernières aux professionnels de santé ou autres organismes visées par l'article L.1453-1 du CSP.

De même, le décret d'application devra définir un seuil de valeur au dessus duquel les entreprises seront obligées de rendre publics les avantages qu'elles octroient.

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[55] En plus des professionnels de santé visés par la loi anti-cadeaux, sont donc également visés par le Sunshine Act:
- les préparateurs en pharmacie et les préparateurs en pharmacie hospitalière,
- les pédicures-podologues,
- les ergothérapeutes,
- les psychomotriciens,
- les manipulateurs d'électroradiologie médicale,
- les techniciens de laboratoire médical,
- les audioprothésistes,
- les opticiens-lunetiers,
- les prothésistes et orthésistes pour l'appareillage des personnes handicapées,
- les diététiciens,
- les aides-soignants,
- les auxiliaires de puériculture,
- les ambulanciers,
- les étudiants se préparant à une profession régie par le Livre 4 du CSP.

[56] Article 41-II de la loi du 29 décembre 2011.

Disciplinary Proceedings

When they are incorporated, the duty of the professional association is to ensure the principles of morality, probity and dedication that are essential to exercise the profession.

Professional associations are authorized to sanction professionals who violate professional regulations or the profession's code of ethics. With respect to the acceptance of an advantage prohibited by Article L.4113-6, the following disciplinary sanctions can be enforced against the professional at fault: warning; reprimand; temporary suspension of the right to practice; and expulsion from the association.

These disciplinary sanctions do not preclude proceedings that might be filed by the public prosecutor or by individuals in the criminal courts.

Criminal Proceedings

The opinion issued by the professional association in application of Article L.4113-6 is part of a preventive approach. Precedent has confirmed the advisory (i.e., not mandatory) nature of said opinion.

This preliminary procedure does not prevent the triggering of later enquiries. Under the terms of Article L.4113-6 of the FCPH, inspecting pharmacists or inspecting physicians, the inspectors of the ANSM, the agents of the DGCCRF , or even agents of the French Customs Agency (*Direction Générale des Douanes*) or the French Tax Authority (*Direction générale des Impôts*) are authorized to look for and establish infractions of Article L.4113-6.

In practice, enquiries are generally carried out by DGCCRF agents. The inspection is conducted during or after execution of the research contract or the scientific or promotional event, and it focuses on the actual conditions of realization of the operations carried out by the companies.

Both the professional associations and the companies may be subject to this type of inspection. For this reason, such companies are advised to keep all documentation establishing the fact that their operation complies with the requirements laid down in Article L.4113-6.

Such inspections may trigger proceedings before the judicial courts. By way of illustration, a pharmaceutical company has been sentenced to a fine of EUR20,000 following the organization of various dinners with physicians on the occasion of medical congresses. An inspection report of the DGCCRF

Procédé de divulgation et mise en application dans le temps

Ici aussi, le décret d'application du Sunshine Act devra préciser le support de publication (vraisemblablement l'internet) ainsi que les périodicités à considérer pour la divulgation des informations par les entreprises.

Entrée en vigueur

La loi du 29 décembre 2011 prévoit que l'obligation de divulgation devient applicable à la date de publication du décret d'application du Sunshine Act, ou au plus tard le 1er août 2012 si le décret n'est pas publié à cette date.[57]

Etant donné que l'obligation de divulgation apparaît inapplicable en pratique en l'absence de ce décret, il serait souhaitable que dans l'hypothèse où il ne serait pas publié au 1er août, le Ministère de la Santé publie à tout le moins un moratoire pour sécuriser les entreprises qui décideraient de ne rien divulguer, car le non respect de l'obligation de divulgation est sanctionné pénalement.

Sanctions

Le non respect des dispositions de l'article L.4113-6 du CSP peut entraîner l'application de sanctions disciplinaires et pénales. Les règles relatives à la publicité sont par ailleurs assorties de sanctions administratives et peuvent également donner lieu à des poursuites pénales.

A titre liminaire, il doit être mentionné que le non respect par une entreprise des dispositions de l'article L.4113-6 du CSP peut par ailleurs être considéré par une entreprise concurrente comme étant un fait constitutif de concurrence déloyale lui causant un préjudice. Ainsi, la méconnaissance de cet article peut déboucher également sur un contentieux devant les juridictions commerciales entre entreprises concurrentes.[58]

Violation des dispositions de l'article L.4113-6 du CSP

Le non respect du principe d'interdiction des avantages peut s'analyser, d'une part, en une aliénation de l'indépendance du professionnel qui a bénéficié de l'avantage prohibé et fonder l'instance ordinale à prononcer des sanctions disciplinaires. Indépendamment de ces sanctions professionnelles,

[57] Article 41-II de la loi du 29 décembre 2011.
[58] Pour une application : Cour d'appel de Versailles, 12ème Ch., 6 mai 2003, Pharmacia c/ Alcon, arrêt n° 260.

had indeed evidenced that the cost per physician for these dinners was not reasonable and exceeded the costs that the company had declared to the CNOM and for which the CNOM had issued a positive opinion.[59]

FCPH Article L.4163-6 provides, essentially, that if a healthcare professional benefits from an advantage granted by a company in violation of FCPH Article L.4113-6, such infraction is punishable by two years' imprisonment and a fine of up to EUR75,000, unless the infraction falls within the scope of the exceptions provided for in relation to research contracts and hospitality offered for scientific or promotional events.

In addition to the main penalty, the courts may prohibit the person from practicing for a period of 10 years.

FCPH Article L.4163-2 of the FCPH also provides for the sanctioning of companies (as legal entities), under the same terms, for having offered or procured advantages for members of the medical profession[60] in violation of Article L.4113-6. In addition, Article L.4163-2 provides that corporate entities can be held criminally liable under the conditions provided in Article 121-2 of the Criminal Code. In this case, the sanctions applicable to legal entities are fines equal to up to five times the fines levied against individuals for the same infraction (Article 131-38 of the Criminal Code). Therefore, a company, as a legal entity, can be sanctioned with a fine of up to EUR375,000 (i.e., EUR75,000 x 5) for violating Article L.4113-6. Furthermore, the sanctions determined for individuals can also be applied to the managers of the companies if they are individually prosecuted.

In addition, sanctions decided against legal entities must be reported to the Economic Committee of Health Products (*Comité Economique des Produits de Santé*, "CEPS").

[59] Tribunal of Clermond-Ferrand, Criminal Section, 15 March 2010.

[60] Surprisingly, FCPH Article L.4163-2 only refers to "members of medical professions" (i.e., physicians, midwives and dental surgeons), to the exclusion of the other healthcare professionals who are also subject to the prohibition of gifts pursuant to FCPH Article L.4113-6 (i.e., medical auxiliaries and pharmacists). In consequence, should any case of violation of the Anti-Gift Law in connection with an interaction with a medical auxiliary or a pharmacist be brought before a criminal court, the issue regarding the enforceability of the sanctions determined by FCPH Article L.4163-2 could be debatable.

l'article L.4113-6 du CSP est assorti de sanctions pénales et sa méconnaissance peut déclencher des poursuites du Parquet.

Procédure disciplinaire

Lorsqu'ils sont institués, les ordres professionnels ont pour mission de veiller au maintien des principes de moralité, de probité, et dévouement indispensables à l'exercice de la profession.

Ces ordres sont habilités à prononcer des sanctions à l'encontre des professionnels qui ont enfreint la réglementation professionnelle ou le code de déontologie de la profession. Concernant, l'acceptation d'un avantage prohibé par l'article L.4113-6 du CSP, les sanctions disciplinaires suivantes peuvent être prononcées à l'encontre du professionnel fautif: avertissement, blâme, interdiction temporaire d'exercer, radiation de l'ordre.

Ces sanctions disciplinaires ne font pas obstacles aux poursuites que peuvent engager le Procureur de la République ou les particuliers devant les tribunaux répressifs.

Procédure pénale

L'avis ordinal rendu par l'ordre professionnel compétent en application de l'article L.4113-6 du CSP s'inscrit dans un cadre préventif. La jurisprudence a confirmé le caractère consultatif de cet avis.

Cette procédure préalable n'empêche pas le déclenchement d'enquêtes ultérieures. Aux termes de l'article L.4163-1 du CSP, les pharmaciens inspecteurs ou médecins inspecteurs de la santé publique, les inspecteurs de l'ANSM, les agents de la DGCCRF, ou encore les agents de la Direction Générale des Douanes ou de la Direction générale des Impôts, sont habilités à procéder à la recherche et à la constatation des infractions qui sanctionnent la méconnaissance de l'article L.4113-6 du CSP.

En pratique, les enquêtes sont généralement diligentées par les agents de la DGCCRF. Le contrôle intervient ici pendant ou après l'exécution du contrat de recherche ou le déroulement de la manifestation scientifique ou promotionnelle, et s'exerce sur les conditions effectives de la réalisation des opérations menées par les entreprises.

Peuvent être ainsi soumis à ce contrôle aussi bien les instances ordinales que les entreprises. C'est pourquoi il est recommandé à ces entreprises de conserver toute documentation établissant que l'opération concernée satisfait aux exigences de l'article L.4113-6 du CSP.

CEPS is the public entity responsible for the pricing of medicinal products or medical devices covered by the French Health Insurance Program, by way of agreements with the companies which commercialize them. It must be noted that the pricing agreements signed between CEPS and companies may include obligations for such companies to limit their budgets allocated to the promotion of certain reimbursable medicinal products. However, it is unlikely that CEPS would require the renegotiation of a pricing agreement in case of a breach of Article L.4113-6 by the signing company. In potential cases where a company may have granted undue advantages to health professionals during a promotional event, it should be demonstrated that the limitations to promotional budgets binding the company pursuant to its pricing agreement have been exceeded. As of today, we have not been aware of practical consequences on pricing agreements which would follow a violation of Article L.4113-6.

Sanctions can also be levied in case of violation of the rules and regulations concerning advertising.

Violations of the Rules Concerning Advertising

The legal definition of advertising for health products is extremely broad. In particular it extends to "any form of information" on such products.[61]

For example, with regard to medicinal products, the scope of this definition includes invitations issued by pharmaceutical companies to health professionals to take part in promotional events, the delivery of free samples and the advantages of negligible value granted to them. Article R.5122-12 of the FCPH also specifies that any type of contribution to financing scientific conferences or meetings constitutes sponsorship that must be characterized as advertising.

The ANSM controls advertising of health products and is empowered to take administrative sanctions against companies in the event of violation of the advertising rules. Moreover the provisions of the FCPH on advertising also contain criminal sanctions.[62]

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[61] FCPH Article L.5122-1 for advertising of medicinal products, FCPH Article L.5223-1 for advertising of medical devices.

[62] See in particular FCPH Article L.5422-9: the granting of, or the promise to offer, to persons prescribing of delivering medicinal products any benefit in cash or in kind, unless the benefit is of negligible value, in the framework of the promotion of medicinal products, can be sanctioned by a criminal fine of up to EUR37,500.

Les contrôles ainsi effectuées peuvent déclencher une action répressive devant les tribunaux judiciaires. Ainsi par exemple, un laboratoire pharmaceutique s'est vu condamné à une amende de 20 000 EUR pour avoir organisé des dîners avec des médecins à l'occasion de divers congrès. Le coût par médecin s'était avéré, à la suite d'une enquête de la DGCCRF, supérieur au coût que le laboratoire avait déclaré au CNOM et pour lequel le CNOM avait émis un avis favorable.[59]

L'article L.4163-2 du CSP dispose en substance que le fait pour un membre d'une profession médicale d'avoir bénéficié d'un avantage consenti par une entreprise en violation des termes de l'article L.4113-6 du CSP est puni de deux ans d'emprisonnement et de 75000 EUR d'amende, sauf à ce que l'infraction constatée tombe dans le champ d'application des dérogations prévues pour les contrats de recherche et pour l'hospitalité offerte à l'occasion de manifestations scientifiques ou promotionnelles.

Outre ces sanctions, les tribunaux peuvent prononcer l'interdiction temporaire d'exercer la profession pendant une période de dix ans accessoirement à la peine principale.

L'article L.4163-2 du CSP prévoit également que les entreprises peuvent être sanctionnées par la même peine pour avoir proposé ou procurer un avantage aux membres des professions médicales[60] en violation de l'article L.4113-6 du CSP. En outre, l'article L.4163-2 du CSP prévoit que les personnes morales peuvent être déclarés pénalement responsables dans les conditions prévues à l'article 121-2 du Code Pénal. Dans ce cas, les sanctions encourues par les personnes morales sont des amendes dont le montant est égal au quintuple du montant de l'amende prévue à l'encontre des personnes physiques pour la même infraction (article 131-38 du Code Pénal). En conséquence, une entreprise peut, en tant que personne morale, être condamnée à une amende de 375000 EUR (i.e. 75.000 x 5) pour violation de l'article L.4113-6 du CSP. Et les sanctions prévues à l'encontre des

[59] TGI Clermond Ferrand, Chambre Correctionnelle, 15 mars 2010.

[60] De manière surprenante, l'article L.4163-2 du CSP ne vise que les membres des professions médicales (*i.e.* médecins, sages-femmes et dentistes), à l'exclusion des autres professionnels de santé (auxiliaires médicaux et pharmaciens) qui sont aussi soumis à l'interdiction des cadeaux prévue par l'article L.4113-6 du CSP. De ce fait, la question de l'applicabilité des sanctions prévues par l'article L.4163-2 en cas de violation de l'article L.4113-6 à l'occasion d'une relation avec un auxiliaire médical ou un pharmacien pourrait être très débattue devant les tribunaux correctionnels.

Non-Compliance with the Disclosure Obligation Provided for by the "French Sunshine Act"

FCPH Article L.1454-3 provides for a criminal fine of up to EUR45,000 against any company which does not voluntarily disclose information that must be made available to the public pursuant to FCPH Article L.1453-1.

personnes physiques peuvent aussi être prononcées à l'encontre des dirigeants des entreprises s'ils sont poursuivis individuellement.

Par ailleurs, l'article L.4163-2 du CSP exige que les sanctions prononcées à l'encontre des personnes morales soient portées à la connaissance du Comité Economique des Produits de Santé (« CEPS »).

Le CEPS est l'organisme public habilité à fixer le prix de vente au public des produits remboursables par la sécurité sociale par voie de convention avec les entreprises qui les exploitent. Il est rappelé que les conventions ayant pour objet la fixation du prix de vente des produits remboursables signées entre le CEPS et les entreprises qui exploitent ces produits peuvent contenir des engagements de ces entreprises visant à limiter leurs budgets en terme de promotion pour certains des médicaments remboursables concernés. Il est néanmoins peu probable que le CEPS puisse exiger la renégociation d'une convention de prix après avoir été informé d'une infraction à l'article L.4113-6 du CSP commise par une entreprise.

L'hypothèse serait par exemple celle d'une infraction par laquelle l'entreprise aurait octroyé des avantages excessifs à des professionnels de santé à l'occasion d'invitations à des manifestations promotionnelles, le montant des avantages illicites provoquant par ailleurs un dépassement des seuils sur lesquels l'entreprise s'était engagée pour limiter ses dépenses de publicité dans la convention signée avec le CEPS. A notre connaissance, le cas d'une méconnaissance de l'article L.4113-6 du CSP n'a encore jamais eu d'incidences pratiques sur les conventions de fixations de prix conclues avec le CEPS.

Des sanctions peuvent en outre être prononcées en cas d'infraction à la réglementation sur la publicité.

Infraction aux règles relatives à la publicité

La définition légale de la publicité en faveur des produits de santé est extrêmement large. Elle s'entend notamment de « *toute forme d'information* » sur ces produits.[61]

[61] Article L.5122-1 du CSP pour la publicité des médicaments; article L.5223-1 du CSP pour la publicité des dispositifs médicaux.

A titre d'exemple pour les médicaments, tombent ainsi dans le champ d'application de cette définition les invitations lancées par les entreprises pharmaceutiques pour convier les professionnels de santé à participer à des manifestions promotionnelles, les remises d'échantillons gratuits qui leur sont faites, ou encore les avantages de valeur négligeable qui leur sont procurés. L'article R.5122-12 du CSP précise en outre que toute forme de contribution au financement des congrès ou réunions scientifiques constitue un parrainage devant être qualifié de publicité.

L'ANSM exerce un contrôle de la publicité des médicaments à l'issue duquel peuvent être prises des sanctions administratives. Par ailleurs, les dispositions du CSP relatives à la publicité sont également sanctionnées pénalement.[62]

Non Respect de l'obligation de divulgation du "Sunshine Act" à la française

L'article L.1454-3 du CSP prévoit une amende de 45000 EUR à l'encontre de toute entreprise qui omettrait sciemment de rendre publiques certaines informations couvertes par l'obligation de divulgation prévues à l'article L.1453-1 du même Code.

[62] Voir notamment l'article L.5422-9 du CSP : « *L'octroi, l'offre ou la promesse à des personnes habilitées à prescrire ou à délivrer des médicaments d'une prime, d'un avantage pécuniaire ou en nature, à moins que ceux-ci ne soient de valeur négligeable, pour promouvoir des médicaments, est puni de 37500 EUR d'amende* ».

Deutschland

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Einleitung

Die Interaktionen zwischen Unternehmen der Pharma- und Medizinprodukteindustrie einerseits und Ärzten bzw. Krankenhäusern andererseits ziehen seit Jahrzehnten die Aufmerksamkeit seitens des Gesetzgebers, Behörden (einschl. Staatsanwaltschaften), Industrieverbänden sowie der Medien auf sich.

Da eine Vielzahl von Beteiligten mit ihren jeweiligen Interessen zusammen kommen, müssen unterschiedliche Rechtsgebiete und Regelungsmaterien beachtet und miteinander in Einklang gebracht werden. Nur so gelingt es, die manchmal schwierigen Fahrwasser bei der konkreten Zusammenarbeit mit Ärzten und Kliniken zu durchschiffen. Neben den einschlägigen Antikorruptionsvorschriften des Strafrechts ist das ärztliche Berufsrecht genauso zu beachten wie etwa das Heilmittelwerberecht, das Recht der Gesetzlichen Krankenversicherung sowie Verhaltenskodizes von einzelnen Industrieverbänden. Außerdem sollte man die vielschichtige und sich mitunter rasch fortentwickelnde Einzelfallrechtsprechung im Auge behalten, insbesondere auch um sicherzustellen, dass die unternehmenseigenen Verhaltenskodizes stets die aktuelle Rechtslage widerspiegeln.

In diesem Kapitel werden die anwendbaren Regelungen umrissen und es wird Überblick über die wichtigsten “Do’s” and “Don’ts” der Außenkommunikation und Interkation mit Gesundheitsdienstleistern gegeben, insbesondere hinsichtlich der Förderung und Unterstützung von Ärzten oder Krankenhäusern.

Beschränkungen nach Maßgabe heilmittelwerberechtlicher Vorschriften

Rechtliche Rahmenbedingungen

Die EU-Richtlinie 91/28/EWG über die Werbung für Humanarzneimittel, die inzwischen in den Gemeinschaftskodex 2001/83/EEG für Humanarzneimittel integriert worden ist, wurde in Deutschland im Gesetz über die Werbung auf dem Gebiet des Heilwesens (Heilmittelwerbegesetz/”HWG”) umgesetzt. Das HWG findet Anwendung auf jede Werbung für Arzneimittel und Medizinprodukte (“Heilmittel”). Darüber hinaus sind die Vorschriften des

Germany

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Introduction

Interactions between pharmaceutical companies or med-tech companies on the one hand, and healthcare professionals on the other, have been for decades a constant focus of attention for legislators, regulators, law enforcement bodies, industry associations and the media.

Since there is a plurality of stakeholders and interests involved, different legal regimes have to be taken into account and different sets of rules have to be applied and consolidated in order to navigate through the landscape of the many modalities of interactions with healthcare professionals.

Apart from the basic anti-bribery provisions of criminal law, rules of professional conduct for physicians have to be considered, as well as specific promotional restrictions set forth by medical advertisement law, public health insurance regulations and codes of conduct adopted by various industry associations. In addition, fast progressing case law calls for regular updates of the compliance policies implemented by manufacturers of medical products.

This chapter surveys the applicable rules and provides an overview of the most relevant do's and don'ts for promotional activities, specifically with regard to offering benefits and support to medical practitioners.

The Regulatory Framework

EU directive 92/28/EEC on advertising of medicinal products for human use, which has since been integrated into the Community Code 2001/83/EEC relating to medicinal products for human use, has been implemented in Germany in the act regarding advertising of medicinal products (*Heilmittelwerbegesetz* — "HWG"). The HWG applies to any advertising of drugs and medical devices (remedies — *Heilmittel*). HWG regulations are also applicable to cosmetics, procedures, treatments and products if advertising statements refer to the diagnosis, removal or alleviation of diseases, conditions, bodily injury or pathological complaints in humans or animals. In this context, the term "advertising" is to be given a very broad meaning. "Advertising" includes all measures intended to promote the sale of

HWG anwendbar, wenn für Kosmetika, Verfahren, Behandlungen und Gegenstände geworben wird, soweit sich die Werbeaussage auf die Erkennung, Beseitigung oder Linderung von Krankheiten, Leiden, Körperschäden oder krankhaften Beschwerden bei Mensch oder Tier bezieht. Dabei ist der Begriff der Werbung sehr weit zu verstehen. Unter "Werbung" fallen alle Maßnahmen, die darauf angelegt sind, den Absatz der genannten Produkte zu fördern oder beim Publikum den Wunsch wachzurufen, sich im Bedarfsfall eines solches Produktes zu bedienen. Unter den Werbebegriff des HWG fallen nicht nur typische Werbeanpreisungen für Heilmittel, sondern auch objektiv gehaltene Sachinformationen wie etwa wissenschaftliche Publikationen, wenn diese von einem Unternehmen eingesetzt werden, um den Absatz der betreffenden Heilmittel zu fördern.

Allerdings sind die Regelungen und Beschränkungen des HWG nur anwendbar, wenn es um Absatzwerbung für bestimmte oder bestimmbare Heilmittel geht. Sofern ein Unternehmen für die Gesamtheit seiner Leistungen oder sein Ansehen wirbt oder pauschal die Qualität und Preiswürdigkeit seiner Produkte herausstellt, ohne die Aufmerksamkeit des Publikums auf ein bestimmtes oder bestimmbares Heilmittel zu lenken, handelt es sich um sogenannte Imagewerbung, auf die die Vorschriften des HWG nicht anwendbar sind (BGH GRUR 1995, 223 - Pharma-Hörfunkwerbung; BGH GRUR 1992, 1873 - Pharma-Werbespot). So kann zum Beispiel eine Betriebsbesichtigung, die vorrangig eine wissenschaftlich-informative Zielsetzung hat oder durch die der hohe wissenschaftliche Standard des werbenden Unternehmens unter Beweis gestellt werden soll, eine allgemeine Imagewerbung für das einladende Unternehmen darstellen, ohne dass auf diese Werbung die Vorschriften des HWG anwendbar wären.

Neben den Vorschriften des HWG sind bei der Werbung für Heilmittel die allgemeinen wettbewerbsrechtlichen Vorschriften des Gesetzes gegen unlauteren Wettbewerb ("UWG") zu berücksichtigen. Das UWG enthält zum einen in § 3 eine Generalklausel, wonach Handlungen, die geeignet sind, den Wettbewerb zum Nachteil der Mitbewerber oder Verbraucher nicht nur unerheblich zu beeinträchtigen, unzulässig sind. In § 4 UWG sind eine Vielzahl von Regelbeispielen für unlautere Wettbewerbshandlungen normiert. Zu den Regelbeispielen gehört etwa die Behinderung von Wettbewerbern, die Verletzung von Normen, die im Interesse der Marktteilnehmer das Marktverhalten regeln, oder auch das übertriebene Anlocken. Die Beurteilung, ob eine bestimmte Werbemaßnahme im Einzelfall sittenwidrig ist, orientiert sich letztendlich an dem sehr weit und differenziert entwickelten Richterrecht. Darüber hinaus enthält das UWG als zentrale Vorschriften in § 6 die Anforderungen an eine zulässige

the above products or to arouse the desire of the public to use such a product if the need for its use arises. The concept of advertising under the HWG not only encompasses typical highlighting of remedies, but also objectively presents factual information such as scientific publications if they are used by companies to promote the sale of such remedies.

The regulations and restrictions of the HWG are only applicable, however, where the sales advertising is for certain or definable remedies. If a company advertises its goods and services as a whole or seeks to advance its reputation, or emphasizes in a non-specific manner the quality and good value of its products without drawing the attention of the public to a certain or definable remedy, this is deemed to be image advertising — which is not regulated by the HWG (BGH GRUR 1995, 223 — pharmaceutical advertising on the radio; (BGH GRUR 1992, 1873 — pharmaceutical commercial). So, for example, a tour of a business facility, the primary objective of which is to impart scientific information or to provide evidence of the high scientific standards of the business that is promoting itself, will constitute general image advertising on the part of the host company and will therefore not be caught by the regulations of the HWG.

In addition to the regulations of the HWG, the general provisions of the Act Against Unfair Competition ("UWG") must also be taken into account when advertising is used for remedies. Sec. 3 UWG prohibits all actions which may impede or restrain fair competition to the disadvantage of other competitors or consumers. Sec. 4 UWG sets forth a number of examples of unethical advertising behavior. Such conduct includes the obstruction of competitors, the violation of rules regulating the market in the interest of the market participants, or excessive enticement. The judgment of whether a particular advertising measure is contrary to public policy in an individual case will ultimately be decided by the very broad and highly differentiated case law.

In addition, sec. 6 UWG contains central provisions governing the requirements for permissible comparative advertising. Pursuant to sec. 5 UWG, misleading advertisements are prohibited. Sec. 7 UWG prohibits promotional activities that are annoying or irritating to others, which, for example, applies to unrequested or unsolicited phone calls or emails.

Permitted and Prohibited Practices

Two cardinal rules of successful marketing in the healthcare sector are to emphasize the positive features of the marketed products in suitable advertising media and to create a positive environment for customer

vergleichende Werbung sowie in § 5 das Verbot der irreführenden Werbung und in § 7 Regelungen, die sich gegen belästigende Werbung richtigen; hierunter fällt unter anderem unaufgeforderte Telefon- oder E-Mailwerbung.

Erlaubte und verbotene Werbepraktiken

Es gehört zum Einmaleins eines erfolgreichen Marketings im Gesundheitsbereich nicht nur die vorteilhaften Eigenschaften der vertriebenen Produkte in geeigneten Werbemedien herauszustellen, sondern auch eine positiv ausgerichtete Kundenbeziehung herzustellen. Um dies zu erreichen, stellt die Industrie ihren Kunden nicht nur Informationen zu den vertriebenen Produkten zur Verfügung, sondern unterstützt diese auch in vielerlei Hinsicht. Die Gewährung von Zuwendungen an medizinische Fachkreise ist jedoch nur sehr eingeschränkt zulässig. Im Folgenden soll deshalb zunächst erläutert werden, welche wettbewerbsrechtlichen Vorschriften es in Deutschland gibt, die von Pharma-und Medizinprodukteunternehmen bei der Gewährung von Zuwendungen an Mitglieder der medizinischen Fachkreise beachtet werden müssen. Die strafrechtlichen Aspekte der Zuwendungspraxis der Gesundheitsindustrie werden weiter unten im Abschnitt 3 behandelt.

Geschenke, Seminare, Bewirtung und Unterhaltung

Zur üblichen Zuwendungs- oder Sponsoringpraxis von im Gesundheitsbereich tätigen Unternehmen zählt das Überreichen von Geschenken, die Einladung von Ärzten zu Seminaren, Kongressen oder Workshops sowie die Bewirtung und Unterhaltung von Kunden in Zusammenhang mit der Durchführung von wissenschaftlichen Veranstaltungen oder dem Besuch des Außendienstes beim Arzt. Die wettbewerbsrechtlichen Grenzen für derartige Zuwendungen lassen sich wie folgt umreißen:

Geschenke

§ 7 HWG sieht ein grundsätzliches Verbot von Werbegaben vor. Gemäß Abs. 1 Satz 1 HWG ist es grundsätzlich unzulässig, Zuwendungen und sonstige Werbegaben (Waren oder Leistungen) anzubieten, anzukündigen oder zu gewähren. Das generelle Zuwendungsverbot erstreckt sich auf wirtschaftliche Vorteile jeder Art. So können hierunter Sachbücher, Büroartikel, Uhren, Sportartikel oder auch die Überlassung von Aktien, Computersoftware, Wartungsleistungen, etc. fallen. Allerdings wird das generelle Zuwendungsverbot des § 7 Abs. 1 Satz 1 HWG im zweiten Halbsatz durch mehrere Ausnahmetatbestände durchbrochen.

relationships. In order to achieve this, the industry not only provides its customers with information on the marketed products, but also supports them in many ways. However, the provision of gifts to medical professionals is only permitted to a very limited extent. For this reason, we will first look at what competition regulations in Germany must be observed by pharmaceutical and medical device companies. We will then discuss the criminal law aspects of providing gifts.

Gifts, Seminars, Hospitality and Entertainment

The giving of gifts and invitations for physicians to attend seminars, congresses or workshops — as well as dining and entertainment for customers in connection with the conduct of scientific seminars and the like, or calls on physicians by company sales staff — all belong to the customary benefits or sponsoring practice of companies active in the healthcare sector. The limitations on these types of benefits under competition law can be outlined as follows:

Gifts

Sec. 7 HWG provides a basic prohibition of advertising gifts. Under sec. 7 (1) sentence 1 HWG, it is generally illegal to offer, announce or grant benefits and other advertising gifts such as goods or services. This general prohibition of benefits also extends to economic benefits of any kind. This can include non-fiction books, office materials, athletic goods or even the giving of company shares, computer software or maintenance services.

This general prohibition of benefits in sec. 7 (1) sentence 1 HWG is modified by several exceptions in the second half of the sentence.

Not included under the prohibition of benefits, for instance, is the provision of advertising gifts of low value which permanently and clearly bear the company and/or product name (see sec. 7 (1) no. 1, 1st alternative HWG). This includes typical advertising items such as notepaper, calendars, and pens and pencils whose function as advertising media dominates their use given the advertising displayed on them. The low value of advertising items is not judged by the cost of its manufacture or procurement, but by the value of consumption or the market value it has for the recipient (BGHZ 11,260, 274 — plastic figures I; BGH GRUR 1991, 329, 330 — family ticket). It is not possible to generally assign a number to its value. The rule of thumb is that items with a value above EUR1 are not to be deemed of low value (*cf Doepner, Heilmittelwerbegesetz*, margin note 36 on sec. 7 HWG).

So sind vom Zuwendungsverbot zum einen Werbegaben von geringem Wert, die dauerhaft und deutlich mit dem Firmen- und/oder dem Produktnamen gekennzeichnet sind (§ 7 Abs. 1 Ziffer 1 erste Alternative HWG) ausgenommen. Hierunter fallen die typischen Reklamegegenstände wie Notizblöcke, Kalender und Stifte, deren Funktion als Werbeträger durch den Reklameaufdruck gegenüber der Gebrauchseignung dominiert. Die Geringwertigkeit des Reklamegegenstandes bemisst sich dabei nicht nach dessen Herstellungs- oder Anschaffungswert, sondern maßgeblich ist der Verbrauchs- oder Verkehrswert, den der zugewendete Gegenstand für den Empfänger hat (BGHZ 11, 260, 274 - Kunststofffiguren I; BGH GRUR 1991, 329, 330 - Family-Karte). Ein betragsmäßiger Wert lässt sich nicht allgemein festlegen.

Als Faustregel kann jedoch gelten, dass Gegenstände, deren Wert jenseits der Grenze von etwa EUR 1,00 liegen, nicht mehr als geringwertig angesehen werden (vgl. Doepner, Heilmittelwerbegesetz, Rnd. 36 zu § 7 HWG). Eine weitere Ausnahme vom Zuwendungsverbot gilt für geringwertige Kleinigkeiten (§ 7 Abs. 1 Satz 1 Ziffer 1, zweite Alternative HWG). Darunter werden Werbegaben verstanden, die einen so geringen Handels- oder Verkehrswert haben, dass sie nicht nur wirtschaftlich, sondern auch gegenständlich belanglos sind, da sie vom Empfänger nicht sonderlich geachtet werden. Für die Wertermittlung gelten die gleichen Grundsätze wie bei den Gegenständen von geringem Wert; das heißt, nach der Rechtsprechung darf der Wert von EUR 1,00 nicht überschritten werden, wenngleich in der Praxis häufig Kleinigkeiten mit höherem Wert verteilt werden.

Was immer von einem Unternehmen an Angehörige der Heilberufe abgegeben wird, muss zur Verwendung in ärztlicher, tierärztlicher oder pharmazeutischer Praxis bestimmt sind. Hieraus folgt, dass die Zuwendung von Gegenständen oder Leistungen, die dem privaten Bereich eines Arztes zu dienen bestimmt sind, von vornherein unzulässig sind. Entsprechend wäre also die Überlassung von Sportartikeln, Spielzeug oder Reiseführen in Zusammenhang mit der Bewerbung von medizinischen Produkten unzulässig.

Seminare, Bewirtung und Unterhaltung

§ 7 Abs. 2 HWG legt fest, dass das generelle Zuwendungsverbot des § 7 Abs. 1 HWG nicht für Zuwendungen im Rahmen ausschließlich berufsbezogener wissenschaftlicher Veranstaltungen gilt, sofern diese einen vertretbaren Rahmen nicht überschreiten, insbesondere in Bezug auf den wissenschaftlichen Zweck der Veranstaltung von untergeordneter Bedeutung

Another exception from the prohibition of benefits applies to small items of low value (see sec. 7 (1) sentence 1 no. 1, 2nd alternative HWG). This is understood to mean advertising gifts that have such a low commercial or market value that they are not given much attention from the recipient. The same principles as those described above apply for items of low value. This means that, under the case law, the figure of EUR1 cannot be exceeded even though, in fact, small items of greater value are usually handed out.

Anything given by a company to a member of the medical community must be intended for use in medical, veterinary or pharmaceutical practice. This means that the provision of items or services intended to serve the personal needs of a physician is illegal. The provision of athletic goods, toys or travel guides in the context of advertising for medical products is also illegal.

Seminars, Hospitality and Entertainment

Sec. 7 (2) HWG makes it clear that the general prohibition of benefits in sec. 7 (1) HWG does not apply to benefits provided within the scope of exclusively work-related scientific seminars and events, as long as they do not exceed a reasonable level, particularly if they are of subordinate significance in relation to the scientific purpose of the event and are not extended to anyone other than individuals working in the healthcare sector. This clearly establishes that it is permissible to assume responsibility for travel and hotel expenses and, if applicable, the conference fees of members of the profession. However, it is essential to ensure that the benefits provided within this framework are not exaggerated. Accordingly, it is prohibited to invite members of the medical professions to stay at luxury hotels, or to select luxurious means of travel that serve leisure rather than travel purposes (e.g., passage to the US by cruise ship). Providing dinner and entertainment for physicians and pharmacists at conferences is permitted if the provision of these benefits remains subordinate to the purpose of the conference. So as not to exceed reasonable limits, it must be ensured that the time taken up by the scientific program is considerably greater than that taken up by the leisure program. Aside from this, the entertainment program must not be so attractive from the standpoint of an objective observer that it overshadows the scientific reason for the conference. It is therefore not permissible to extend invitations to popular musical performances and sports events, or invitations to dinners in luxury restaurants. The costs for these types of events are to be paid for by the attendees themselves.

In addition, sec. 7 (2) HWG clearly states that the recipients of permitted support services within the scope of scientific conferences may only be individuals working in the field of healthcare. This means that the

sind und sich nicht auf andere als im Gesundheitswesen tätige Personen erstreckt. Hierdurch wird klargestellt, dass wettbewerbsrechtlich die Übernahme von Reise- und Übernachtungskosten sowie gegebenenfalls Kongressgebühren an Mitglieder der Fachkreise wettbewerbsrechtlich zulässig ist. Allerdings muss gewährleistet sein, dass die in diesem Rahmen gewährten Zuwendungen nicht übertrieben sind. Entsprechend verbietet es sich, Angehörige von Heilberufen in Luxushotels einzuladen oder luxuriöse Beförderungsmittel zu wählen, die mehr dem Vergnügen als der Beförderung dienen (z.B. Reise nach USA mit dem Schiff). Auch die Bewirtung und Unterhaltung von Ärzten und Apothekern bei wissenschaftlichen Kongressen ist zulässig, wenn die Gewährung dieser Vorteile von untergeordneter Bedeutung bleibt. Um die Grenze des Angemessenen nicht zu überschreiten, ist deshalb sicherzustellen, dass in zeitlicher Hinsicht das wissenschaftliche Programm das Beiprogramm eines wissenschaftlichen Seminars deutlich überwiegt. Außerdem darf das Unterhaltungsprogramm vom Standpunkt eines objektiven Betrachters nicht so attraktiv ausgestaltet sein, dass es den wissenschaftlichen Anlass dominiert. Es verbietet sich deshalb, die Einladung zu attraktiven Musikaufführungen, Sportereignissen oder Einladungen zu Abendessen in Restaurants der Luxusklasse. Die Kosten für solche Veranstaltungen sind von den Fachkreisen selbst zu zahlen.

Des Weiteren ist in § 7 Abs. 2 HWG klargestellt, dass Empfänger von zulässigen Unterstützungsleistungen im Rahmen von wissenschaftlichen Kongressen nur Personen sein dürfen, die im Gesundheitswesen tätig sind. Hieraus folgt, dass Angehörige oder Freunde von in Heilberufen tätigen Personen nicht von der Industrie unterstützt werden dürfen. Sollte ein Arzt oder Apotheker eine Begleitperson zu einer von der Industrie gesponsorten Veranstaltung mitbringen, sind die zusätzlichen Kosten für die Begleitperson von dem betreffenden Arzt oder Apotheker selbst zu tragen. Dies gilt etwa für die Reisekosten der Begleitperson oder auch für die erhöhten Kosten, die bei der Buchung eines Doppelzimmers anfallen.

Da die Übernahme von Reisekosten nur im Rahmen berufsbezogener wissenschaftlicher Veranstaltungen übernommen werden darf, ist es problematisch, wenn der unterstützte Arzt oder Apotheker die Anreise zum Veranstaltungsort nutzt, um anschließend eine Urlaubsreise zu machen. Entsprechend ist darauf zu achten, dass die Reiseunterstützung nur für den Zeitraum des Kongresses gewährt und nicht ein Rückflugtermin gebucht wird, der zeitlich erheblich nach dem Ende des Kongresses liegt. Auch die Buchung von Zwischenstops, die etwa ein Arzt oder Apotheker aus privaten Gründen für wünschenswert hält, müssen vermieden werden.

participation of relatives or friends of individuals working in medical professions may not be funded by the industry. If a physician or pharmacist brings a guest to an event sponsored by the industry, the additional costs relating to the guest must be paid for by the physician or pharmacist. This applies, for instance, to the travel expenses of the guest or the increased costs of booking a double room.

Because the assumption of travel expenses is only permitted within the scope of scientific conferences and events relating to the profession, there are inevitably difficulties whenever the supported physician or pharmacist uses the trip to a particular event to then go on vacation. Accordingly, care must be taken that the support for the trip is only provided for the period of the conference and that no return flight is booked on a date significantly later than the end of the conference. The booking of stopovers, which the physician or pharmacist may consider desirable for personal reasons, must also be avoided.

Other Promotional Activities

Although the Rebate Act and the Gift Item Regulations have now been abolished, advertising for medical products by granting rebates in cash or in goods is only permitted in certain circumstances. Cash rebates for drugs are not permitted if they are granted in breach of the price regulations. This means, for example, that no cash rebate may be granted to pharmacies on deliveries of prescription drugs if such rebate causes the so-called supply price of the pharmaceutical entrepreneur (*Abgabepreis des pharmazeutischen Unternehmers* — "ApU") to be undercut. On the contrary, in the case of direct supplies to pharmacies, the pharmaceutical company must as a minimum add the fixed additional fee of the wholesaler's trade margin, which is currently EUR0.70, to the ApU. In addition, wholesalers of pharmaceuticals must also not receive cash rebates which fall below the ApU. The aforementioned restrictions regarding the granting of cash rebates do not apply to over-the-counter ("OTC") drugs (non-prescription) and medical devices. It must be ensured, however, that the cash rebate consists of a certain cash amount or of a cash amount to be calculated in a particular way. Coupons are only considered equivalent to permissible cash rebates if they can actually be cashed in.

As regards drugs subject to sale by pharmacists only, rebates in kind may not be granted on any commercial level. Rebates in kind on OTC drugs or medical devices are permitted if they consist of a specific number of the same goods or several of the same goods that are to be calculated in a particular manner. The phrase "the same goods" is to be understood to mean that the

Zwar sind in Deutschland das Rabattgesetz und die Zugabeverordnung mittlerweile abgeschafft worden. Für die Bewerbung von medizinischen Produkten sind jedoch die Einräumung von Geld- und Warenrabatten nur unter bestimmten Voraussetzungen zulässig. Geldrabatte für Arzneimittel sind unzulässig, wenn sie entgegen den Preisvorschriften gewährt werden. Hieraus folgt, dass zum Beispiel Apotheken bei Lieferung von verschreibungspflichtigen Arzneimitteln keine Geldrabatte gewährt werden dürfen, wenn hierdurch der sogenannte Abgabepreis des pharmazeutischen Unternehmers (ApU) unterschritten wird; im Gegenteil der pharmazeutische Unternehmer muss bei Direktbelieferung von Apotheken dem ApU zumindest den Festzuschlag der Großhandelsmarge in Höhe von derzeit EUR 0,70 hinzusetzen. Arzneimittelgroßhändlern dürfen ebenfalls keine Geldrabatte eingeräumt werden, die den ApU unterschreiten. Für nicht verschreibungspflichtige Arzneimittel und Medizinprodukte gelten die vorgenannten Einschränkungen zur Einräumung von Geldrabatten nicht. Es muss lediglich sichergestellt sein, dass der Geldrabatt in einem bestimmten oder auf bestimmte Art zu berechnenden Geldrabatt besteht. Gutscheine können nur dann zulässige Geldrabatte darstellen, wenn sie in bar einzulösen sind.

Für apothekenpflichtige Arzneimittel dürfen Warenrabatte auf keiner Handelsstufe gewährt werden. Für nicht apothekenpflichtige Arzneimittel und Medizinprodukte sind Warenrabatte erlaubt, wenn sie in einer bestimmten oder auf bestimmte Art zu berechnenden Menge gleicher Ware bestehen. “Gleiche Ware” ist dahingehend zu verstehen, dass die zugegebene Ware mit der gekauften Ware identisch sein muss (BGH GRUR 1978, 547/549 - Automatentruhe). Gleichartigkeit oder auch nur Betriebsverwandtheit der Waren genügt nicht. Das heißt, es ist einem Unternehmen verwehrt, einem Kunden im Rahmen eines Kundenbindungsprogramms für den Bezug einer bestimmten Menge Ware des Typs A einen Naturalrabatt durch Überlassung von Ware des Typs B zu gewähren.

Des Weiteren ist es gemäß § 7 Abs. 1 Satz 1 Nr. 3 HWG zulässig, mit der Zuwendung von handelsüblichem Zubehör zur Ware oder handelsüblichen Nebenleistungen zu werben. Handelsüblich sind Zubehörteile und Nebenleistungen, wenn sie sich nach der Anschauung der beteiligten Verkehrskreise im Rahmen vernünftiger kaufmännischer Gepflogenheiten halten. Das heißt, die Handelsüblichkeit muss im jeweiligen Einzelfall bestimmt werden. Darüber hinaus können zulässige Zuwendungen in der

goods provided free of charge must be identical to the purchased goods (BGH GRUR 1978, 547/549 — vending machine chest). A similarity or a mere connection by virtue of their being from the same manufacturer is not sufficient. This means that, within the framework of a customer loyalty program, a company is prohibited from granting a rebate in kind for buying a certain volume of type A goods by providing type B goods.

In addition, it is permitted under sec. 7 (1) sentence 1 no. 3 HWG to advertise by providing customary accessories for the goods or to provide customary ancillary services. Accessories and services are customary if, in the opinion of the parties involved, they are in keeping with reasonable commercial practice. This means that the question of what is customary must be decided on a case-by-case basis. In addition, permissible benefits may comprise the provision of information and advice (see sec. 7 (1) sentence 1 no. 4 HWG) or in the delivery of customer magazines (see sec. 7 (1) sentence 1 no. 5 HWG).

Samples

The provision of samples is permitted. This applies to both drugs and medical devices. Although there is no legal definition in German law as to what constitutes a sample, given the direction of its purpose, a sample serves to inform the physician about the drug or medical device. As far as the drug sector is concerned, only authorized finished drugs in retail packaging, bearing the additional information that it is "sample not for sale" may be provided (see sec. 10 (1) no. 11 Drug Act (*Arzneimittelgesetz* — "AMG")). The permitted recipients of samples are physicians, dentists, veterinarians and places of learning for healthcare professions (e.g., universities). Homeopaths may only be given samples of OTC drugs. No sample drugs may be given to pharmacists.

Under sec. 47 (4) AMG, samples may only be provided upon written request. This means that the recipient must sign an equivalent letter of request. Telephone orders — or the signing of a request form with a facsimile stamp — are not sufficient.

A pharmaceutical company may only provide two samples of a finished drug to an authorized recipient each year, in the smallest package size (N1) and where the various forms of dosage and strength of dosage are counted separately. In places of learning for healthcare professionals, samples may be provided if they are in a range that is appropriate to the purpose of educational training. Pharmaceutical companies must keep separate records for each recipient of the samples and of the type, scope and date of provision, and must present these records to the authorities upon request. The provision

Erteilung von Auskünften und Ratschlägen (§ 7 Abs. 1 Satz 1 Ziffer 4 HWG) oder in der Abgabe von Kundenzeitschriften (§ 7 Abs. 1 Satz 1 Ziffer 5 HWG) bestehen.

Muster

Die Abgabe von Mustern ist zulässig. Dies gilt sowohl für Arzneimittel als auch für Medizinprodukte. Es gibt im deutschen Recht zwar keine Legaldefinition für den Begriff des Musters. Von der Zweckrichtung her dient jedoch ein Muster zur Information des Arztes über den Gegenstand des Arzneimittels oder des Medizinproduktes.

Was den Arzneimittelbereich anbetrifft, dürfen als Muster nur zugelassene Fertigarzneimittel in der Handelspackung abgegeben werden, die mit dem zusätzlichen Hinweis "unverkäufliches Muster" (§ 10 Abs. 1 Nr. 11 Arzneimittelgesetz/"AMG") gekennzeichnet sind. Rechtmäßige Empfänger von Mustern sind Ärzte, Zahnärzte, Tierärzte sowie Ausbildungsstätten für die Heilberufe (z.B. Universitäten). Heilpraktikern dürfen nur Muster von nicht-verschreibungspflichtigen Arzneimitteln überlassen werden. An Apotheker dürfen keine Arzneimittelmuster abgegeben werden. Gemäß § 47 Abs. 4 AMG darf die Abgabe von Mustern nur auf schriftliche Anforderung erfolgen. Das heißt, der betreffende Empfänger muss ein entsprechendes Anforderungsschreiben unterzeichnen. Telefonische Bestellung oder die Unterzeichnung eines Anforderungsbogens mit einem Facsimilestempel reicht nicht aus.

Pro Jahr darf ein Pharmaunternehmen an einen berechtigten Empfänger nur zwei Muster von einem Fertigarzneimittel in der jeweils kleinsten Packungsgröße (N1) abgeben. Dabei sind allerdings unterschiedliche Darreichungsformen und - stärken getrennt zu beurteilen. In Ausbildungsstätten für Heilberufe dürfen Muster in einem dem Zweck der Ausbildung angemessenen Umfang abgegeben werden. Über die Empfänger von Mustern sowie über Art, Umfang und Zeitpunkt der Abgabe hat das pharmazeutische Unternehmen für jeden Empfänger gesondert Nachweise zu führen und auf Verlangen den zuständigen Behörden vorzulegen. Die Abgabe von Mustern für Fertigarzneimittel, die unter das Betäubungsmittelgesetz fallen, ist nur äußerst eingeschränkt zulässig.

§ 7 Abs. 1 Satz 3 HWG verweist für die Zulässigkeit der Musterabgabe lediglich auf die Regelung in § 47 Abs. 3 AMG. Eine gesetzliche Ausnahme für die Abgabe von Medizinproduktemustern ist nicht vorgesehen. Tatsächlich existiert im Medizinproduktegesetz ("MPG") auch keine Regelung, die mit § 47 Abs. 3 und Abs. 4 AMG vergleichbar wäre. Hieraus

of samples of finished drugs that fall under the Narcotics Act is only permitted in extremely limited circumstances.

Sec. 7 (1) sentence 3 HWG only refers to the legality of providing samples within the rule set down in sec. 47 (3) AMG. There is no statutory waiver for the provision of samples of medical devices. Indeed, no rule exists under the Medical Devices Act (*Medizinproduktegesetz* — "MPG") which is comparable to sec. 47 (3) and (4) AMG. One cannot assume, however, that the provision of samples of medical devices is illegal. Rather, one must assume that this was an oversight by lawmakers because the MPG has not yet laid down any special rule governing the provision of samples of medical devices. But because there is an understandable need in the medical products sector to have samples provided — and as the provision of samples has been regarded as customary until now, and without criticism by the literature, the courts or the authorities — one may assume that the provision of samples of medical devices is permissible as long as this is kept within a range that cannot be considered to be in contravention of public policy. The provision of samples could contravene public policy if it assumes a scope that obstructs competitors. In this case, there could be a violation of sec. 3 UWG.

Consequences of Breach

A violation of the general prohibition of advertising gifts in sec. 7 (1) HWG is an administrative offense within the meaning of sec. 15 (1) no. 4 HWG and is punishable by a fine of up to EUR50,000. The fine can be levied against both the responsible employee of the company that grants benefits in an illegal manner when selling its medical products, as well as against the member of the profession accepting the particular benefit (sec. 15 (1) no. 4a HWG).

Although the appropriate supervisory authority is responsible for monitoring compliance with the provisions of the HWG, the German supervisory authorities do not, in fact, check the advertising activities of the medical industry. Accordingly, there are only very isolated procedures for fines relating to violations of the provisions of the HWG and the UWG.

However, this lack of activity on the part of the supervisory authorities does not mean that the provisions of the HWG and the UWG are legally obsolete. Given the manner in which the law is designed, lawmakers rely on market players to monitor whether a competitor complies with the restrictions of the HWG and the UWG. If a competitor violates the regulations governing competition, it is possible for the injured company to pursue this in the civil law courts because of the very effective instruments that are in place for its

darf jedoch nicht gefolgert werden, dass die Abgabe von Medizinproduktemustern unzulässig wäre. Es ist vielmehr davon auszugehen, dass es sich hierbei um ein gesetzgeberisches Versehen handelt, weil das MPG bisher keine Spezialregelungen für die Musterabgabe von Medizinprodukten vorsieht. Da jedoch im Medizinproduktebereich ebenfalls das nachvollziehbare Bedürfnis zur Abgabe von Mustern existiert und die Abgabe von Mustern bisher auch üblich war, ohne dass von Literatur, Rechtsprechung oder Behörden die Abgabe von Medizinproduktemustern beanstandet worden wäre, ist davon auszugehen, dass die Abgabe von Medizinproduktemustern zulässig ist, solange sich die Musterabgabe in einem Rahmen hält, in dem sie nicht als sittenwidrig angesehen werden kann. Sittenwidrig könnte eine Musterabgabe sein, wenn die Abgabe von Mustern einen Umfang annimmt, der zur Behinderung anderer Wettbewerber führt. In diesem Fall könnte ein Verstoß gegen § 3 UWG vorliegen.

Konsequenzen einer Rechtsverletzung

Ein Verstoß gegen das generelle Werbegabenverbot des § 7 Abs. 1 HWG stellt eine Ordnungswidrigkeit im Sinne des § 15 Abs. 1 Nr. 4 HWG dar und kann mit einer Geldbuße bis zu EUR50.000,00 geahndet werden. Die Geldbuße droht sowohl dem verantwortlichen Mitarbeiter des Unternehmens, das in unzulässiger Weise beim Absatz seiner medizinischen Produkte Zuwendungen gewährt, als auch den Angehörigen der Fachkreise, die die entsprechende Zuwendung annehmen (§ 15 Abs. 1 Nr. 4a HWG).

Die Einhaltung der Vorschriften des HWG obliegt zwar den zuständigen Aufsichtsbehörden. Tatsächlich überprüfen die deutschen Aufsichtsbehörden jedoch nicht die Werbeaktivitäten der medizinischen Industrie. Entsprechend gibt es nur sehr vereinzelt Bußgeldverfahren wegen des Verstoßes gegen Vorschriften des HWG oder UWG.

Diese Untätigkeit der Aufsichtsbehörden führt jedoch nicht dazu, dass Vorschriften des HWG und UWG juristisch leer laufen. Denn der Gesetzgeber vertraut konzeptionell darauf, dass die Marktteilnehmer selbst darauf achten, ob ein Wettbewerber die Beschränkungen des HWG und UWG einhält. Falls ein Wettbewerber einen Wettbewerbsverstoß begeht, ist es dem verletzten Unternehmen aufgrund eines sehr effektiven Rechtsschutzinstrumentariums möglich, hiergegen zivilrechtlich vorzugehen. Jede Verletzung einer HWG-Norm stellt grundsätzlich zugleich einen Verstoß gegen §§ 3, 4 Nr. 11 UWG dar, ohne dass ein Verschulden des Verletzers nachgewiesen werden müsste. Unternehmen, die gegen heilmittelwerberechtliche Vorschriften verstoßen, können daher von

legal protection. Each violation of a regulation in the HWG is generally a violation of sections 3, 4 no. 11 UWG without the necessity of proving the negligence of the perpetrator.

Therefore, companies violating the regulations governing medical advertising may be sued by their competitors for a cease and desist order and, if applicable, for damages. In addition, there are associations in Germany acting as competition watchdogs that have the legal status to take action against companies violating competition regulations.

If a company wants to contest a violation of competition law by a competitor, it usually sends the competitor a warning notice and demands that they cease and desist from further engaging in the specific violation upon payment of a penalty. If the competitor refuses to issue the demanded cease and desist declaration which, if infringed upon, gives rise to a contractual penalty, the company that demanded the cease and desist declaration may seek injunctive relief and apply for a temporary injunction order whereby the competitor will be ordered by the court to cease and desist from continuing with the violation. Temporary injunction can be obtained within hours, but generally takes between one and two days. If the injured company provides sufficient *prima facie* evidence for the violation, the court will decide on the issue without hearing the other party. This speedy action by the courts acts as an effective stop to advertising measures taken in violation of competition law by competing firms. In order to present a complete picture, though, it should be noted that it is not necessary to send a warning notice to the competitor before filing an application for a temporary injunctive order. However, failing to do so could result in an unfavorable cost result because the lawyers' fees and the court costs incurred following a successful warning notice and court proceedings are generally borne by the losing party. If a company immediately proceeds with a temporary injunction against a competitor without having previously cited the violation to them, and if the competitor gives a commitment to be subject to the duty to cease and desist after the court order has been served on them, the company filing for the order will have to bear the incurred lawyers' fees and court costs itself.

As far as the actual enforcement of compliance with sec. 7 (1) HWG is concerned, it has to be admitted that there has only been a very small number of court decisions dealing with the provision. The reason for this could be that companies are reluctant to proceed against competitors for violations of sec. 7 (1) HWG because they may be themselves engaged in advertising activities susceptible to attack under sec. 7 HWG.

Wettbewerbern auf Unterlassung und gegebenenfalls auch Schadensersatz in Anspruch genommen werden. Daneben gibt es in Deutschland auch Wettbewerbsvereine, die aus eigenem Recht gegen Unternehmen vorgehen können, welche gegen Wettbewerbsvorschriften verstoßen.

Sofern sich ein Unternehmen gegen einen Wettbewerbsverstoß eines Wettbewerbers zur Wehr setzten möchte, sendet es dem Wettbewerber üblicherweise ein sogenanntes Abmahnschreiben und fordert ihn auf, den konkreten Wettbewerbsverstoß bei Meidung einer Vertragsstrafe zukünftig zu unterlassen. Sofern der Wettbewerber sich weigert, die geforderte strafbewehrte Unterlassungserklärung abzugeben, kann das verletzte Unternehmen in kürzester Zeit eine einstweilige Verfügung erlangen, mit der dem Wettbewerber die Fortführung der Verletzungshandlung gerichtlich untersagt wird. Der Erlass einer einstweiligen Verfügung kann innerhalb von Stunden erreicht werden, dauert aber im Regelfall zwischen ein und drei Tagen. Sofern das verletzte Unternehmen die Verletzungshandlung hinreichend glaubhaft macht, entscheidet das Gericht ohne Anhörung der Gegenseite. Durch das schnelle Tätigwerden der Gerichte im Rahmen von einstweiligen Verfügungsverfahren können wettbewerbswidrige Werbemaßnahmen von Konkurrenzunternehmen effektiv unterbunden werden. Der Vollständigkeit halber sei darauf hingewiesen, dass es für die Beantragung einer einstweiligen Verfügung nicht erforderlich ist, vorher den Wettbewerber anzumahnen; das Unterlassen einer Abmahnung kann jedoch Kostennachteile zufolge haben. Denn die Anwalts- und Gerichtskosten, die bei Durchführung eines erfolgreichen Abmahn- oder Gerichtsverfahrens entstehen, sind regelmäßig von der unterlegenen Partei zu tragen. Geht ein Unternehmen gegen einen Wettbewerber sofort mit einer einstweiligen Verfügung vor, ohne die Verletzungshandlung vorher abgemahnt zu haben, und gibt der Wettbewerber nach Zustellung des Gerichtsbeschlusses eine Unterwerfungserklärung ab, hat der angreifende Unternehmer die anfallenden Anwalts- und Gerichtskosten selbst zu tragen.

Was die faktische Durchsetzung der Einhaltung des § 7 Abs. 1 HWG anbetrifft, ist einzuräumen, dass es bisher nur sehr wenige Gerichtsentscheidungen gibt, die sich mit dieser Regelung beschäftigt haben. Hintergrund könnte möglicherweise sein, dass sich Unternehmen scheuen, gegen Wettbewerber wegen Verstoß gegen § 7 Abs. 1 HWG vorzugehen, weil sie möglicherweise selbst Werbeaktivitäten entfalten, die gemäß § 7 HWG angreifbar wären.

Professional Codes of Conduct

In addition to the statutory provisions of the law of competition, there are various codes and recommendations of conduct in Germany dealing with the problem area of cooperation between the medical industry on the one hand, and physicians and hospitals on the other. These industry-wide codes provide recommendations for action and conduct intended to inform market participants of the limits to legal sponsoring practice. At the same time, industry associations are pursuing the goal of achieving equal opportunity for the companies in competition with one another.

Medical Devices Code

In 1997, *Bundesverband Medizintechnologie eV* ("BVMed" — Federal Medical Technology Association) published the Medical Devices Code in collaboration with the top organizations of the health insurance authorities. The code concentrates on conduct recommendations in the field of research and development, third-party funding accounts, progress and advanced learning, donations, gifts, and advisory contracts to the extent that they affect cooperation between medical facilities and the employees working there. There are five core principles, compliance with which is the prerequisite for legal sponsoring practice. These are as follows:

- The principle of separation — No services, whether or not for consideration, are to be provided to medical facilities or to employees working there if such provision is dependent on sales transactions with the medical facility.
- The principle of transparency — All benefits provided to a medical facility or to its employees are to be disclosed to the principal or employer, as the case may be, and thus made transparent.
- The principle of authorization — If benefits are provided to an employee of a medical facility, prior written authorization from the employee's principal or the facility's administrative head is required.
- The principle of equivalence — Within the scope of cooperation between the industry and a medical facility, performance and consideration must stand in reasonable relationship to one another.
- The principle of documentation — Performance rendered by a medical facility or employees working there must be documented.

Although the Medical Devices Code was originally intended to address companies and medical facilities and their employees involved in the development, marketing and use of medical products, the rules

Verhaltensregeln der medizinischen Industrie und der Ärzteschaft

Neben der gesetzlichen Regelung des Wettbewerbsrechts gibt es mittlerweile in Deutschland verschiedene Kodices und Verhaltensempfehlungen, die sich mit dem Problemkreis der Zusammenarbeit zwischen der medizinischen Industrie auf der einen Seite und Ärzten und Krankenhäusern auf der anderen Seite beschäftigen. Diese unternehmensübergreifenden Kodices geben Handlungs- und Verhaltensempfehlungen, um die Marktteilnehmer über die Grenzen einer zulässigen Sponsoringpraxis zu informieren. Gleichzeitig verfolgen die Industrieverbände mit der Verhaltensempfehlung das Ziel, Chancengleichheit für die im Wettbewerb stehenden Unternehmen zu erreichen.

Kodex “Medizinprodukte”

1997 hat der Bundesverband Medizintechnologie e.V. (BVMed) gemeinsam mit den Spitzenverbänden der Krankenkassen den Kodex “Medizinprodukte” veröffentlicht. Der Kodex “Medizinprodukte” konzentriert sich auf Verhaltensempfehlungen im Bereich Forschung und Entwicklung, Drittmittelkonten, Fortschritt und Weiterbildung, Spenden, Geschenke und Beraterverträge, soweit die Kooperation mit medizinischen Einrichtungen und den dort beschäftigten Mitarbeitern betroffen ist. Es werden fünf zentrale Grundsätze quasi vor die Klammer gestellt, deren Einhaltung Voraussetzung für eine rechtmäßige Sponsoringpraxis sind:

- Trennungsprinzip: Es sollen keine entgeltlichen oder unentgeltlichen Leistungen an medizinische Einrichtungen oder an dort beschäftigte Mitarbeiter gewährt werden, die in Abhängigkeit von Umsatzgeschäften mit der medizinischen Einrichtung erfolgen.
- Transparenzprinzip: Alle Zuwendungen, die einer medizinischen Einrichtung oder deren Mitarbeitern gewährt werden, sollen gegenüber dem Dienstherrn bzw. Arbeitgeber offengelegt und damit transparent gemacht werden.
- Genehmigungsprinzip: Sofern Zuwendungen an einen Beschäftigten einer medizinischen Einrichtung gewährt werden, bedarf dies der vorherigen schriftlichen Einwilligung des Dienstherrn bzw. seiner Verwaltungsleitung.
- Äquivalenzprinzip: Im Rahmen der Zusammenarbeit zwischen der Industrie und einer medizinischen Einrichtung müssen Leistungen und Gegenleistungen in einem angemessenen Verhältnis stehen.

contained in the code are general in nature and can be applied to all companies in the healthcare industry.

AKG Code

The *Arzneimittel und Kooperation im Gesundheitswesen e.V.* ("AKG" — the registered association "Drugs and Cooperation in the Healthcare Sector") issued a code intended to prevent unfair competition in connection with the marketing of drugs. The AKG Code (in the current version dated 1 April 2009) closely follows the requirements of the HWG and also contains a few rules concerning the practice of providing benefits. The AKG Code applies when a company carries out product-related advertising for a prescription drug and when the advertising is directed to medical professionals.

In addition, general rules for collaborating with healthcare professionals ("HCPs") are determined. It is specifically set down in sec. 17 that pharmaceutical companies may only pay fees to physicians if a written agreement on the performance to be rendered by the physician is first executed, and the performance and consideration stand in reasonable relationship to one another. It further provides recommendations for conduct when carrying out informational events.

The organization, conduct and/or support of educational seminars outside of the EEA and outside of Switzerland or the coverage of costs for participants is only permissible if the majority of the participants come from a country other than that where the member company has its headquarters or if the necessary resources or specialized knowledge are available at the event venue, and in view of this, there are appropriate logistical reasons for choosing a venue in a different country.

In addition, the AKG Code stipulates that the principles of transparency and equivalence should be applied. The AKG Code is not, however, generally applicable, but only legally binding for the members of AKG.

Common Standpoint of the Associations

In 2000, comprehensive guidelines were drafted and adopted by leading hospital associations and physicians as well as the medical technology and pharmaceutical industries. These provide valuable orientation, in a simple and easily understandable manner, for the cooperation between industry and medical facilities such as clinics and their employees. The guidelines are known as the "common standpoint" of the associations and give information applicable to all associations concerning cooperation in the field of clinical

- Dokumentationsprinzip: Sofern von der medizinischen Einrichtung oder den dort beschäftigten Mitarbeitern Leistungen erbracht werden, müssen diese dokumentiert sein.

Der Kodex "Medizinprodukte" richtet sich zwar von seiner Genese her an Unternehmen und medizinische Einrichtungen sowie deren Mitarbeiter, die mit Entwicklung, Vertrieb und Anwendung von Medizinprodukten befasst sind. Die darin enthaltenen Regelungen sind jedoch allgemeiner Natur und können unproblematisch auf alle Unternehmen der Gesundheitsindustrie übertragen werden.

AKG-Kodex

Der Arzneimittel und Kooperation im Gesundheitswesen e.V. (AKG) hat einen Kodex herausgegeben, mit dem unlauteren Wettbewerb in Zusammenhang mit der Vermarktung von Arzneimitteln entgegengewirkt werden soll. Der AKG-Kodex (Stand vom 21. April 2009) lehnt sich eng an die Vorgaben des HWG an und enthält auch einige Regelungen, die die Zuwendungspraxis betreffen. Der AKG-Kodex findet Anwendung, wenn ein Unternehmen produktbezogene Werbung für ein verschreibungspflichtiges Arzneimittel betreibt und die Werbung gegenüber den medizinischen Fachkreisen erfolgt. Außerdem werden allgemeine Regeln der Zusammenarbeit mit Angehörigen der Fachkreise festgelegt. Namentlich in § 17 ist normiert, dass pharmazeutische Unternehmen Honorare an Ärzte nur zahlen sollen, wenn zuvor eine schriftliche Vereinbarung über die vom Arzt zu erbringenden Leistungen geschlossen wurde und außerdem Leistungen und Gegenleistungen in einem angemessenen Verhältnis stehen. Ferner werden in Verhaltensempfehlungen für die Durchführung von Informationsveranstaltungen gegeben. Die Organisation, Durchführung und/oder Unterstützung von Fortbildungsveranstaltungen außerhalb des EWR und der Schweiz oder die Übernahme von Kosten für die Teilnehmer ist nur zulässig, wenn die Mehrzahl der Teilnehmer aus einem anderen Land als dem kommt, in dem das Mitgliedsunternehmen seinen Sitz hat oder an dem Veranstaltungsort notwendige Ressourcen oder Fachkenntnisse zur Verfügung stehen und angesichts dessen jeweils logistische Gründe für die Wahl des Veranstaltungsortes in einem anderen Land sprechen. Der AKG-Kodex macht außerdem deutlich, dass das Transparenz- und Äquivalenzprinzip gelten sollten. Der AKG-Kodex ist allerdings nicht generell gültig, sondern nur für die Mitglieder des AKG.

research and support in advanced and continuing studies for physicians. The common standpoint uses the Medical Devices Code as its base, and limits its own area of application to the relationship between the industry and medical facilities and employees working there. Its main purpose is to avoid the risk of corruption during cooperation by setting down detailed requirements. The common standpoint does not address the issue of how the industry should behave in the area of sponsoring that relates to physicians in private practice.

FSA Code

The *Verband Forschender Arzneimittelhersteller e.V.* ("VfA" — the German Association of Research-Based Pharmaceutical Companies) founded the FSA which, in turn, published and bound its members to very specific conduct recommendations ("FSA Code for HCPs") for the cooperation between the pharmaceutical industry and physicians. The FSA Code for HCPs is based on the Medical Devices Code and the common standpoint, and gives specific advice intended to make it easier to comply with the existing legal parameters as well as promote good-faith cooperation. In deviation from the Medical Devices Code and the common standpoint, the FSA Code for HCPs applies to the relationship between the industry and medical facilities and their employees, as well as with physicians in private practice. The scope of application of the FSA Code, however, is expressly limited to product-related advertising for prescription drugs for human use which is addressed to a professional audience. Accordingly, the FSA Code for HCPs does not cover OTC drugs.

Regarding the field of cooperation agreed to under contract, the FSA Code for HCPs demands the execution of a written contract in which performance and consideration are clearly stated. The remuneration to be paid by the industry may not exceed what is reasonable; the scale of fees for physicians set down in statute is to be applied. At the same time, the FSA Code for HCPs allows for reasonable hourly rates to be used as the basis for calculating the remuneration for medical services. The FSA Code for HCPs clearly condemns the execution of sham contracts, which are contracts for the performance of services that are of no interest to the customer but which are executed merely to create a contractual basis for paying a fee.

The FSA Code for HCPs also deals with monitoring studies. When studies are conducted, compliance with the recommendations and guidelines published by *Bundesinstitut für Arzneimittel und Medizinprodukte* (the Federal Institute for Drugs and Medical Products) is required. Among other things, the code stipulates that a company must justify and document the planned number of patients and the amount of remuneration per observation

“Gemeinsamer Standpunkt” der Verbände

Im Jahr 2000 ist zwischen den führenden Verbänden der Krankenhäuser und Ärzte sowie der medizin-technologischen und pharmazeutischen Industrie ein sehr umfangreicher Leitfaden erarbeitet und verabschiedet worden, der wertvolle Orientierungshilfen in einfacher und leicht verständlicher Weise für die Zusammenarbeit von Industrie auf der einen und medizinischen Einrichtungen wie Kliniken und deren Mitarbeitern auf der anderen Seite gibt. Dieser Leitfaden ist als “gemeinsamer Standpunkt” der Verbände bekannt und gibt verbandsübergreifende Hinweise für die Zusammenarbeit auf dem Gebiet der klinischen Forschung und bei der Unterstützung von Fort- und Weiterbildung von Ärzten. Der gemeinsame Standpunkt knüpft an den Kodex Medizinprodukte an und beschränkt seinen Anwendungsbereich auf das Verhältnis zwischen Industrie und medizinischen Einrichtungen sowie den dort beschäftigten Mitarbeitern. Es geht insbesondere darum, durch detaillierte Vorgaben korruptionsrechtliche Risiken bei der Zusammenarbeit zu vermeiden. Zur Frage, wie sich die Industrie gegenüber niedergelassenen Ärzten im Bereich des Sponsoring verhalten soll, geht der gemeinsame Standpunkt nicht ein.

FSA-Kodex

Der Verband Forschender Arzneimittelhersteller e. V. (VfA) hat die Gründung des FSA initiiert, der seinerseits sehr konkrete Verhaltungsempfehlungen für die Zusammenarbeit der pharmazeutischen Industrie und Ärzten herausgegeben und für seine Mitglieder verbindlich gemacht hat (FSA-Kodex Fachkreise). Der FSA-Kodex Fachkreise knüpft an den Kodex Medizinprodukte sowie den gemeinsamen Standpunkt an und gibt konkrete Hinweise, die die Einhaltung der bestehenden rechtlichen Rahmenbedingungen erleichtern und eine lautere Zusammenarbeit fördern sollen. In Abweichung vom Kodex Medizinprodukte und dem gemeinsamen Standpunkt beansprucht der FSA-Kodex Fachkreise jedoch nicht nur Geltung für die Beziehung zwischen Industrie und medizinischen Einrichtungen sowie deren Mitarbeitern, sondern fordert Einhaltung der im FSA-Kodex Fachkreise enthaltenen Regelungen auch für das Verhältnis zum niedergelassenen Arzt. Allerdings ist der Anwendungsbereich des FSA-Kodex Fachkreise ausdrücklich auf produktbezogene Werbung von verschreibungspflichtigen Humanarzneimitteln beschränkt, die gegenüber den Fachkreisen erfolgt. Entsprechend sind nicht verschreibungspflichtige Arzneimitteln von den Regelungen des FSA-Kodex Fachkreise nicht erfasst.

sheet. Under no circumstance should the fee for monitoring studies be calculated so that the fee is an incentive to prescribe the drug to be monitored.

Invitations to job-related advanced learning seminars are also regulated in the FSA Code for HCPs. Under the code, it is generally permissible to invite physicians to attend a company's in-house job-related advanced learning seminars, and to assume responsibility for the payment of reasonable travel costs and the necessary costs of accommodation. Entertainment costs, however, must be borne by the attendee himself. The attendance of the participants during the program of the seminar should be documented. A *bona fide* subject-matter-related aspect will not be acknowledged if the location of the seminar has been selected primarily because of its recreational significance (e.g., ski or other resort areas). The financial support of offsite advanced learning seminars should be permitted within reasonable boundaries, but the entertainment programs should not be supported by donations. In addition, companies must work towards having their support disclosed by the outside organizer both in the announcement of the event and during its execution. But under no circumstances may the costs relating to people accompanying participants to in-house or offsite events be assumed by medical product companies.

As far as gifts are concerned, the FSA Code for HCPs contains simply a reference to the limits set down in sec. 7 HWG with respect to product-related advertising. As regards non-product-related advertising (image advertising), the amended FSA Code for HCPs as published in 2006 stipulates that pharmaceutical companies may only provide gifts on special occasions (e.g., for the opening of a practice or anniversaries). The FSA does not deem Christmas a special occasion within the meaning of the aforementioned provision.

Entertainment (to a reasonable and socially acceptable extent) is permissible under the FSA Code for HCPs during advanced learning seminars and conferences. The same applies to working dinners. This refers to dining invitations issued by employees of a pharmaceutical company to a physician in order to discuss a joint project. However, the reason for the working dinner must be documented by the company.

In addition to the FSA Code for HCPs, the FSA published guidelines of the Board of the FSA, in which certain terms such as "insignificant remuneration" or "reasonable travel costs" or "extravagant" are described. The code also sets price limits. For example, hospitality is considered

Was den Bereich der vertraglichen Zusammenarbeit anbetrifft, verlangt der FSA-Kodex Fachkreise den Abschluss eines schriftlichen Vertrages, in dem Leistungen und Gegenleistungen eindeutig festgelegt werden. Die von der Industrie zu zahlende Vergütung darf das Maß des Angemessenen nicht übersteigen, wobei als Anhaltspunkt für eine angemessene Vergütung die Gebührenordnung für Ärzte herangezogen werden soll; gleichzeitig lässt es der FSA-Kodex Fachkreise jedoch auch zu, angemessene Stundensätze zur Berechnung der Vergütung von ärztlichen Leistungen zugrunde zu legen. Eine klare Absage erteilt der FSA-Kodex Fachkreise dem Abschluss von sogenannten "Scheinverträgen"; hierbei handelt es sich um Verträge über die Durchführung von Leistungen, die für den Auftraggeber nicht von Interesse sind, sondern nur deshalb abgeschlossen werden, um eine vertragliche Basis für die Gewährung eines Honorars zu schaffen.

Der FSA-Kodex Fachkreise geht des Weiteren auf sogenannte Anwendungsbeobachtungen ein. Bei deren Durchführung wird die Einhaltung der vom Bundesinstitut für Arzneimittel und Medizinprodukte veröffentlichten Empfehlungen und Leitlinien verlangt. Der Kodex legt zusätzlich zu den gesetzlichen Anforderungen fest, dass ein Unternehmen die geplante Anzahl der Patienten sowie die Höhe der Vergütung pro Beobachtungsbogen begründen und dokumentieren muss. Keinesfalls darf die Vergütung einer Anwendungsbeobachtung so bemessen sein, dass durch die Vergütung ein Anreiz zur Verordnung des zu beobachtenden Arzneimittels entsteht.

Auch die Einladung zu berufsbezogenen wissenschaftlichen Fortbildungsveranstaltungen ist im FSA-Kodex Fachkreise geregelt. Hiernach ist es grundsätzlich zulässig, Ärzte zu eigenen (internen) berufsbezogenen Fortbildungsveranstaltungen einzuladen und auch angemessene Reise- und notwendige Übernachtungskosten zu übernehmen. Allerdings müssen Kosten für die Unterhaltung vom Teilnehmer selbst übernommen werden. Die Anwesenheit der Teilnehmer für das durchgeführte Programm der Veranstaltung soll dokumentiert werden. Tagungsorte sind nur aufgrund von sachlichen Gesichtspunkten auszuwählen. Ein solcher sachlicher Gesichtspunkt ist nicht gegeben, wenn der Tagungsort lediglich in Hinblick auf seinen Freizeitwert ausgewählt wird (Skigebiet, Urlaubsorte). Auch die finanzielle Unterstützung von externen Fortbildungsveranstaltungen soll in angemessenem Umfang zulässig sein. Allerdings dürfen dabei Unterhaltungsprogramme nicht finanziell durch Spenden unterstützt werden. Darüber hinaus müssen Unternehmen darauf hinwirken, dass ihre Unterstützung sowohl bei der Ankündigung als auch bei der Durchführung

"reasonable" when the amount of EUR60 is not exceeded. For events outside of Germany, the price level may be higher. At the same time, the various decisions of the FSA Court of Arbitration regarding individual measures are to be considered.

Furthermore, the FSA Code for HCPs makes the recommendations contained in the common standpoint of the associations binding on member companies. A decision has been taken to establish a procedure whereby sanctions may be levied against companies that violate the FSA Code for HCPs. These sanctions range from a warning, the delivery of an undertaking coupled with the promise to pay a penalty in the event of a breach, the levying of fines, and the publication of the violation on the internet. The parties entitled to apply for these sanctions are member companies that have submitted themselves to the FSA sanction regime, and other third parties.

Finally, the FSA issued a code for the collaboration with patient organizations ("FSA Code for Patient Organizations"). This code outlines that members of the FSA must not compromise the neutrality and independence of patient organizations. Moreover, the FSA Code for Patient Organizations defines publication obligations.

Master Code of Professional Standards for Medical Doctors

Whereas the provisions of HWG and the abovementioned codes primarily address donors, the fundamental prohibition of benefits for recipients is expressed in the Master Code of Professional Standards for German Medical Doctors (*Musterberufsordnung* — "MBO"). The major points of the MBO have been adopted with identical wording in the charters of the state medical associations. The professional duties contained in the codes of professional standards apply to all licensed physicians, and thus also apply to hospital physicians.

Under sec. 31 (1) MBO, a physician is not allowed to demand or accept economic benefits from a manufacturer or seller for prescribing drugs, remedies and health aids. Consequently, all benefits granted to a physician contingent on his prescription of drugs and the like is professionally unethical. Without exception, the acceptance by a physician of sales commissions or gifts from the industry which are dependent on sales transactions is prohibited.

Physicians are not prevented, however, from claiming an appropriate fee for the services they perform. The demand and acceptance of remuneration for

der Veranstaltung von dem externen Veranstalter offengelegt wird. Keinesfalls dürfen bei internen oder externen Fortbildungsveranstaltungen Kosten für Begleitpersonen übernommen werden. Was die Gewährung von Geschenken anbetrifft, belässt es der FSA-Kodex Fachkreise für den Bereich der produktbezogenen Werbung auf den Verweis der Grenzen in § 7 HWG. Für den Bereich der nicht produktbezogenen Werbung (Imagewerbung) wurde in der im Jahr 2006 veröffentlichten Novelle des FSA-Kodex Fachkreise festgelegt, dass Pharmaunternehmen Geschenke nur zu besonderen Anlässen (z. B. Praxis- Eröffnung, Jubiläen) gewähren dürfen. Nach Auffassung des FSA stellt z. B. Weihnachten keinen besonderen Anlass im Sinne der vorgenannten Regelung dar.

Bewirtung im Rahmen von wissenschaftlichen Fortbildungsveranstaltungen und Kongressen sind nach dem FSA-Kodex Fachkreise in einem angemessenen und sozial adäquaten Umfang zulässig. Das gleiche gilt für Arbeitsessen. Hierunter sind Essenseinladungen zu verstehen, bei denen der Mitarbeiter eines Pharmaunternehmens einen Arzt einlädt, um über ein gemeinsames Projekt zu sprechen. Allerdings ist der Anlass des Arbeitsessens vom Unternehmen zu dokumentieren. Zusätzlich zu dem FSA-Kodex Fachkreise hat der FSA Leitlinien des Vorstandes des FSA veröffentlicht, in denen bestimmte Begriffe sowie etwa „geringfügige Vergütung" oder „angemessene Reisekosten" oder „extravagant" erläutert werden. Es werden auch Preisgrenzen festgesetzt. Z.B. wird eine Bewirtung als „angemessen" angesehen, wenn der Betrag von EUR 60,00 nicht überschritten wird. Bei Auslandsveranstaltungen kann das Preisniveau gegebenenfalls sogar höher liegen. Daneben sind die vielfältigen Entscheidungen des FSA Schiedsgericht zu Einzelmaßnahmen zu beachten.

Ferner macht der FSA-Kodex Fachkreise die im gemeinsamen Standpunkt der Verbände enthaltenen Empfehlungen für die Mitgliedsunternehmen verbindlich. Es ist des Weiteren beschlossen worden, ein Verfahren zu etablieren, auf deren Grundlage gegen Unternehmen Sanktionen verhängt werden können, die den FSA-Kodex Fachkreise verletzen. Die Sanktionen reichen von Verwarnung, Abgabe einer strafbewehrten Unterlassungserklärung, Verhängung von Geldbußen bis zur Veröffentlichung der Verletzungshandlung im internet. Beschwerdeführer für die Verhängung derartiger Sanktionen können sowohl Mitgliedsunternehmen sein, die sich dem Sanktionsregime des FSA unterworfen haben, als auch sonstige Dritte. Schließlich hat der FSA einen Kodex zum Umgang mit Patientenorganisationen herausgegeben (FSA Kodex Patientenorganisationen). Aus diesem Kodex ergibt sich, dass die Mitglieder des FSA die Neutralität und Unabhängigkeit von Patientenorganisationen

conducting a clinical trial or monitoring study or even the production of expert reports is generally permitted.

Sec. 33 MBO puts a limit on the acceptance of benefits in this area. To the extent that physicians perform services for the manufacture of drugs, remedies, health aids or medical equipment, the fees they are to receive must be appropriate for the services they perform, and the fees for the physician's performance must be proportionate to the services provided. The question of what is "reasonable" must be judged on a case-by-case basis. One measure for a reasonable fee is the fee customary to the industry; the statutory fee schedule for physicians (*Gebührenordnung für Ärzte* — "GOÄ") can be used as a guideline. Pursuant to sec. 33 (2) MBO, the contracts regarding the cooperation with physicians are to be concluded in writing and shall be submitted to the physicians' associations.

A violation of the regulations of professional law can result in disciplinary measures under professional ethics law. The rules in the MBO are not binding on the industry, but a suit can be brought against a company under sec. 3 UWG if it is proved that that company deliberately exploits the unethical conduct of a physician.

Social Law Aspects

Sec. 128 *Sozialgesetzbuch V* (Volume V of the Social Insurance Code — "SGB V") sets out a special provision for the cooperation between service providers and contracted physicians of patients who are members of a public health insurance. Subsection 2 of this provision stipulates that service providers may not grant physicians in private practice and/or hospital physicians and/or other employees of medical institutions, any economic benefits in connection with the prescription of pharmaceuticals. This restricts, *inter alia*, the provision of free or discounted equipment or material and the conduct of training activities, the lease of premises or personnel or the sharing of related costs. Pursuant to subsection 6 of this provision, these rules also apply between pharmaceutical companies, pharmacies, pharmaceutical wholesalers and other healthcare providers, and apply to contracted physicians, hospital physicians and hospital owners.

Liability Under Criminal and Civil Law

Since the "heart valve scandal," cooperation between the medical industry and physicians has become a matter for criminal law. In recent years, German investigators have accused a number of pharmaceutical and medical technology companies of corruption and have instituted criminal proceedings

nicht beeinträchtigen dürfen. Außerdem sind in dem FSA-Kodex Patientenorganisationen Publikationspflichten festgelegt.

Musterberufsordnung für Ärzte

Während sich die Vorschriften des HWG und die vorgenannten Kodices sich vorrangig an die Geberseite richten, hat das grundsätzliche Zuwendungsverbot für die Empfängerseite seinen Niederschlag in der Musterberufsordnung für die deutschen Ärzte ("MBO") gefunden. Die MBO ist in den wesentlichen Punkten gleichlautend von den Landesärztekammern als Satzung beschlossen worden. Die in den Berufsordnungen enthaltenen Berufspflichten gelten für alle approbierten Ärzte, demnach auch für Krankenhausärzte.

Gemäß § 31 Abs. 1 MBO ist es einem Arzt nicht gestattet, für die Verordnung von Arznei-, Heil- und Hilfsmitteln von dem Hersteller oder Händler wirtschaftliche Vergünstigungen zu fordern oder anzunehmen. Folglich sind alle Zuwendungen, die einem Arzt in Abhängigkeit von seiner Verordnungstätigkeit gewährt werden, berufsrechtlich unzulässig. Die Vereinnahmung von umsatzabhängigen Provisionen eines Arztes von der Industrie oder die Annahme von Geschenken in Abhängigkeit von Umsatzgeschäften sind ausnahmslos verboten. Ärzten ist es indes nicht verwehrt, für die von ihnen erbrachten Dienstleistungen ein der Leistung entsprechendes Honorar zu beanspruchen. Die Forderung und Entgegennahme einer Vergütung für die Durchführung einer klinischen Prüfung oder Anwendungsbeobachtung oder auch die Erstellung von Gutachten ist grundsätzlich zulässig.

§ 33 MBO setzt der Annahme von Zuwendungen in diesem Bereich jedoch Grenzen. Soweit Ärzte Leistungen für die Herstellung von Arznei-, Heil- und Hilfsmitteln oder medizinisch-technischen Geräten erbringen, muss die hierfür bestimmte Vergütung der erbrachten Leistung entsprechen. Die Vergütung des Arztes muss im Verhältnis zur erbrachten Leistung angemessen sein. Was angemessen ist, muss im Einzelfall in Abhängigkeit von der jeweils zu erbringenden Leistungen beurteilt werden. Anhaltspunkt für ein angemessenes Honorar ist das in der Branche übliche Honorar; als Orientierungsmaßstab kann die Gebührenordnung für Ärzte ("GOÄ") herangezogen werden. Die Verträge über die Zusammenarbeit mit Ärzten sind gemäß § 33 Satz 2 MBO schriftlich abzuschließen und sollen der Ärztekammer vorgelegt werden.

against hundreds of physicians for being the recipients of benefits granted to them by the industry. The bases for criminal prosecution in the types of cooperation which were normal in the past are generally the bribery laws of sec. 331 et seq and sec. 299 of the German Penal Code ("StGB") which penalize the grant or acceptance of benefits in connection with the sale of medical products. In the meantime, case law clearly defining the limits of permissible sponsoring has been developed. With respect to donors, the legal situation can be summarized as follows.

Grant of Benefits Under Section 333 German Penal Code ("StGB")

Under sec. 333 StGB, it is punishable for a person to offer, promise or grant a benefit to an official for himself or for a third party for exercising his duties (granting of benefits). An "official" under sec. 11 (2) no. 2 (a) StGB is, first of all, a civil servant. Physicians may be civil servants if they are engaged as professors at a university or are there as civil servants for a certain period in their capacity as senior physicians. Secondly, an official can be anyone who performs the duties of public administration anywhere else, where this also includes the field of public welfare.

Hospitals operated by a public law body (public hospitals) are facilities belonging to the public welfare. The organizational form of a hospital is not the determining factor for it to qualify as a public hospital. Both hospitals run by a public law body as publicly owned enterprises and hospitals organized under private law (e.g., as a company with limited liability) perform duties of public administration such that the employees working there can be considered public officials. To the extent the employees of these hospitals are able to have a functional influence on purchasing decisions, it must be assumed that they are classified as officials. The group of individuals subject to this ultimately includes, for example, head physicians, senior physicians, junior physicians, nursing heads, nurses, pharmacists, administrative heads and purchase managers.

Not included in the group of officials are employees in hospitals run solely by private owners and employees in church-run facilities. The provisions of sec. 333 et seq German Penal Code do not apply to the employees of these facilities, but the criminal statute of sec. 299 StGB (Corruption and Corruption in Business Transactions) does.

As far as private practice is concerned, bribery laws will not apply at all because of the lack of any official status. In the past, higher courts qualified physicians in private practice accepting benefits in the context of the prescription of pharmaceuticals as representatives of public health insurances

Eine Verletzung von Vorschriften des Berufsrechts kann für den Arzt ein berufsrechtliches Disziplinarverfahren nach sich ziehen. Für die Industrie sind die Regelungen der MBO nicht verbindlich. Allerdings kann gegen ein Unternehmen auf der Grundlage von § 3 UWG vorgegangen werden, wenn nachweisbar ist, dass das betreffende Unternehmen im Wettbewerb zielgerichtet berufsstandsvergessenes Verhalten eines Arztes ausnutzt.

Sozialrechtliche Aspekte

In § 128 Sozialgesetzbuch V (SGB V) findet sich eine spezialgesetzliche Regelung für die Zusammenarbeit zwischen Leistungserbringern und Vertragsärzten von gesetzlich versicherten Patienten. In Absatz 2 ist festgelegt, dass Leistungserbringer, niedergelassene n Ärzten, Krankenhausärzten und anderen Mitarbeitern von medizinischen Einrichtungen nicht irgendwelche wirtschaftlichen Vorteile in Zusammenhang mit der Verordnung von medizinischen Produkten gewähren dürfen. Hierzu zählt auch die unentgeltliche oder verbilligte Überlassung von Geräten oder Materialien sowie auch die Durchführung von Schulungsmaßnahmen, die Bestellung von Räumlichkeiten oder Personal oder die Beteiligung an den Kosten hierfür. Gemäß Absatz 6 dieser Vorschrift gelten die Regelungen auch zwischen pharmazeutischen Unternehmern, Apotheken, pharmazeutischen Großhändlern und sonstigen Anbietern von Gesundheitsleistungen als auch jeweils gegenüber Vertragsärzten, Ärzten in Krankenhäusern und Krankenhausträgern.

Strafrechtliche Aspekte

Seit dem sogenannten “Herzklappenskandal” ist die Zusammenarbeit zwischen medizinischer Industrie und Ärzten strafrechtlich problematisiert worden. Die deutschen Ermittlungsbehörden haben in den letzten Jahren einer Vielzahl von pharmazeutischen und medizin-technischen Unternehmen korruptives Verhalten vorgeworfen und gegen viele hundert Ärzte als Empfänger von Vorteilen, die ihnen die Industrie gewährt hat, Strafverfahren eingeleitet. Anknüpfungspunkt für die strafrechtliche Verfolgung von in der Vergangenheit üblichen Formen der Zusammenarbeit sind regelmäßig die Korruptionstatbestände der §§ 331 ff. Und 299 Strafgesetzbuch (“StGB”), die unter bestimmten Voraussetzungen die Gewährung bzw. die Annahme von Vorteilen in Zusammenhang mit dem Vertrieb von medizinischen Produkten unter Strafe stellen. Mittlerweile liegt zu diesem Problemkomplex auch höchstrichterliche Rechtsprechung vor, die die Grenzen eines zulässigen

and, therefore, condemned them of corruption in accordance with sec. 299 StGB (*OLG Braunschweig 1 ZS 2010, 584*). In a recent decision, the Supreme Court (*Bundesgerichtshof* — "BGH") stated, however, that physicians in private practice do not perform duties of public administration and are, thus, not representatives of public health insurances (3 StR 458/10 und 5 StR 115/11). Consequently, physicians who are contracted by public health insurances (*Kassenärzte*) cannot be convicted of corruption if they accept donations in connection with the use of drugs and medical devices. This certainly holds true for self-employed physicians who are contracted by public health insurances. For physicians in private practice having employee status, prosecution under criminal law for corruption is possible under sec. 299 StGB.

The application of sec. 333 StGB requires that an official is offered, promised or given a benefit. A benefit is understood to be any consideration to which the official does not have a legal claim and which improves the official's position in any way, whereby the amount of the benefit is immaterial. Consequently, even benefits of little value can still fulfill the substantive requirements of a crime. The benefits may be tangible or intangible. This means that the provision of work materials such as books or computers, funding to participate in a conference, and even the provision of financing for research projects, are benefits within the meaning of sec. 333 (1) StGB. Although the benefits satisfying the substantive requirements of sec. 333 (1) can be intangible benefits according to the case law of the Federal Court of Justice, this is understood in this context to mean that the reputation of a physician will be enhanced or his career opportunities will improve because of the support of a company. The Federal Court of Justice has thus considerably reduced the significance of the intangible benefit as grounds for the accusation of corruption repeatedly put forward by public prosecutors and some of the lower courts, by demanding that this intangible benefit be capable of being tangibly measured in order to be used against the official.

Furthermore, it is to be noted in this context that benefits will fulfill substantive requirements not only if they are granted to the official personally, but also if they accrue to a third party on the basis of an agreement entered into between the official and the industry. This type of situation can exist if the industry grants a benefit to a family member of the official for favorable treatment by the official, or if an association with which the official is closely associated is benefited. A benefit is also to be attributed to an official if a company provides material means to an association of physicians upon the official's mediation by, for instance, financially supporting the conduct of a seminar.

Sponsoring deutlich werden lässt. Für die Geberseite lässt sich die Rechtslage wie folgt skizzieren:

Vorteilsgewährung gemäß § 333 StGB

Gemäß § 333 StGB macht sich strafbar, wer einem Amtsträger für die Dienstausübung einen Vorteil für diesen oder einen Dritten anbietet, verspricht oder gewährt (Vorteilsgewährung). Zu den Amtsträgern zählen gemäß § 11 Abs. 1 Nr. 2 a) StGB zum einen Beamte. Ärzte können Beamtenstatus haben, wenn sie etwa an einer Hochschule als Professoren tätig sind oder dort als Oberarzt als Beamter auf Zeit tätig werden. Zum anderen gehört zum Kreis der Amtsträger jeder, der bei einer sonstigen Stelle Aufgaben der öffentlichen Verwaltung wahrnimmt, wozu auch der Bereich der öffentlichen Daseinsvorsorge zählt. Krankenhäuser, die von einem öffentlich-rechtlichen Träger betrieben werden (öffentliches Krankenhaus), sind Einrichtungen der öffentlichen Daseinsvorsorge.

Auf die Organisationsform kommt es für die Qualifizierung als öffentliches Krankenhaus nicht an. Sowohl Krankenhäuser, die von einem öffentlich-rechtlichen Träger im Regiebetrieb geführt werden, als auch Krankenhäuser, die mit einer Organisationsform des Privatrechts (z.B. einer GmbH) betrieben werden, nehmen Aufgaben der öffentlichen Verwaltung wahr, so dass die dort beschäftigten Mitarbeiter als Amtsträger angesehen werden können. Soweit Mitarbeiter dieser Krankenhäuser funktionellen Einfluss auf Beschaffungsentscheidungen nehmen können, muss deshalb davon ausgegangen werden, dass sie als Amtsträger eingeordnet werden. Der betroffene Personenkreis erstreckt sich im Ergebnis auf Chefärzte, Oberärzte, Assistenzärzte, Pflegeleitung, Krankenschwestern, Apotheker, Verwaltungsleitung, Einkäufer.

Nicht zu den Amtsträgern zählen Mitarbeiter von Krankenhäusern, die in rein privater Trägerschaft geführt werden oder auch Mitarbeiter von kirchlich geführten Einrichtungen. Auf Mitarbeiter dieser Einrichtungen sind die Vorschriften der §§ 333 ff. StGB nicht anwendbar; allerdings ist für Mitarbeiter solcher Häuser die Strafvorschrift des § 299 StGB (Bestechlichkeit und Bestechung im geschäftlichen Verkehr) einschlägig.

Was den niedergelassenen Bereich anbetrifft, scheidet für die Praxisinhaber eine Anwendung der Korruptionsvorschriften von vornherein mangels Vorliegen einer Amtsträgereigenschaft aus. In der Vergangenheit hatten Obergerichte niedergelassene Ärzte bei der Annahme von Vorteilen in

Finally, the fulfillment of the substantive requirements of an unlawful grant of a benefit within the meaning of sec. 331 (1) StGB requires that the official receives a benefit for having performed the service. This means that an "agreement to break the law" must be entered into between the donor and the recipient. No particularly strict requirements are set for the assumption of an "agreement to break the law." It will suffice that each of the parties involved agrees that the granted benefit is related to the work activities of the recipient. Therefore, this rules out cases in which the official is granted benefits and there is no connection whatsoever with the official's work activities.

If the substantive requirements for the grant of a benefit pursuant to sec. 331 (1) StGB exist, the provision of the benefit is not punishable if the employer of the official has given his authorization for the acceptance of the benefit. The authorization must be specific. It generally will not suffice that the official has been granted "side-job permission." Consequently, companies are advised to only provide benefits to members of medical facilities if it has been confirmed to them by the appropriate employer (head of the administration) that he or she has authorized the acceptance of benefits by the employee. The authorization should be in writing so that it may be presented to investigators in the event of a criminal investigation, which can never be ruled out.

Bribery Under Section 334 StGB

Whereas the substantive requirements of the grant of a benefit under sec. 333 StGB require that a benefit has been granted for performing an employment duty, the acceptance of a benefit qualifies as bribery within the meaning of sec. 334 StGB if the benefit is consideration for a service, the performance of which represents a dereliction of duty. In the context of purchasing medical products, the duties of an official means that he or she must select these products upon compliance with objective criteria and that the decision to make a purchase may not be dependent on their receiving benefits for themselves. Thus, if a sales executive attempts to induce a physician to buy a product by offering the official a benefit (e.g., by promising a donation or offering a consulting contract), the sales executive is guilty of bribery with intent. The provision of a benefit which is considered to be bribery cannot be authorized.

An action in the line of duty does not become illegal within the meaning of sec. 334 StGB when an official only makes an arbitrary decision and accepts a disadvantageous commercial offer due to the granted benefit; but it will be illegal if the official allows himself to be influenced by the benefit within the scope of discretionary decision-making to which he is entitled. This is

Zusammenhang mit der Verordnung von Medikamenten für gesetzlich versicherte Patienten als Beauftragte der Krankenkassen eingeordnet und deshalb die niedergelassenen Ärzte wegen Korruption gemäß § 299 StGB verurteilt (OLG Braunschweig 1 ZS 2010, 584). In einer neuen Entscheidung des Bundesgerichtshofs (3 StR 458/10 und 5 StR 115/11) hat der Bundesgerichtshof jedoch festgestellt, dass niedergelassene Kassenärzte keine Aufgaben der öffentlichen Verwaltung wahrnehmen und sie auch keine Beauftragten der Krankenkassen sind. Entsprechend können Kassenärzte nicht wegen Korruption verurteilt werden, wenn sie Zuwendungen in Zusammenhang mit der Anwendung von Arzneimitteln und Medizinprodukten annehmen. Dies gilt jedenfalls für die selbständig tätigen Kassenärzte. Für angestellte Ärzte einer niedergelassenen Praxis kann aus korruptionsrechtlichen Gesichtspunkten eine strafrechtliche Verfolgung gemäß § 299 StGB in Betracht kommen.

Die Anwendbarkeit des § 333 StGB setzt voraus, dass einem Amtsträger ein Vorteil angeboten, versprochen oder gewährt wird. Unter einem Vorteil ist jede Leistung zu verstehen, auf die der Amtsträger keinen gesetzlichen Anspruch hat und die ihn irgendwie besser stellt. Dabei ist die Höhe der Zuwendung unbeachtlich. Es sind somit auch Vorteile von geringem Wert durchaus tatbestandsmäßig. Die Vorteile können materieller oder immaterieller Art sein. Das heißt, die Überlassung von Sachmitteln wie Bücher, Computer oder die Unterstützung zur Teilnahme an einem Kongress oder auch die zur Verfügungsstellung von Finanzmitteln für Forschungsprojekte sind Vorteile im Sinne des § 333 Abs. 1 StGB. Zwar können nach höchstrichterlicher Rechtsprechung tatbestandsmäßige Vorteile auch immaterieller Art sein. Hierunter wird im fraglichen Kontext verstanden, dass ein Arzt durch die Unterstützung eines Unternehmens seinen Ruf steigert oder seine Karrierechancen verbessert. Indes hat der Bundesgerichtshof die Bedeutung des von Staatsanwaltschaften und einigen Instanzgerichten immer wieder bemühten immateriellen Vorteils für den Tatvorwurf der Korruption insoweit erheblich relativiert, als er fordert, dass dieser immaterielle Vorteil konkret messbar sein muss, um ihm dem Amtsträger tatbestandlich entgegenhalten zu können.

Des Weiteren ist in diesem Zusammenhang anzumerken, dass Vorteile nicht nur dann tatbestandsmäßig sind, wenn sie dem Amtsträger selbst gewährt werden, sondern auch dann, wenn sie aufgrund einer zwischen dem Amtsträger und der Industrie getroffenen Vereinbarung einem Dritten zufließen. Eine solche Konstellation kann vorliegen, wenn die Industrie für das Wohlverhalten eines Amtsträgers etwa einem Familienmitglied des

expressly stated in sec. 334 (3) no. 2 StGB. Accordingly, dereliction of duty within the scope of a discretionary decision will exist if an official considers the granted benefit when weighing the pros and cons of a decision. The benefit does not need to be the decisive factor within the scope of the discretionary decision. It is sufficient that the official has shown that he will allow himself to be influenced by the benefit when making his decision.

Hospital physicians have a certain leeway when deciding on the purchase of medical products such that these decisions are discretionary in nature. The case law on the dereliction of duty within the scope of discretionary decision-making discussed above has meant that several courts have criminalized as bribery the acceptance by hospital physicians of invitations to go as passive attendees on conference trips. The Federal Court of Justice has clarified in its most recent decisions that the mere acceptance of a benefit cannot establish a dereliction of duty, for this would mean that any grant or acceptance of a benefit would automatically qualify as a bribe or as bribery. In order to avoid this consequence, the Federal Court of Justice demands for the assumption of an act of bribery that the benefit is, or is intended to be, consideration for an act which is, as such, a breach of duty (BGH I StR 372/01; BGH I StR 541/01). The lower courts must determine, on a case-by-case basis, the parties' motivation behind the granting and acceptance of the benefit, and which specific duty was supposed to be influenced by the benefit.

It should be noted in this context that the customary invitation of physicians to a meal is generally not prosecuted as a grant of an illegal benefit, but that these invitations are considered an indication that a web of relationships forming the basis of corrupt behavior exists between industry and officials. For this reason, it is strongly advised that reasonable standards are not exceeded when dinner invitations are extended and that the purpose of the working dinner is documented.

Corruption and Bribery in Commercial Transactions Under Section 299 StGB

Employees of a privately owned hospital do not have official status so the provisions of sec. 331 et seq StGB do not apply to them. The same is true for physicians in hospitals owned by churches and for physicians working as employees for a private practice. Corruption and bribery in these areas are covered by sec. 299 StGB instead.

Under sec. 299 (2) StGB, it is unlawful for any person to offer, promise or grant a benefit in commercial transactions, for the purposes of competition, to an employee or authorized representative of a business operation, for this

Amtsträgers einen Vorteil einräumt oder auch einen Verein begünstigt, der dem Amtsträger nahe steht. Allerdings ist einem Amtsträger ein Vorteil auch dann zuzurechnen, wenn etwa auf seine Vermittlung ein Industrieunternehmen einer medizinischen Fachgesellschaft materielle Mittel zukommen lässt, indem es etwa die Durchführung einer Veranstaltung finanziell unterstützt.

Schließlich ist es für die Tatbestandsmäßigkeit einer unzulässigen Vorteilsgewährung im Sinne des § 331 Abs. 1 StGB erforderlich, dass der Amtsträger einen Vorteil für die Dienstausübung erhält. Das heißt, es muss eine sogenannten Unrechtsvereinbarung zwischen Geber und Nehmer geschlossen werden. Für die Annahme einer Unrechtsvereinbarung werden keine besonders hohen Anforderungen gestellt. Es reicht aus, dass die jeweils beteiligten Personen darüber einig sind, dass der gewährte Vorteil in Zusammenhang mit der dienstlichen Tätigkeit des Empfängers steht. Ausgeschlossen werden also Fälle, in denen einem Amtsträger Vorteile eingeräumt werden, ohne dass irgendein Bezug zu seiner Diensttätigkeit ersichtlich ist.

Liegen die tatbestandlichen Voraussetzungen für eine Vorteilsgewährung gemäß § 331 Abs. 1 StGB vor, ist die Überlassung des Vorteils nicht strafbar, wenn der Dienstherr gemäß § 333 Abs. 3 StGB dem Amtsträger eine Genehmigung für die Annahme des Vorteils erteilt hat. Die Genehmigung muss konkret sein. Es reicht grundsätzlich nicht aus, dass dem Amtsträger von seinem Dienstherrn eine sogenannte Nebentätigkeitserlaubnis erteilt worden ist. Folglich ist Unternehmen anzuraten, Mitarbeitern von medizinischen Einrichtungen nur dann Vorteile zukommen zu lassen, wenn ihnen der entsprechende Dienstherr (Verwaltungsleitung) bestätigt, dass er die Annahme des Vorteils durch den Mitarbeiter der medizinischen Einrichtung genehmigt. Die Genehmigung sollte schriftlich vorliegen, um sie im Falle von nicht auszuschließenden Ermittlungsverfahren den Ermittlungsbehörden präsentieren zu können.

Bestechung gemäß § 334 StGB

Während der Tatbestand der Vorteilsgewährung gemäß § 333 StGB voraussetzt, dass ein Vorteil für die Dienstausübung gewährt wurde, qualifiziert die Entgegennahme eines Vorteils als Bestechung im Sinne des § 334 StGB, wenn der Vorteil die Gegenleistung für eine Dienstleistung ist, die sich als pflichtwidrig darstellt. Zur Pflicht eines Amtsträgers gehört es im Zusammenhang mit der Beschaffung medizinischer Produkte, dass er diese

person or for a third party, as consideration for the preferential treatment of himself or another when goods or commercial services are purchased. Preferential treatment exists if the grantor of the benefit does not have any legal claim to the advantage he or she is pursuing. Any direct or indirect advantage in the ordering, delivery, inspection, acceptance or payment of goods and/or services will suffice. Preferential treatment may occur if business relationships are continued or products of the competitors of the grantor of the benefit are no longer bought because, for instance, an employee physician insists for no objective reason that a specific product of the grantor of the benefit be used in the private hospital.

A managing director is considered an employee and authorized representatives of a business operation. However, the owner of the operation himself is not a subject for bribery. This means that a physician in private practice will not fall within the scope of sec. 299 StGB.

Although the substantive requirements of sec. 299 StGB are different from those of sec. 331 et seq StGB, and because sec. 299 StGB is an offense which will only be pursued if a complaint is filed, as it is somewhat difficult to prosecute, companies are advised not to differentiate within their sponsoring practices between medical facilities which fall under sec. 331 et seq StGB and those falling under sec. 299 StGB, but to deal with publicly and privately owned medical facilities in accordance with the same principles.

Permissible and Prohibited Advertising Measures

With respect to the legal situation described above, which has led to considerable uncertainty in legal practice with respect to support afforded to physicians, the following recommendations are given for the conduct of some of the customary advertising and sponsoring measures:

Gifts

Companies must refrain from giving gifts which can be considered to be for a physician's personal use. If the intention is to provide a physician with items such as computers or medical equipment for his professional use, care must be given that the equipment is not provided to the physician personally, but that ownership is transferred to the medical facility and that the medical facility also authorizes this transfer. Medical books should be included in the inventory of the library of the medical facility, but the books can then be provided to the physician for his use. Even financial support for the procurement of professional journals should be in the name of the medical facility and not in the name of an individual physician.

unter Beachtung sachgerechter Kriterien auswählt und die Kaufentscheidung nicht von der Erlangung eigener Vorteile abhängig macht. Versucht also ein Außendienstmitarbeiter den Arzt eines Krankenhauses dadurch zum Bezug eines von ihm angebotenen Produktes zu bestimmen, indem er dem Amtsträger einen Vorteil anbietet (z.B. durch das Versprechen einer Drittmittelspende, Anbieten eines Beratervertrages) macht er sich einer vorsätzlichen Bestechung schuldig. Die Gewährung eines Vorteils, die als Bestechung zu werten ist, kann auch nicht genehmigt werden.

Rechtswidrig ist eine Diensthandlung im Sinne des § 334 StGB nicht erst dann, wenn ein Amtsträger sachwidrig entscheidet und ein wirtschaftlich ungünstiges Angebot in Hinblick auf den gewährten Vorteile annimmt, sondern bereits dann, wenn sich ein Amtsträger bei einer ihm zustehenden Ermessensentscheidung von dem Vorteil beeinflussen lässt. Dies wird in § 334 Abs. 3 Nr. 2 StGB ausdrücklich klargestellt. Entsprechend ist die Pflichtwidrigkeit einer Diensthandlung bei einer Ermessenentscheidung schon dann gegeben, wenn ein Amtsträger den ihm gewährten Vorteil auf die Waagschale seiner Entscheidung legt. Den Vorteil muss im Rahmen der Ermessensentscheidung auch nicht den Ausschlag geben; es reicht aus, dass sich der Amtsträger bereit gezeigt hat, sich bei seiner Entscheidung von dem Vorteil beeinflussen zu lassen. Bei dem Bezug von medizinischen Produkten haben Krankenhausärzte einen Beurteilungsspielraum; damit handelt es sich hierbei um Ermessensentscheidungen. Die vorgeschilderte Rechtsprechung zur Pflichtwidrigkeit von Ermessensentscheidungen hat dazu geführt, dass verschiedene Gerichte die Annahme von Einladungen zur passiven Teilnahme an Kongressreisen durch Krankenhausärzte als Bestechlichkeit kriminalisiert haben. Der Bundesgerichtshof hat jedoch in jüngster Zeit klargestellt, dass allein die Annahme eines Vorteils nicht die Pflichtwidrigkeit begründen kann. Denn dies würde bedeuten, dass jede Vorteilsgewährung bzw. Vorteilsannahme automatisch als Bestechung bzw. Bestechlichkeit zu qualifizieren wäre. Um dieses Ergebnis zu vermeiden, verlangt der Bundesgerichtshof für die Annahme einer Bestechungstat, dass der Vorteil die Gegenleistung für eine schon an sich pflichtwidrige Handlung ist oder sein sollte (BGH I StR 372/01; BGH I StR 541/01). Es muss von den Instanzgerichten im Einzelfall festgestellt werden, welche Vorstellungen über den Zweck der Vorteilsgewährung und deren Annahme bei den Beteiligten bestanden haben und welche konkrete Diensthandlung durch den Vorteil beeinflusst werden sollte.

Benefits which are socially acceptable are permitted. Benefits are considered socially acceptable if they are in accordance with customary courtesy or are a gratuitous favor and accepted as such under local custom. Tokens of appreciation which are of low value and given on the occasion of anniversaries or personal celebrations are generally acceptable. When it comes to clinics, a bouquet of flowers or a bottle of wine given upon a physician's appointment as chief physician or senior physician, or his/her habilitation (recognition as university lecturer) would be considered appropriate.

Invitations to Seminars and Conferences

Given the fact that the support of physicians as passive attendees of seminars and conferences constitutes a benefit for the relevant physician, it appears advisable to allow the institution to select the employees who may attend. Although the invitation to attend a conference can be sent to an employee of a medical facility, it should be made clear on the invitation that it does not extend to a specific official. It is absolutely necessary, however, for the head of administration to give his written authorization for the attendance of a physician or any other employee of a medical facility, and that the company is in possession of this authorization.

As has already been discussed earlier in this chapter, support provided by the industry must not exceed reasonable boundaries. In this context, reference is made to the above statements. In no event may business matters and personal affairs be combined. Normal ancillary hotel services which are part of an individual's personal preferences — such as the costs of a mini-bar and other services — should not be reimbursed to an employee of a medical facility. It is also advisable to clarify with the head of administration of a hospital whether the expenses incurred by an employee during a conference are to be directly remitted to their personal account or if the payments are to be made exclusively to the account of the medical facility. If travel documents are to be procured by the company, it is to be made clear in the invitation that the documents will be given directly to the attendees.

The above recommendations apply both to invitations to events organized by an outside conference management firm and to in-house events at the individual company.

To the extent that an official is asked to take an active part in a conference by giving a speech or being a moderator of the event, the above considerations will apply but with the notable difference that the company may also pay additional compensation for this involvement. This will require the execution

In diesem Zusammenhang ist darauf hinzuweisen, dass die üblichen Einladungen von Ärzten zum Essen zwar grundsätzlich nicht als Gewährung von unzulässigen Vorteilen verfolgt werden; indes werden diese Esseneinladungen als Hinweise dafür angesehen, dass möglicherweise ein Beziehungsgeflecht zwischen Industrie und Amtsträger besteht, welche die Grundlage für korruptives Verhalten bildet. Insoweit ist dringend darauf zu achten, dass bei Essenseinladungen das Maß des Angemessenen nicht überschritten und der Anlass für das Arbeitsessen dokumentiert wird.

Bestechlichkeit und Bestechung im geschäftlichen Verkehr gemäß § 299 StGB

Mitarbeiter eines Krankenhauses in privater Trägerschaft (Privatkrankenhaus) haben keine Amtsträgereigenschaft, so dass die Vorschriften der §§ 331 ff. StGB auf sie nicht anwendbar sind. Dasselbe gilt für Ärzte von kirchlichen Krankenhäusern oder angestellten Ärzten in niedergelassener Praxis. Die passive und aktive Bestechung in diesem Bereich wird jedoch durch die Vorschrift des § 299 StGB erfasst.

Gemäß § 299 Abs. 2 StGB wird bestraft, wer im geschäftlichen Verkehr zu Zwecken des Wettbewerbs einen Angestellten oder Beauftragten eines geschäftlichen Betriebes einen Vorteil für diesen oder einen Dritten als Gegenleistung dafür anbietet, verspricht oder gewährt, dass er ihn oder einen anderen bei dem Bezug von Waren oder gewerblichen Leistungen in unlauterer Weise bevorzugt. Eine Bevorzugung ist gegeben, wenn der Vorteilsgeber auf den von ihm erstrebten Vorteil keinen Rechtsanspruch hat. Jeder unmittelbare oder mittelbare Vorteil bei Bestellung, Lieferung, Prüfung, Abnahme oder Zahlung von Waren und/oder Dienstleistungen genügt. So kann eine Bevorzugung schon darin bestehen, dass Geschäftsbeziehungen aufrecht erhalten oder Produkte der Wettbewerber des Vorteilsgebers nicht mehr gekauft werden, weil zum Beispiel ein angestellter Arzt ohne sachlichen Grund darauf besteht, dass ein ganz bestimmtes Produkt des Vorteilsgebers im Privatkrankenhaus verwendet wird.

Zu den Angestellten und Beauftragten eines geschäftlichen Betriebes zählen auch Geschäftsführer. Kein taugliches Bestechungsobjekt ist jedoch der Betriebsinhaber selbst. Das heißt, ein Arzt in eigener niedergelassener Praxis fällt nicht unter den Anwendungsbereich des § 299 StGB.

of an appropriate agreement which is to be authorized by the head of administration of the medical facility.

Donations

The solicitation and grant of outside funding for research activities of physicians and medical facilities is a common practice. At universities, the decision to appoint a physician is often made in consideration of the individual's potential to solicit outside funding. At the same time, this funding constitutes benefits which could be relevant under bribery laws.

Given the paradox inherent in the situation that researchers at universities are called upon, on the one hand to solicit outside funding but are prohibited under bribery laws, and on the other hand from accepting benefits, the Federal Court of Justice has limited the application of bribery laws for outside funding solicited for the promotion of research and education. The Federal Court of Justice has set down that the acceptance or grant of a benefit pursuant to the substantive requirements of the law will not exist if there is compliance with the legal regulations governing universities. Compliance with the legal regulations governing universities ensures that the principles of transparency and authorization are sufficiently honored. As has been established by the Federal Court of Justice, the object of legal protection under bribery law is the integrity of the civil service. This will not be compromised, however, if the applicable regulations for soliciting outside funding are observed. This means that, where there is compliance with the laws governing universities, the Federal Court of Justice rejects that the substantive facts establishing the existence of corruption are present. A justifying authorization within the meaning of sec. 333 (3) StGB is not required to establish the legality of the action of the company providing the third-party donation.

A third-party donation granted outside the university sector will continue to be legally possible only if authorization by the employer or the head of the administration of the medical facility has been procured. Accordingly, care must be taken that third-party donations are disclosed to the head of the administration, and that the authorization for providing them has been given. For this reason, third-party donations may only be paid onto official accounts of medical facilities. Payments made to the accounts of so-called friends and patrons invite suspicion regarding transparency and thus could be considered to constitute illegal provision of benefits to a certain official.

Zwar unterscheiden sich die Tatbestandsvoraussetzungen des § 299 StGB von denjenigen in §§ 331 ff. StGB. Da es sich bei § 299 StGB um einen Antragsdelikt handelt, ist die Verfolgung etwas erschwert. Indes ist Unternehmen zu empfehlen, im Rahmen der Sponsoringpraxis zwischen medizinischen Einrichtungen, die unter §§ 331 ff. StGB fallen und solchen, die unter § 299 StGB fallen, keine Unterschiede zu machen, sondern die medizinischen Einrichtungen in öffentlicher und privater Trägerschaft nach den gleichen Grundsätzen zu behandeln.

Erlaubte und verbotene Werbemaßnahmen

In Hinblick auf die vorgeschilderte Rechtssituation, die in der Praxis zu erheblicher Unsicherheit über die Zulässigkeit der Unterstützung von Ärzten geführt hat, sollen nachfolgend Empfehlungen für die Durchführung einiger üblicher Werbe- und Sponsoringmaßnahmen gegeben werden:

Geschenke

Auf die Überlassung von Geschenken, die dem privaten Bereich von Ärzten zuzurechnen sind, muss verzichtet werden. Wenn es darum geht, einem Arzt Gegenstände für den beruflichen Gebrauch zur Verfügung zu stellen, wie etwa Computer oder medizinische Geräte, ist darauf zu achten, dass die Geräte dem Arzt nicht privat überlassen werden, sondern die Übertragung des Eigentums an die medizinische Einrichtung erfolgt und diese die Übertragung des Eigentums auch genehmigt. Medizinische Fachbücher sollten vorzugsweise bei der Bibliothek der medizinischen Einrichtung inventarisiert werden; das Buch kann dann durchaus dem Arzt zum Gebrauch überlassen werden. Auch die finanzielle Unterstützung für die Beschaffung von Fachzeitschriften sollte im Namen der medizinischen Einrichtung und nicht im Namen eines individuellen Arztes erfolgen. Zulässig sind indes Zuwendungen, die der Sozialadäquanz unterfallen. Als sozialadäquat werden solche Leistungen angesehen, die der Höflichkeit oder Gefälligkeit entsprechen und als gewohnheitsrechtlich anerkannt gelten. Typische Fälle sind geringwertige Aufmerksamkeiten aus Anlass von Jubiläen oder persönlichen Feiertagen. Im Klinikbereich wird man hierzu die Ernennung zum Chefarzt oder Oberarzt oder die Habilitation eines Arztes rechnen können. Zu denken ist an einen Blumenstrauß, eine Flasche Wein oder ähnliches.

Where it is important for a company to support a scientific event of a physician by providing money, it is advisable to enter into what is known as an exhibitor agreement, which is to be authorized by the medical facility.

Social donations are not acceptable, i.e., financial support for events serving to promote the social interchange between employees working at a medical facility. Typical examples are Christmas parties, employee excursions, building dedications or birthday parties. Support for these kinds of events, which are to be ascribed to the personal lifestyle of the organizers, are not acceptable from a legal standpoint. This would apply even if authorization had been given.

Research

The cooperation between industry and medical facilities or their employees in the field of research is ordinarily permitted. However, research contracts should generally not be entered into with an employee of a medical facility. Rather, the medical facility is to be selected as the other party to the contract.

Public Purchasing, Fraud and Breach of Trust

Whenever medical products are purchased by public medical facilities, the Service Regulations, Chapter A (*Verdingungsordnung für Leistungen, Teil A* — "VOL") must be observed. Depending on the volume of a contract, it may be necessary to conduct a call for tender and comply with certain procedural regulations when contracts are awarded. Although compliance with the VOL is a matter for the public-law buyer, non-compliance with the applicable regulations can have indirect ramifications for a medical supplier because a violation of the Service Regulations can render the supplier contracts void.

Problems with fraud can only arise in the context of the sale of medical products if physicians are granted rebates for the purchase of medical products to which the health insurance authorities are actually entitled. In the field of imaging products, accusations have been made that suppliers have given kickbacks to physicians, which actually should have been credited to the health insurance authorities. Because suppliers charged the full price to the health insurance authorities, the accusation of fraud was raised, to the detriment of the health insurance authorities. Furthermore, public prosecutors also prosecute physicians with a private practice who receive unjustified benefits from the industry in connection with the prescription of medical products to patients with compulsory insurance under the aspect of breach of trust under criminal and civil law.

In Hinblick darauf, dass die Unterstützung von Ärzten zur passiven Teilnahme an Seminaren und Kongressen einen Vorteil für den betreffenden Arzt darstellt, erweist es sich als günstig, die Auswahl der teilnehmenden Mitarbeiter der Institution selbst zu überlassen. Die Einladung zur Teilnahme an einem Kongress kann zwar einem Mitarbeiter einer medizinischen Einrichtung übermittelt werden. Es sollte aber auf der Einladung deutlich gemacht werden, dass sich die Einladung nicht auf einen konkreten Amtsträger bezieht. Zwingend muss jedoch vor der Gewährung von Unterstützungsleistungen für die Teilnahme eines Arztes oder eines sonstigen Mitarbeiters einer medizinischen Einrichtung die schriftliche Genehmigung der Verwaltungsleistung eingeholt werden und dem Unternehmen vorliegen.

Wie bereits oben unter 1.2.1 ausdrücklich ausgeführt, darf die Unterstützungsleistung der Industrie das Maß des Angemessenen nicht überschreiten. Auf die dort genannten Ausführungen sei an dieser Stelle verwiesen. Keinesfalls darf in diesem Zusammenhang Privates mit Beruflichem vermischt werden. Hotelübliche Nebenleistungen, die zur privaten Lebensführung gehören, wie etwa Kosten für die Minibar und sonstige Serviceleistungen sollten einem Mitarbeiter einer medizinischen Einrichtung nicht erstattet werden. Es ist des weiteren angezeigt, mit der Verwaltungsleitung eines Krankenhauses abzuklären, ob etwaige Auslagen, die einem Mitarbeiter während der Kongressreise entstehen, direkt auf sein Privatkonto überwiesen werden oder Zahlungen ausschließlich auf das Konto der medizinischen Einrichtung erfolgen sollen. Wenn Reisedokumente vom Unternehmen selbst besorgt werden, ist im Rahmen der Einladung deutlich zu machen, dass die Unterlagen dem Teilnehmer direkt überlassen werden. Vorstehende Empfehlungen gelten sowohl für Einladungen zu Veranstaltungen, die von einem externen Kongressveranstalter organisiert werden, als auch für interne Veranstaltungen des jeweiligen Unternehmens.

Soweit ein Amtsträger gebeten wird, sich aktiv an einem Kongress zu beteiligen, indem er etwa einen Vortrag hält oder bei der Veranstaltung moderiert, gelten die vorstehenden Überlegungen mit der Maßgabe, dass das Unternehmen hierfür auch eine zusätzliche Vergütung zahlen darf. Es bedarf jedoch hierzu des Abschlusses eines entsprechenden Vertrages, der von der Verwaltungsleitung der medizinischen Einrichtung zu genehmigen ist. Es sei diesbezüglich auf die nachstehenden Ausführungen unter Abschnitt 4.0 verwiesen.

Sanctions

If there is a violation of the prohibition of granting benefits under sec. 331 StGB, the perpetrator can be sentenced to imprisonment for up to three years or to a fine. For bribery under sec. 334, the perpetrator faces imprisonment of three months to five years. In aggravated cases, a perpetrator can be sentenced to imprisonment for up to 10 years. The sanction provided for under the law governing corruption and bribery in commercial transactions in sec. 299 StGB is a fine or imprisonment for up to three years. Any person in a company making a relevant contribution to the provision of an unlawful grant of a benefit or of bribery can be held responsible under criminal law. Generally, this will be managing directors, sales representatives and the head of finance. To the extent that a company has appointed a compliance officer and it is included in his/her duties to prevent the granting of illegal benefits, this compliance officer may also be held criminally responsible under certain circumstances. It must also be taken into account that if corruption is proved, the medical facility suffering injury may sue the corrupt company for damage.

The damage for which compensation is to be paid is the amount the official was unlawfully provided. In other words, if a pharmaceutical company buys its way into sales at a medical facility and perhaps pays a bonus to its sales force for the sales they have procured, it is in danger of ultimately paying an extremely high price for these sales.

Contracts with Healthcare Professionals and Medical Institutions

With respect to the legal situation relating to the support of medical facilities and their employees described above, it is recommended that the medical industry organize a standardized contractual procedure for cooperation with its customers and complies with the principles of transparency and authorization as well as with the principles of separation and documentation. It is important to take into account that there could be corruption issues wherever agreements are executed under which a medical facility or a physician agrees to perform a service for a company and receives compensation as consideration for doing so. This will apply even if the remuneration paid by the industry is reasonable with respect to the performance rendered by the physician, and one could therefore argue that the party rendering performance is entitled to the remuneration.

The benefit relevant to bribery law within the meaning of sec. 331 et seq StGB in these cases can comprise the fact that the physician or the medical

Spenden

Die Einwerbung und Gewährung von Drittmitteln für die Forschungstätigkeit von Ärzten und medizinischen Einrichtungen ist allgemeine Praxis. In Universitäten erfolgt die Entscheidung über die Berufung eines Arztes häufig auch unter Berücksichtigung seines Potentials, Drittmittel einzuwerben. Gleichzeitig stellen diese Drittmittel Vorteile dar, die korruptionsrechtlich relevant sein können.

In Hinblick auf den Wertungswiderspruch, der darin besteht, dass Wissenschaftler an Hochschulen zum einen aufgefordert werden, Drittmittel einzuwerben und zum anderen, die Korruptionsvorschriften die Annahme von Zuwendungen verbieten, hat der Bundesgerichtshof für Drittmittel, die zur Förderung von Forschung und Lehre eingeworben werden, die Anwendbarkeit der Korruptionsvorschriften eingegrenzt. Der Bundesgerichtshof hat festgelegt, dass tatbestandlich eine Vorteilsannahme bzw. eine Vorteilsgewährung dann ausscheidet, wenn bei Einwerbung von Drittmittelgeldern die hochschulrechtlichen Vorschriften über die Einwerbung von Drittmitteln konsequent eingehalten werden. Die Einhaltung der hochschulrechtlichen Vorschriften stellt nämlich sicher, dass dem Transparenz- und Genehmigungsprinzip hinreichend Geltung verschafft wird. Wie der Bundesgerichtshof feststellt, ist das Schutzgut der Korruptionsvorschriften die Lauterkeit des öffentlichen Dienstes. Diese stehe hingegen nicht in Frage, wenn bei der Drittmitteleinwerbung die anwendbaren Hochschulvorschriften für Dritteinwerbung beachtet werden. Das heißt, der Bundesgerichtshof schließt das Vorliegen einer Korruptionstat bei Beachtung der anwendbaren Hochschulvorschriften bereits auf der Tatbestandsebene aus. Eine rechtfertigende Genehmigung im Sinne des § 333 Abs. 3 StGB ist für die Straflosigkeit des Unternehmens, dass die Drittmittelspende leistet, nicht erforderlich.

Für Drittmittelspenden, die außerhalb des Hochschulbereichs gewährt werden, gilt jedoch weiterhin, dass eine Drittmittelspende nur dann rechtlich möglich ist, wenn hierfür eine Genehmigung seitens des Dienstherrn bzw. der Verwaltungsleitung einer medizinischen Einrichtung vorliegt. Entsprechend muss darauf geachtet werden, dass Drittmittelspenden gegenüber der Verwaltungsleitung transparent gemacht werden und die Genehmigung zur Annahme vorliegt. Drittmittelspenden sollten deshalb nur auf offizielle Konten von medizinischen Einrichtungen gezahlt werden. Zahlungen, die auf Konten von sogenannten Freundes- und Förderkreisen getätigt werden, bergen die Gefahr in sich, dass diese nicht für die medizinische Einrichtung

facility was offered the opportunity to enter into the agreement. In other words, the benefit under bribery law is considered to be the fact that the physician in question has been selected to provide consulting services, for instance, for the company. It is therefore recommended that the procedure described below is observed.

Research Contracts

Companies in the medical industry usually need the support of physicians in the fields of basic research, clinical research and development, the creation of case reports or even for the conduct of monitoring studies or epidemiological studies. There is nothing to be said against having these kinds of services performed by physicians in medical facilities. However, the agreement should not be made directly with the physicians but with the medical facility where the physician works. This means that research agreements of such nature are to be signed by the employer or the head of administration. The physician conducting the research can be appointed project head, and then additionally sign the agreement in such capacity.

Performance and consideration are to be defined exactly in a research agreement. On evidential grounds, it must also be established that the rendered performance is documented. This does not pose any conceptual problems for research contracts because an interim or final report on the conducted research is regularly requested from the researcher. If the research contract ends without any result, there must be documentation on the kind of performance the physician provided for the company.

As far as monitoring studies (non-interventional studies) are concerned, it must be ensured that these are not mere sham performances of no importance for the principal. Rather, care must be taken that the published recommendations on the design and conduct of monitoring studies set down by *Bundesinstitut für Arzneimittel und Medizinprodukte* are followed. The report forms must not only be put on file but must also be evaluated. In addition, it is preferable to plan to have the findings published after the monitoring study has been conducted and evaluated.

The remuneration paid by the industry for conducting research must be reasonable in light of the rendered performance. This means that the remuneration may not be exceedingly high. The basis of calculating a reasonable fee is the time required to perform the scientific work. One approach can be the appropriate fee items of the statutory schedule of fees for physicians or GOÄ, even if it is to be noted that only a relatively low fee will be acceptable if the GOÄ is used as the standard. It may be difficult to

transparent sind und deshalb möglicherweise als unzulässige Gewährung von Vorteilen an einen bestimmten Amtsträger angesehen werden können.

Wenn es einem Unternehmen darum geht, die wissenschaftliche Veranstaltung eines Arztes durch Geldmittel zu unterstützen, ist es sinnvoll, einen sogenannten Ausstellervertrag abzuschließen, der von der medizinischen Einrichtung zu genehmigen ist; hierzu mehr unter Abschnitt 4.0.

Nicht akzeptabel sind die sogenannten Sozialspenden. Hierbei handelt es sich um finanzielle Unterstützungsleistungen von Veranstaltungen, die dem sozialen Miteinander der in einer medizinischen Einrichtung beschäftigten Mitarbeiter dienen. Typische Beispiele sind Weihnachtsfeiern, Betriebsausflüge, Hauseinweihungen oder Geburtstagspartys. Die Unterstützung derartiger der privaten Lebensführung zuzurechnenden Veranstaltungen ist aus rechtlicher Sicht nicht akzeptabel. Dies gilt selbst dann, wenn eine Genehmigung vorliegen würde.

Forschung

Die Zusammenarbeit zwischen Industrie und medizinischen Einrichtungen bzw. deren Mitarbeitern im Bereich der Forschung ist grundsätzlich zulässig. Allerdings sollten Forschungsverträge im Regelfall nicht mit einem Mitarbeiter einer medizinischen Einrichtung abgeschlossen werden; als Vertragspartner ist vielmehr die medizinische Einrichtung selbst auszuwählen.

Öffentliche Beschaffung, Betrug und Untreue

Bei der Beschaffung von medizinischen Produkten sind medizinische Einrichtungen der öffentlichen Hand gehalten, die Verdingungsordnung für Leistungen (VOL) Teil A zu beachten. Je nach Auftragsvolumen kann es erforderlich sein, eine Ausschreibung durchzuführen und bestimmte Verfahrensvorschriften bei der Vergabe zu berücksichtigen. Zwar ist die Berücksichtigung der VOL Sache des öffentlichen Bestellers. Die Nichtberücksichtigung der anwendbaren Vorschriften kann jedoch mittelbar eine Auswirkung für ein medizinisches Lieferunternehmen haben, da ein Verstoß gegen die Verdingungsordnung zur Unwirksamkeit der Lieferverträge führen kann.

establish in the individual case which fee is reasonable for a rendered performance. In order to build up a defensible position if there are problems at a later point, it is advisable for a company to document the calculative basis for determining the amount of the fee. This calculation can take into account how long a physician will require, in the company's view, to render the performance that he or she owes under the terms of contract. In addition, the level of difficulty of the performance, the pressure to comply with deadlines and the market situation for these kinds of services can be taken into account in the calculation. A company is not prohibited from increasing the remuneration for a certain service if the company establishes that no physicians will be willing to perform the desired research services if they are not offered a higher fee.

It must further be ensured that research contracts are only entered into with medical facilities that have people with sufficient qualifications to render the specific research performance on the basis of generally accepted standards of scientific research.

Finally, an anti-corruption clause should be added to all contracts with medical facilities. In this clause, the employer or the head of administration confirms that the execution and performance of the agreement does not violate statutory or internal regulations of the medical facility or its owner, and that the performance of the contract does not constitute any dereliction of duty on the part of the employee appointed to perform under the contract.

Consulting Contracts

Pharmaceutical and medical device companies often require medical consultants for both marketing and research and development in order to discuss and clarify possible questions or application issues. The involvement as consultant is generally not provided by the medical facility but is provided personally by the individual consultant. Accordingly, it is appropriate that consulting contracts are not entered into with the medical facility but signed directly with the consultant. This will not meet any problems if the execution of the consulting contract is authorized by the employer. It is to be noted once again, however, that the authorization required under bribery law is not identical to the second job authorization which allows a physician to work for a third party in a second job in addition to his main work.

Care should be taken with consulting contracts to ensure that they are very specific. Remuneration must be reasonable. Otherwise, it is recommended that no flat-rate fee is paid, but that an hourly fee is agreed to and that the consultant is obliged to submit detailed settlement sheets of the services he or

Probleme des Betruges können sich in Zusammenhang mit dem Absatz von medizinischen Produkten dann ergeben, wenn Ärzten Rabatte für den Bezug von medizinischen Produkten eingeräumt werden, die eigentlichen den Krankenkassen zustehen. Im Bereich der Lieferung von Kontrastmitteln ist in der Vergangenheit der Vorwurf erhoben worden, dass Lieferunternehmen an Ärzte bestimmte Vorteile als sogenannte Kick-Backs bezahlt haben, die sie eigentlich den Krankenkassen hätten gut bringen müssen. Da die Lieferunternehmen gegenüber den Krankenkassen den vollen Preis abgerechnet haben, wurde der Vorwurf des Betruges zulasten der Krankenkassen erhoben. Zudem verfolgen Staatsanwälte mittlerweile auch niedergelassene Ärzte, die von der Industrie in Zusammenhang mit der Verordnung von medizinischen Produkten an gesetzlich versicherte Patienten ungerechtfertigte Vorteile erhalten unter dem strafrechtlichen Gesichtspunkt der Untreue.

Sanktionen

Bei Verstoß gegen das Verbot der Vorteilsgewährung gemäß § 331 StGB droht dem Täter Freiheitsstrafe bis zu drei Jahren oder Geldstrafe. Im Fall der Bestechung gemäß § 334 StGB hat der Täter mit Freiheitsstrafe von drei Monaten bis zu fünf Jahren zu rechnen. In schweren Fällen kann eine Freiheitsstrafe bis zu zehn Jahren verhängt werden. Die Strafvorschrift des § 299 StGB betreffend Bestechlichkeit und Bestechung in geschäftlichem Verkehr sieht als Sanktion Freiheitsstrafe bis zu drei Jahren oder Geldstrafe vor. Im Unternehmen kann jeder strafrechtlich zur Verantwortung gezogen werden, der einen relevanten Beitrag zur Verwirklichung einer unzulässigen Vorteilsgewährung oder Bestechung leistet. In Betracht kommen regelmäßig der Geschäftsführer, die Außendienstmitarbeiter sowie der Finanzleiter. Soweit ein Unternehmen einen Compliance Officer bestellt hat und es diesem obliegt, rechtswidrige Zuwendungen zu verhindern, kann auch dieser unter Umständen strafrechtlich zur Verantwortung gezogen werden. Des Weiteren ist zu berücksichtigen, dass bei Nachweis einer Korruptionsstraftat die geschädigte medizinische Einrichtung Anspruch auf Schadenersatz gegenüber dem korruptiven Unternehmen geltend machen kann. Als Schaden ist derjenige Betrag zu ersetzen, der dem Amtsträger unzulässigerweise zur Verfügung gestellt wurde. Mit anderen Worten: wenn sich ein Pharmaunternehmen Umsätze in einer medizinischen Einrichtung erkauft und möglicherweise für die erreichen Umsätze seinen Außendienstmitarbeitern einen Bonus zahlt, läuft es Gefahr, diese Umsätze schlussendlich sehr teuer zu bezahlen.

she has performed. This has the advantage of having the performed consulting services, which could include telephone conversations or meetings, be presented as documented proof of performance.

Speakers' Contracts

If physicians of medical facilities are invited to speak, written speaker contracts should be executed. The fee to be paid to a speaker should be at the normal market level. Accordingly, it will be perfectly acceptable for a prominent member of the medical community to be paid more than a junior physician. Speakers' contracts must also be approved by the employer in writing. If a certain speaker is to be used regularly by one company, a master speaker's contract can also be signed. This contract should set down the fee, number of speeches and other general terms. The agreement on the place, time and topic of the speech can be resolved by the parties separately. A master speaker's contract must be authorized by the employer.

Exhibitor Agreements

Medical companies are often asked by the organizers of scientific conferences for their support. At the same time, companies are offered the opportunity to set up a stand at the conference or otherwise advertise their products. In this context, it is recommended that an exhibitor contract is signed. This means that one-sided financial support of a conference is to be avoided. Rather, a written two-way contract should be signed, by which the company pays the organizer a reasonable fee for the opportunity to conduct specific advertising activities. If the event is hosted by a medical facility, it is self-explanatory that the exhibitor agreement is made with the medical facility. If the event constitutes the personal project of a member of the medical facility, the agreement can be made with this physician. In this case, however, authorization should be procured wherever possible. The problems which arise when authorizations are to be procured can be complex, but they are not unsolvable.

Recommendations

Advertising for medical products is ultimately fraught with numerous civil and criminal law risks. If a company violates the provisions of the HWG or the UWG, this may lead to unpleasant and expensive legal disputes. At the end of the day, competition proceedings belong to the everyday business of a lawyer and are controllable for a company.

Verträge mit Ärzten und medizinischen Einrichtungen

In Hinblick auf die vorgeschriebene Rechtslage in Bezug auf die Unterstützung von medizinischen Einrichtungen und deren Mitarbeitern empfiehlt es sich, für die medizinische Industrie die Zusammenarbeit mit ihren Kunden auf standardisierte, vertragliche Grundlagen zu stellen und dabei die Prinzipien der Transparenz und Genehmigung sowie das Trennungsprinzip und Dokumentationsprinzip zu beachten. Es gilt nämlich zu berücksichtigen, dass auch bei Abschluss von Vereinbarungen, in denen sich eine medizinische Einrichtung bzw. ein Arzt verpflichtet, für ein Unternehmen eine Leistung zu erbringen und hierfür als Gegenleistung eine Vergütung erhält, Korruptionsprobleme auftreten können. Dies gilt selbst dann, wenn die von der Industrie gezahlte Vergütung in Hinblick auf die von dem Arzt erbrachte Leistung angemessen ist und deshalb argumentiert werden kann, dass der Leistungserbringer einen begründeten Anspruch auf die Vergütung hat. Der korruptionsrechtliche Vorteil im Sinne der §§ 331 ff. StGB kann in diesen Fällen nämlich darin bestehen, dass dem Arzt bzw. der medizinischen Einrichtung die Möglichkeit geboten wurde, den betreffenden Vertrag abschließen zu dürfen. Anders ausgedrückt: der korruptionsrechtliche Vorteil ist darin zu sehen, dass der betreffende Arzt ausgewählt wurde, z.B. Beratungsleistungen für ein Unternehmen zu erbringen. Im Einzelnen empfiehlt sich deshalb folgendes Vorgehen:

Forschungsverträge

Unternehmen der medizinischen Industrie benötigen üblicherweise die Unterstützung von Ärzten im Bereich der Grundlagenforschung, der klinischen Forschung und Entwicklung, bei der Erstellung von Kasuistiken oder auch bei der Durchführung von Anwendungsbeobachtungen oder epidemiologischen Studien. Es spricht auch nichts dagegen, derartige Leistungen durch Ärzte in medizinischen Einrichtungen durchführen zu lassen. Allerdings sollte der Vertrag nicht mit den Ärzten direkt abgeschlossen werden, sondern der Vertrag ist mit der medizinischen Einrichtung abzuschließen, bei der der betreffende Arzt tätig ist. Das heißt, Forschungsverträge der vorstehend genannten Art sind vom Dienstherrn bzw. der Verwaltungsleitung zu unterzeichnen. Der die Forschung ausführende Arzt kann im Vertrag als Projektleiter benannt werden und den Vertrag als Projektleiter zusätzlich unterzeichnen.

The situation is different if the conduct of a company constitutes criminal behavior. The consequences of such situation are acceptable neither for the company and its management, nor for the employees who have engaged in the activity. In order to lower the risks of criminal prosecution, the following action points are recommended:

- Avoid giving unilateral benefits from the industry (principle of consideration); the physician must actively do something.
- Do not give benefits that are linked to a sales transaction.
- Do not give benefits that serve the private purposes of the recipient.
- Cooperation agreements are generally to be executed with the medical facility and not directly with a physician from the medical facility.
- Procure written authorization from the head of administration/employer of the medical facility for the grant of unilateral benefits and the execution of contracts.
- Draft a company code of conduct that is binding for the employees of the company.
- Prepare standard contracts that can be used for cooperation with medical facilities and physicians.
- Organize the conduct of internal or external compliance audits.
- Arrange for regular compliance training.

In einem Forschungsvertrag sind Leistungen und Gegenleistungen genau zu konkretisieren. Aus Beweisgründen muss im Übrigen sichergestellt sein, dass die erbrachten Leistungen auch dokumentiert werden. Dies wirft bei Forschungsverträgen kein konzeptionelles Problem auf, da vom Forscher regelmäßig Zwischen- oder Abschlussberichte über die von ihm getätigte Forschung verlangt werden. Sollte ein Forschungsauftrag ohne Ergebnis enden, muss allerdings dokumentiert sein, welche Leistungen der betreffende Arzt für das Unternehmen geleistet hat.

Was die Durchführung von Anwendungsbeobachtungen (nicht-interventionelle Studien) anbetrifft, ist sicherzustellen, dass es sich hierbei nicht um reine Scheinleistungen handelt, die für den Auftraggeber ohne Belang sind. Vielmehr ist darauf zu achten, dass die vom Bundesinstitut für Arzneimittel und Medizinprodukte veröffentlichen Empfehlungen bei Konzeption und Durchführung von Anwendungsbeobachtungen Berücksichtigung finden. Die Berichtsbögen sind nicht nur abzuheften, sondern sollten ausgewertet werden. Vorzugsweise sollte nach Durchführung der Anwendungsbeobachtung und deren Auswertung auch eine Veröffentlichung der Ergebnisse ins Auge gefasst werden.

Die für die Durchführung der Forschungstätigkeit von der Industrie gezahlte Vergütung muss in Hinblick auf die erbrachten Leistungen angemessen sein. Das heißt, die Vergütung darf nicht übertrieben hoch ausfallen. Bei der Berechnung einer angemessenen Vergütung ist auf den Zeitaufwand abzustellen, den die Erbringung der wissenschaftlichen Leistung erfordert. Als Orientierungshilfe kann auf passende Gebührenziffern der GOÄ für Ärzte rekurriert werden, wenngleich an dieser Stelle darauf hingewiesen werden muss, dass bei Anlegung des GOÄ-Maßstabes nur eine vergleichsweise geringe Vergütung akzeptabel sein wird. Es mag zwar schwierig sein, im Einzelfall festzustellen, welche Vergütung für eine erbrachte Leistung angemessen ist. Um für spätere Beanstandungen eine verteidigbare Position aufzubauen, ist es jedoch für ein Unternehmen in jedem Fall empfehlenswert, die Kalkulationsgrundlage für die Ermittlung der Vergütung zu dokumentieren. In einer solchen Kalkulation kann berücksichtigt werden, wie lange nach Auffassung des Unternehmens ein Arzt benötigt, um die vertraglich geschuldeten Leistungen zu erbringen. Des Weiteren kann der Schwierigkeitsgrad der Leistungen, der Druck durch einzuhaltende Fristen oder auch die Marktlage für derartige Leistungen in der Kalkulation Berücksichtigung finden. Es ist einem Unternehmen nicht verwehrt, die Vergütung für eine bestimmte Leistung zu erhöhen, wenn das Unternehmen feststellt, dass Ärzte ohne Anbieten einer etwas erhöhten

Vergütung nicht bereit sind, die gewünschten Forschungsleistungen zu erbringen.

Ferner ist sicherzustellen, dass Forschungsverträge nur mit solchen medizinischen Einrichtungen geschlossen werden, die Personen mit ausreichender Qualifikation haben, um die konkreten Forschungsleistungen tatsächlich auf der Grundlage eines allgemein anerkannten wissenschaftlichen Standards erbringen zu können. Schlussendlich sollte in alle Verträge mit medizinischen Einrichtungen eine sogenannte Antikorruptionsklausel eingefügt werden. Hierin bestätigt der Dienstherr bzw. die Verwaltungsleitung, dass Abschluss und Durchführung des Vertrages nicht gegen gesetzliche oder interne Vorschriften der medizinischen Einrichtung oder ihres Trägers verstoßen und die Durchführung des Vertrages für die hiermit beauftragten Mitarbeiter keine Dienstpflichtverletzung darstellt.

Beratervertrag

Sowohl für das Marketing als auch für Aufgaben der Forschung und Entwicklung benötigen Pharma- und Medizinprodukteunternehmen häufig ärztliche Berater, um fachliche Fragestellungen oder Anwendungsproblematiken abzuklären. Die Beratertätigkeit wird im Regelfall nicht von einer medizinischen Einrichtung, sondern von dem jeweiligen Berater persönlich erbracht. Entsprechend ist es sachgerecht, Beraterverträge nicht mit medizinischen Einrichtungen, sondern tatsächlich mit dem Berater direkt abzuschließen. Dies begegnet keinen Bedenken, wenn der Abschluss des Beratervertrages vom jeweiligen Dienstherrn genehmigt worden ist. Es ist in diesem Zusammenhang jedoch noch einmal darauf hinzuweisen, dass die aus korruptionsrechtlicher Sicht geforderte Genehmigung nicht identisch mit der sogenannten Nebentätigkeitserlaubnis ist, die es einem Arzt erlaubt, neben seiner Haupttätigkeit auch noch im Nebenamt für Dritte tätig zu werden.

Bei Beraterverträgen ist darauf zu achten, dass sie sehr konkret gefasst sind. Die Vergütung muss angemessen sein. Im Übrigen empfiehlt es sich, keine Pauschalhonorare zu zahlen, sondern eine stundenmäßige Vergütung zu vereinbaren und den Berater zu verpflichten, die von ihm erbrachten Leistungen detailliert abzurechnen. Dies hat den Vorteil, dass die erbrachten Beratungsleistungen, die möglicherweise in Telefonaten oder Besprechungen bestehen, als dokumentierte Leistungsnachweise vorliegen.

Referentenverträge

Soweit Ärzte von medizinischen Einrichtungen eingeladen werden, ein Referat zu halten oder ein Poster zu präsentieren, sollten schriftliche Referentenverträge geschlossen werden. Die für die Referententätigkeit geschuldete Vergütung sollte marktüblich sein, wobei es durchaus akzeptabel ist, dass einem Meinungsbildner mehr gezahlt wird als einem Assistenzarzt. Auch Referentenverträge müssen vom Dienstherrn schriftlich genehmigt werden. Sofern ein bestimmter Referent häufiger für ein Unternehmen tätig werden soll, können auch Rahmenreferentenverträge geschlossen werden. Hierin werden die Vergütung, die Anzahl der Vorträge und die sonstigen allgemeinen Vertragsbedingungen festgelegt. Die Vereinbarung von Ort, Zeit und Thema des Vortrags kann dann separat zwischen den Parteien vereinbart werden. Der Rahmenreferentenvertrag ist von dem Dienstherrn zu genehmigen.

Ausstellervertrag

Medizinische Unternehmen werden von Veranstaltern wissenschaftlicher Kongresse häufig gebeten, diese zu unterstützen. Gleichzeitig wird den Unternehmen angeboten, dass sie im Rahmen der Veranstaltung einen Stand aufstellen oder sonst Werbung betreiben können. In diesem Zusammenhang wird empfohlen, einen sogenannten Ausstellervertrag zu schließen. Das heißt, es sollte vermieden werden, eine wissenschaftliche Veranstaltung einseitig finanziell zu unterstützen. Vielmehr sollte ein schriftlicher Austauschvertrag geschlossen werden, in dem das Unternehmen dem Veranstalter für die Ermöglichung von konkreten Werbemaßnahmen eine angemessene Vergütung zahlt. Sofern die Veranstaltung von einer medizinischen Einrichtung ausgerichtet wird, ist es selbstverständlich, diesen Ausstellervertrag mit der medizinischen Einrichtung zu schließen. Sofern die Veranstaltung ein eigenes Projekt eines Mitarbeiters der medizinischen Einrichtung darstellt, kann der Vertrag mit dem betreffenden Arzt geschlossen werden. Es sollte jedoch auch in diesem Fall nach Möglichkeit eine Genehmigung eingeholt werden. Die sich bei der Einholung der Genehmigung ergebenden Probleme können komplex sein; sie sind jedoch nie unlösbar.

Empfehlungen

Die Bewerbung von medizinischen Produkten birgt im Ergebnis eine Vielzahl von zivilrechtlichen und strafrechtlichen Risiken. Sofern ein

Unternehmen gegen die Vorschriften des HWG oder UWG verstößt, vermag dies zu unangenehmen und kostenaufwendigen rechtlichen Auseinandersetzungen führen. Im Ergebnis sind Wettbewerbsverfahren jedoch juristisches Alltagsgeschäft, das für ein Unternehmen beherrschbar ist. Anders sieht die Situation aus, wenn sich das Verhalten eines Unternehmens als strafbar darstellt. Die sich hieraus ergebenden Konsequenzen sind weder für das Unternehmen, die handelnden Mitarbeiter noch für die Geschäftsleitung akzeptabel. Um die Risiken einer strafrechtlichen Verfolgung der Zusammenarbeit zwischen medizinischen Unternehmen und Ärzten von medizinischen Einrichtungen zu minimieren, gilt es deshalb folgende Empfehlungen zu beachten:

- Vermeidung der Gewährung von einseitigen Zuwendungen durch die Industrie (Gegenleistungsprinzip); Ärzte müssen aktiviert werden!
- Keine Gewährung von Zuwendungen in Abhängigkeit von Umsatzgeschäften.
- Keine Gewährung von Zuwendungen, die privaten Zwecken eines Empfängers dienen.
- Kooperationsvereinbarungen sind grundsätzlich mit der medizinischen Einrichtung und nicht direkt mit einem Arzt dieser medizinischen Einrichtung abzuschließen.
- Einholung der schriftlichen Genehmigung für die Gewährung von einseitigen Zuwendungen und Abschluss von Verträgen durch die Verwaltungsleitung/den Dienstherrn einer medizinischen Einrichtung.
- Erarbeitung eines Unternehmenskodex, der für die Mitarbeiter des Unternehmens verbindlich gemacht wird.
- Bereitstellung von Standardverträgen, die für die Zusammenarbeit mit medizinischen Einrichtungen und Ärzten verwendet werden können.
- Durchführung von internen oder externen Compliance Audits.
- Regelmäßige Durchführung von Compliance Schulungen.

Magyarország

Helga Bíró, Berekméri-Varró Réka

Bevezetés

Magyarország 2004. május 1-től az Európai Unió tagja és jogszabályai alapvetően összhangban vannak az Európai Unió vonatkozó irányelveivel. A gyógyszergyártók és -forgalmazók gyógyszerreklámozással kapcsolatos tevékenységére vonatkozó magyar jogszabályok ugyanakkor az EU-irányelvek rendelkezéseihez képest néhány esetben bővebb, illetve szigorúbb szabályokat tartalmaznak.

Az európai szabályozással összhangban, a magyar jogszabályoknak is elsődleges célja a betegek és fogyasztók magas fokú védelmének biztosítása. Az időről-időre bekövetkező jogszabályi változások másik fontos célja azonban az egészségügyi szakemberek irányában folytatott promóciós / ösztönző tevékenység korlátozása a gyógyszerkassza kiadásainak csökkentése érdekében.

A jogszabályi keret

A gyógyszerek reklámozásának alapvető szabályait a (i) a biztonságos és gazdaságos gyógyszer-és gyógyászatisegédeszköz-ellátás, valamint a gyógyszerforgalmazás általános szabályairól szóló 2006. évi XCVIII. törvény (a "Gyftv."); (ii) a fogyasztókkal szembeni tisztességtelen kereskedelmi gyakorlat tilalmáról szóló 2008. évi XLVII. törvény ("Fttv.") (iii) a gazdasági reklámtevékenység alapvető feltételeiről és egyes korlátairól szóló 2008. évi XLVIII. Törvény (a "Reklámtörvény"); (iv) az emberi alkalmazásra kerülő gyógyszerekről és egyéb, a gyógyszerpiacot szabályozó törvények módosításáról szóló 2005. évi XCV. törvény ("Gyógyszertörvény"); valamint a (v) az emberi felhasználásra kerülő gyógyszer, illetve gyógyászati segédeszköz ismertetésére, az ismertetői tevékenységet végző személyek nyilvántartására, és a gyógyszerrel, gyógyászati segédeszközzel kapcsolatos, fogyasztókkal szembeni kereskedelmi gyakorlatra vonatkozó részletes

Hungary

Helga Bíró, Berekméri-Varró Réka

Introduction

Hungary became a member of the European Union ("EU") on 1 May 2004 and the laws and regulations applicable to pharmaceutical advertising are generally in line with the relevant EU directives. However, in some cases, Hungarian legislation contains regulations more detailed or stringent than those of EU directives governing the promotional activities of pharmaceutical manufacturers and distributors. The underlying goal of this legislation appears to be to attain of a high level of consumer protection.

The periodic amendments from time to time of the legislation also aim to restrict promotions directed towards healthcare professionals in order to reduce the expenditures of the health insurance budget.

The Regulatory Framework

The following laws contain the basic rules regarding pharmaceutical advertising:

- Act XCVIII of 2006 on the Safe and Economic Supply and Distribution of Medicines and Therapeutic Medical Devices (the "Gyftv.")
- Act XLVII of 2008 on the Prohibition of Unfair Commercial Practices to Consumers ("Fttv.")
- Act XLVIII of 2008 on Basic Conditions and Limits of Economic Advertising Activities (the "Advertising Act")
- Act XCV of 2005 on Medicinal Products for Human Use and on the Amendment of Other Regulations Related to Medicinal Products (the "Medicines Act")
- Decree 3/2009. (II. 25.) of the Minister of Health on the Detailed Rules of the Promotion of Medicinal Products and Therapeutic Medical Devices, the Registration of Medical Sales Representatives and Commercial Practices Targeted to Consumers (the "Promotion Decree")

szabályokról szóló 3/2009. (II.25.) EüM rendelet (a "Promóciós Rendelet") tartalmazzák. Ugyanakkor, ha a promóciós kereskedelmi gyakorlat a gazdasági verseny korlátozására alkalmas, a tisztességtelen piaci magatartás és a versenykorlátozás tilalmáról szóló 1996. évi LVII. törvény (a "Versenytörvény") rendelkezéseit is alkalmazni kell.

A fentieken túl, A Gyógyszer-kommunikáció Etikai Kódexe ("Ágazati Kódex"), melynek aláírói a Magyarországi Gyógyszergyártók Országos Szövetsége, az Innovatív Gyógyszergyártók Egyesülete, a "Védettség" Oltóanyag és Immunbiológiai Termék Gyártók és Forgalmazók Egyesülete és a Generikus Gyógyszergyártók és Forgalmazók Magyarországi Érdekvédelmi Egyesülete, a Magyar Reklámszövetség által kiadott Magyar Reklámetikai Kódex ("Reklámetikai Kódex"), valamint a Magyar Orvosi Kamara Etikai Kódexe ("MOK Kódex") és a Magyar Gyógyszerészi Kamara Etikai Kódexe ("MGYK Kódex") tartalmazzák az egészségügyi szakma és az iparágban, tevékenykedő vállalkozások promóciós tevékenységére vonatkozó, Magyarország területén alkalmazandó etikai normákat.

A szabályozás kategóriái és alapelvei

A magyar jogi szabályozás különbséget tesz a gyógyszerek, az orvostechnikai eszközök, a gyógyászati segédeszközök, a gyógyszernek nem minősülő gyógyhatású készítmények és a hagyományos növényi gyógyszerek között.

Gyógyszer a Gyógyszertörvény szerint bármely anyag vagy azok keveréke, amelyet emberi betegségek megelőzésére vagy kezelésére állítanak elő vagy azok az anyagok vagy keverékei, amelyek farmakológiai, immunológiai vagy metabolikus hatások kiváltása révén az ember valamely élettani funkciójának helyreállítása, javítása vagy módosítása, illetve az orvosi diagnózis felállítása érdekében alkalmazható.

Orvostechnikai eszköz az orvostechnikai eszközökről szóló 4/2009. (III. 17.) EüM rendelet értelmében a) minden olyan, akár önállóan, akár más termékkel együttesen használt készülék, berendezés, anyag, szoftver vagy más termék - ideértve az azok megfelelő működéséhez szükséges szoftvert, amely a gyártó szándéka szerint kifejezetten diagnosztikai, illetve terápiás célra szolgál, valamint a rendelésre készült eszközt, továbbá a klinikai vizsgálatra szánt eszközt is -, amely a gyártó meghatározása szerint emberen történő alkalmazásra szolgál (i) betegség megelőzése, diagnosztizálása, megfigyelése, kezelése vagy a betegség tüneteinek enyhítése, (ii) sérülés

If the promotional commercial practice is likely to have negative effects on economic competition, the relevant provisions of Act LVII of 1996 on the Prohibition of Unfair and Restrictive Market Practices (the "Competition Act") are also applicable.

Furthermore, the ethical rules to be considered by both healthcare professionals and companies advertising or promoting pharmaceuticals within Hungary are contained in the Code of Ethics for Pharmaceutical Communication (the "Industry Code") signed by the Hungarian Pharmaceutical Manufacturers Association, the Association of Innovative Pharmaceutical Manufacturers, the Association "Immunity" of Vaccine and Immunobiological Product Manufacturers and Distributors and the Association of Hungarian Generic Product Manufacturers and Distributors; the Hungarian Code of Ethics for Advertising issued by the Hungarian Association for Advertising (the "HAA Code"): the Code of Ethics issued by the Hungarian Chamber of Medical Practitioners (the "HCMP Code"); and the Code of Ethics of the Hungarian Chamber of Pharmacists (the "HCP Code").

Categories and Basic Principles of the Legislation

Hungarian legislation distinguishes between medicinal products, medical devices, therapeutic medical devices, quasi medicinal products and herbal medicinal products.

Medicinal product: According to the Medicines Act, a medicinal product is any substance or combination of substances offered for treating or preventing disease in human beings, or any substance or combination of substances which may be used in or administered to human beings for restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or for making a medical diagnosis.

Medical device: According to Decree 4/2009. (III.17.) of the Minister of Health on Medical Devices, a medical device means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, as well as custom-made devices and devices intended for clinical investigation which are intended by the manufacturer to be used for the purpose of:

vagy fogyatékosság diagnosztizálása, megfigyelése, kezelése, tüneteinek enyhítése vagy kompenzálása, (iii) az anatómiai felépítés vagy valamely fiziológiai folyamat vizsgálata, helyettesítése, illetve pótlása vagy módosítása, (iv) fogamzásszabályozás céljából, és amely rendeltetésszerű hatását az emberi szervezetben vagy szervezetre elsősorban nem farmakológiai, immunológiai vagy metabolikus módon fejti ki, de működése ilyen módon elősegíthet.

A gyógyászati segédeszköznek nem minősülő orvostechnikai eszközök reklámozása nem esik speciális jogszabályi korlátozás alá.

Gyógyászati segédeszköz az átmeneti vagy végleges egészségkárosodással, fogyatékossággal élő ember személyes használatába adott orvostechnikai eszköz (beleértve az önellenőrzési célt szolgáló in vitro diagnosztikai orvostechnikai eszközt is), vagy orvostechnikai eszköznek nem minősülő ápolási technikai eszköz, amely használata során nem igényli egészségügyi szakképesítéssel rendelkező személy folyamatos jelenlétét. . A Gyftv. részletes szabályokat fogalmaz meg a társadalombiztosítási támogatással rendelhető és a nem támogatott gyógyászati segédeszközök reklámozására vonatkozóan. A Gyftv. továbbá az ajándékozás, a promóciós vendéglátás, a konferencia támogatás és a konferencián való részvétel szponzorációjának szabályait alkalmazni rendeli a gyógyászati segédeszköz rendelésére és forgalmazására jogosultakra is.

Gyógyszernek nem minősülő gyógyhatású készítmény a gyógyszernek nem minősülő gyógyhatású anyagok és készítmények nyilvántartásáról és forgalomba hozataláról szóló 10/1987. (VIII. 19.) EüM rendelet szerint olyan természetes eredetű anyagot tartalmazó készítmény, amely kedvező biológiai hatással rendelkezik, orvosi előírás nélkül is alkalmazható és amely előírásszerű használat esetén egészségi ártalmat nem okoz. A gyógyszernek nem minősülő gyógyhatású készítmények vény nélkül alkalmazhatók, ugyanakkor a Magyarországon történő forgalomba hozatalukat az Gyógyszerészeti és Egészségügyi Minőség- és Szervezetfejlesztési Intézet Országos Gyógyszerészeti Intézet (“GYEMSZI-OGYI”) engedélyezi. A gyógyszernek nem minősülő gyógyhatású készítmények reklámozása a nem vényköteles gyógyszerek reklámozására vonatkozó jogszabályok szerint történik. A gyógyszernek nem minősülő gyógyhatású készítményeket fokozatosan ki kell vonni a forgalomból. Új gyógyszernek nem minősülő gyógyhatású készítmény engedélyezése iránti kérelmet 2005. október 30. után már nem lehet az GYEMSZI-OGYI-hoz benyújtani. A gyártók és a forgalmazók 2011. március 31-ig kérhették a növényi összetevőt is

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
- investigation, replacement or modification of the anatomy or of a physiological process; or
- control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

The advertising of medical devices not qualifying as therapeutic medical devices is not subject to special regulatory restrictions.

Therapeutic medical device: A therapeutic medical device is a medical device for the personal use of patients suffering from temporary or permanent health detriment or deficiency (including *in vitro* diagnostic devices intended for self-use), or care technical devices not qualifying as medical devices during the use of which there is no need for permanent supervision of a healthcare professional. The Gyftv. contains detailed rules on the advertising of therapeutic medical devices, whether supplied with or without a reimbursement. Furthermore, the Gyftv. extends the scope of the promotional rules regarding gift giving, promotional hospitality and sponsorship to the persons entitled to prescribe or supply therapeutic medical devices.

Quasi-medicinal products: According to Decree 10/1987. (VIII.19.) of the Minister of Health, a quasi-medicinal product is a product containing substances of a natural origin which have favorable biological effects and which are not detrimental to health if the product is used consistent with its user instructions. Quasi-medicinal products may be used without a prescription, but must be registered with the Institute for Pharmacological and Healthcare Quality and Operational Development National Institute of Pharmacy (the "GYEMSZI-OGYI") prior to being marketed in Hungary. The same rules apply to the advertising of quasi-medicinal products as to the advertising of medicines that may be used without a prescription. Quasi-medicinal products will be gradually withdrawn from commerce. A new application for the registration of a quasi-medicinal product could not be submitted to the GYEMSZI-OGYI since 30 October 2005. Furthermore, manufacturers and distributors of quasi-medicinal products were required to apply for the re-qualification of their products containing a herbal ingredient (for example, as a medicinal product, cosmetic product or a food supplement) by 31 March 2011. Decree 53/2005. (XI.18.) of the Minister of Health

tartalmazó termékeik gyógyszerré vagy más termékké való átminősítését (például gyógyszerré, kozmetikummá vagy étrend-kiegészítővé). A termékek gyógyszerré történő átminősítésének feltételeit az 53/2005. (XI. 18.) EüM rendelet tartalmazza. A 2011. március 31-én forgalomban lévő olyan gyógyhatású készítmények, amelyek valamennyi sajátosságukat figyelembe véve a hagyományos növényi gyógyszerek kategóriájába sorolhatók a lejárati idejükig, de legkésőbb 2013. április 1-jét hozhatók forgalomba gyógyhatásra történő hivatkozással.

A hagyományos növényi gyógyszer fogalmát az emberi alkalmazásra kerülő gyógyszerek forgalomba hozataláról szóló 52/2005. (XI. 18.) EüM rendelet adja meg. E rendelet szerint a hagyományos növényi gyógyszer az olyan készítmény vagy annak kombinációja, amely (i) kizárólag az adott hatáserősségre és adagolásra jóváhagyott javallat alapján orvosi diagnózis, felügyelet és rendelvény nélkül alkalmazható; (ii) szájon át, külsőleg vagy belélegezve használandó; (iii) irodalmi adatok vagy szakértői jelentések alapján megállapítható, hogy a kérelem alapjául szolgáló termék vagy a megfelelő referencia növényi gyógyszer a kérelem időpontját megelőzően legalább 30 éves időtartamon keresztül gyógyászati használatban volt, ebből legalább 15 évig az Európai Gazdasági Térség területén. A hagyományos növényi gyógyszereket a GYEMSZI-OGYI egyszerűsített forgalomba hozatali eljárásban engedélyezi. Mivel alkalmazásuk orvosi felügyeletet nem igényel, reklámozásuk a nem vényköteles gyógyszerekre vonatkozó szabályok szerint történik. A hagyományos növényi gyógyszerek reklámjában közzé kell tenni azt a figyelmeztetést, hogy "*Hagyományos növényi gyógyszer.A javallatokra vonatkozóan alkalmazása kizárólag a régóta fennálló használaton alapul*".

A fentieken túl, az európai szabályozással összhangban a magyar jogszabályok is megkülönböztetik az anyatej-helyettesítő és az anyatej-kiegészítő tápszereket, valamint a speciális gyógyászati célra szánt tápszereket (a 24/2003. (V. 9.) ESzCsM rendelet, illetve a 20/2008. (V. 14.) EüM rendelet tartalmazza a vonatkozó szabályokat). Eszerint, különösen, az anyatejet-helyettesítő tápszerre vonatkozó reklám csak csecsemőgondozással kapcsolatos, valamint tudományos kiadványban jelenhet meg. A reklám csak tudományos és ténymegállapító információkat tartalmazhat. Az információ nem sugallhatja vagy nem keltheti azt az érzést, hogy a tápszerrel történő táplálás az anyatejjel azonos értékű vagy annál előnyösebb. A speciális gyógyászati célra szánt tápszerek reklámozására az élelmiszerek és étrend-kiegészítők reklámozására vonatkozó szabályokat kell alkalmazni.

contains the conditions for the re-qualification of quasi-medicinal products. Quasi-medicinal products that are on the market by 31 March 2011 that could be categorized as a traditional herbal medicine based on their characteristics may continue to be distributed until their expiry date, but only until 1 April 2013.

The concept of herbal medicinal products is defined in Decree 52/2005. (XI. 18.) of the Minister of Health on the Marketing of Medicinal Products. According to this Decree, herbal medicinal products are herbal ingredients or a combination thereof which: are intended and designed for use without the supervision of a medical practitioner and exclusively for administration in accordance with a specified strength and dosage; are an oral, external and/or inhalation preparation; and have been in medicinal use for a period of at least 30 years preceding the date of the application, including at least 15 years within the EEA. Herbal medicinal products are subject to a special, simplified registration procedure with the GYEMSZI-OGYI. As the use of these products does not require medical supervision, they can be advertised according to the rules applicable to OTC medicinal products. The following warning must be indicated in the advertisement of traditional herbal medicinal products:

“Traditional herbal medicinal product. Regarding the therapeutic indications, its application is solely based on long-standing use.”

Furthermore, in line with the relevant EU legislation, Hungarian law makes a distinction between infant milk and follow-on milk, as well as dietary foods for special medical purposes (Decree 24/2003. (V. 9.) of the Minister of Health and Decree 20/2008. (V. 14.) of the Minister of Health contain these rules). According to this, in particular, the advertisement of infant formulae may only contain information of a scientific and factual nature. Such information may not imply or create a belief that bottle feeding is equivalent or superior to breast-feeding. The advertising rules applicable to food products and food supplements apply to dietary foods for special medical purposes.

The Advertising Act, the Medicines Act, the Promotion Decree and the Gyftv. contain restrictions regarding every aspect of the advertising and promotion of medicinal products and therapeutic medical devices.

A Reklámtörvény, a Gyógyszertörvény, a Promóciós Rendelet és a Gyftv. korlátozó rendelkezéseket fogalmaz meg az emberi felhasználásra kerülő gyógyszerek és gyógyászati segédeszközök reklámozásának és ismertetésének minden formája tekintetében.

A gyógyszer-, gyógyászati segédeszköz reklám fogalma

A Gyftv., illetve a Promóciós Rendelet tartalmazza a gyógyszerekkel, gyógyászati segédeszközökkel kapcsolatos kereskedelmi gyakorlatokra vonatkozó ágazatspecifikus szabályokat.

A Gyftv. alapján a kereskedelmi gyakorlat fogalma nagyon tág, az magában foglal minden, a gyógyszer, illetve gyógyászati segédeszköz rendelésének, beszerzésének, értékesítésének vagy fogyasztásának előmozdítására irányuló tájékoztatást, tevékenységet, kereskedelmi kommunikációt, ideértve a reklámot is.

A Reklámtörvény értelmező rendelkezései tágan határozzák meg a reklám fogalmát, amely szerint reklámnak minősül minden olyan közlés, tájékoztatás, illetve megjelenítési mód, amely

(i) valamely termék, szolgáltatás, ingatlan, vagyoni értékű jog értékesítésének vagy más módon történő igénybevételének előmozdítására; vagy
(ii) e céllal összefüggésben a vállalkozás neve, megjelölése, tevékenysége népszerűsítésére vagy áru, árujelző ismertségének növelésére irányul.

A fenti kiterjesztő definíció alapján a vállalati kommunikáció csaknem minden formája reklámnak minősülhet, ha az a gyógyszer, gyógyászati segédeszköz nevét vagy bármely, a gyógyszert, gyógyászati segédeszközt azonosító utalást (pl. nemzetközi szabadnév vagy a hatóanyag és a gyártó együttes megjelölése, illetve egyéb utalás) tartalmaz.

Az európai szabályozással összhangban a Gyftv. egyértelműen felsorolja azokat az eseteket, amelyek nem tekinthetők gyógyszer, gyógyászati segédeszköz reklámnak. Nem minősül reklámnak a gyógyszer címkéje és betegtájékoztatója, a gyógyászati segédeszköz használati utasítása, valamint az olyan tényszerű informatív bejelentések és tájékoztató jellegű anyagok, amelyek a csomagolás megváltoztatásáról, vagy gyógyszer esetében a kedvezőtlen mellékhatásokról tájékoztatnak, illetve a kereskedelmi árlista,

The Definition of Medicinal Product and Therapeutic Medical Device Advertising

The Gyftv. and the Promotion Decree contain the sector-specific regulation of commercial practices related to medicinal products and therapeutic medical devices.

Based on the Gyftv., the definition of commercial practice is very broad to include any information, activity, commercial communication, including advertising, that aims at fostering the prescription, procurement, sale or consumption of a medicinal product or a therapeutic medical device.

The Advertising Act defines the term "advertisement" broadly, to include any information, communication or manner of presentation intended:

- to foster the sale or use in any way of products, services, real estate, rights of pecuniary value; and
- in connection with the above-mentioned purpose, to facilitate the popularization of the name, designation or activity of an undertaking or the identification of goods.

Given this broad definition, almost every communication from an undertaking might qualify as an advertisement if it contains the name of the medicinal product / therapeutic medical device or a reference identifying the product (for example, a parallel indication of the international common name or the active substance together with the name of the manufacturing company or other reference).

Consistent with the provisions of the European legislation, the Gyftv. unambiguously lists the cases which do not qualify as advertisements of medicinal products, being: the product label and the patient information leaflet of medicines; the instructions for use of therapeutic medical devices; factual, informational materials on the modification of the packaging, or on adverse effects or the commercial price list, provided that they do not contain statements regarding the effects of the medicinal product or the application of the therapeutic medical device.

feltéve hogy az nem tartalmaz a gyógyszer hatásával, vagy a gyógyászati segédeszköz alkalmazásával kapcsolatos állításokat.

Vényköteles és nem vényköteles gyógyszerek, illetve gyógyászati segédeszközök reklámja

Az Európai Unió vonatkozó irányelvével összhangban, a gyógyszerreklámozásra vonatkozó magyar szabályok is megkülönböztetik a vényköteles gyógyszerek és a vény nélkül alkalmazható ("OTC") gyógyszerek kategóriáját. A Gyftv. kiterjesztette az OTC gyógyszerek reklámozásának szabályait a vény nélkül is kiadható gyógyászati segédeszközök reklámozására. Továbbá, a Gyftv. kiterjesztette a vényköteles, társadalombiztosítási támogatással rendelhető gyógyszerek reklámozásának szabályait a társadalombiztosítási támogatással rendelhető gyógyászati segédeszközök reklámozására.

A vényköteles vagy társadalombiztosítási támogatásba befogadott gyógyszerek és a társadalombiztosítási támogatással rendelhető gyógyászati segédeszközök reklámozása kizárólag a gyógyszerek, illetve gyógyászati segédeszközök rendelésére és forgalmazására jogosult szakmai kör számára megengedett (gyógyszerismertetés). Ezen termékek betegek irányában történő reklámozása tilos. A tilalom nem vonatkozik - az egészségnevelési célú - az egészségügyi államigazgatási szerv által egyedileg engedélyezett védőoltási programokat népszerűsítő kampányokra, valamint az ezekhez kapcsolódó gyógyszerekről szóló tájékoztatásra. A Gyftv. szerint a gyógyszerek, illetve gyógyászati segédeszközök rendelésére és forgalmazására jogosult személynek tekinthető az orvos, a gyógyszerész, a gyógyszer-előállító és kereskedő, valamint a gyógyászati segédeszköz-előállító és kereskedő.

Az OTC gyógyszerek és a társadalombiztosítási támogatással nem rendelhető gyógyászati segédeszközök reklámja megengedett, azonban számos korlátozás alá esik. A reklámnak például a következő információkat kell tartalmaznia: a gyógyszer/gyógyászati segédeszköz neve, információ a rendeltetésszerű használatra vonatkozóan, egyértelmű felhívás a betegtájékoztató/használati útmutató elolvasására. Ezen túl a reklámnak tartalmaznia kell a következő figyelmeztető szöveget: (gyógyszerek esetében) "A kockázatokról és a mellékhatásokról olvassa el a betegtájékoztatót, vagy kérdezze meg kezelőorvosát, gyógyszerészét!"; (a társadalombiztosítási támogatással nem rendelhető gyógyászati

Advertisements of Prescription-Only Medicines and Therapeutic Medical Devices and of Medicines and Therapeutic Medical Devices which may be Purchased and Applied without a Prescription

In line with the relevant EU directive, Hungarian pharmaceutical advertising rules also distinguish between prescription medicines and medicines which may be bought and applied without a formal prescription, the latter being the over-the-counter ("OTC") medicines. The Gyftv. extended the scope of the provisions regarding the advertisements of OTC medicines to therapeutic medical devices which may be bought and applied without a formal prescription. Furthermore, the Gyftv. extended the rules regarding the promotion of prescription-only, reimbursed medicines to reimbursed therapeutic medical devices.

The promotion of prescription-only or reimbursed medicines and reimbursed therapeutic medical devices is permitted solely to the specified group of healthcare professionals entitled to prescribe or supply medicinal products and therapeutic medical devices. It is prohibited to advertise the product to the general public. This prohibition does not apply to information conveyed in connection with campaigns for the promotion of vaccination programs which are authorized by the government body in charge of the healthcare system, and to information on the medicinal products connected to these campaigns.

According to the Gytfv., the persons entitled to prescribe and distribute medicinal products and therapeutic medical devices are as follows: medical doctors, pharmacists, and manufacturers and distributors of medical products or therapeutic medical devices.

Although permitted, several restrictions apply to the advertising of OTC products and non-reimbursed therapeutic medical devices. For example, certain specific items of information – the name of the medicinal product or therapeutic medical device; the information required for its correct use; and an express, legible invitation to read the package leaflet – must be indicated in the advertisement. Furthermore, the advertisement must contain the following warnings:

- in case of medicinal products: "For information on risks and adverse effects, please read the patient leaflet or consult with your doctor or pharmacist.";
- and in case of therapeutic medical devices): "For information on risks, please read the instructions for use or consult with your doctor."

segédeszközök esetében) “A kockázatokról olvassa el a használati útmutatót, vagy kérdezze meg kezelőorvosát!”.

Tilos továbbá közzétenni:

(i) Magyarországon nem forgalmazható, illetve nem alkalmazható gyógyszerről, illetve gyógyászati segédeszközről készített reklámot;
(ii) kábítószert vagy pszichotrop anyagot tartalmazó gyógyszerre vonatkozó reklámot;
(iii) vizsgálati készítményt bemutató gyógyszerreklámot; (iv) gyerekkorúaknak szóló reklámot;
(iv) olyan vény nélkül is beszerezhető gyógyszer reklámját, amely gyógyszer nevével azonos elnevezésű, kizárólag orvosi vényre kiadható gyógyszer is forgalomban van;
(v) olyan vény nélkül is beszerezhető gyógyszer reklámját, amelynek árához külön jogszabály alapján a központi költségvetés, illetve az Egészségügyi Alap az arra jogosultaknak támogatást nyújt;
(vi) olyan gyógyászati segédeszköz reklámját, amely a társadalombiztosítás által támogatott gyógyászati segédeszköz nevével azonos elnevezésű – csak jelzőben, számban különböző - eszközt reklámoz.

A gyógyszerek, gyógyászati segédeszközök fogyasztók /betegek felé irányuló reklámozása során figyelemmel kell lenni az általános reklámszabályokra is (Fttv., Reklámtörvény), amelyek tiltják a fogyasztókkal szembeni tisztességtelen (így különösen megtévesztő vagy agresszív) kereskedelmi gyakorlat alkamazását, illetve szigorú feltételeket támasztanak az összehasonlító reklámokkal szemben.

A Gyftv. lehetővé teszi bizonyos OTC gyógyszerek patikán kívüli forgalmazását. A gyógyszertáron kívüli gyógyszer-forgalmazás során is alkalmazni kell az OTC gyógyszerek reklámozására vonatkozó szabályokat.

Megengedett és tiltott magatartások

Ajándékok, tudományos rendezvények, vendéglátás, szórakoztatás

A Gyftv. 14. § (1) bekezdése alapján az ismertető tevékenységet végző a gyógyszerek, illetve gyógyászati segédeszközök rendelésére, forgalmazására jogosultnak ajándékot, anyagi előnyt vagy más természetbeni juttatást nem adhat, nem ajánlhat fel és nem ígérhet, kivéve ha a felsoroltak csekély

Furthermore, it is prohibited to publish advertisements:

- concerning medicinal products or therapeutic medical devices that are not permitted to be distributed or applied in Hungary;
- concerning medicinal products that contain certain psychotropic or narcotic substances;
- concerning investigational medicinal products;
- directed towards children;
- concerning an OTC medicine if there is a prescription-only medicinal product in circulation under the same name;
- concerning an OTC medicine if the product receives reimbursement upon ordering by prescription; and
- concerning a therapeutic medical device if a reimbursed therapeutic medical device is in circulation under the same name.

In addition to the above, the general rules on advertising must also be considered advertising of medicinal products or therapeutic medical devices to consumers /patients (Fttv., Advertising Act). These prohibit unfair commercial practices (especially misleading or aggressive commercial practices) and provide for strict requirements applicable to comparative advertisements.

The Gyftv. allows the distribution of certain OTC medicinal products outside of pharmacies. The rules on the promotion of OTC medicines must also be applied in the case of the non-pharmacy sale of medicines.

Permitted and Prohibited Practices

Gifts, Seminars, Hospitality and Entertainment

Section 14 (1) of the Gyftv. prohibits a company or person engaged in the advertising of medicinal products from giving, offering or promising gifts, pecuniary advantages or benefits in kind to persons qualified to prescribe or supply medicinal products, unless the gifts are inexpensive and relevant to the practice of medicine.

According to the Gyftv., a gift qualifies as inexpensive if its value does not exceed five percent of the current statutory minimum income (in 2012, HUF 93,000, five percent of which is HUF4,650, approximately EUR16). Inexpensive gifts (such as note-pad papers, pens, and books) may be given to those who are entitled to prescribe or distribute medicinal products and therapeutic medical devices. The logo of the company may be indicated on

értékűek és összefüggnek a gyógyszerek rendelésére vagy forgalmazására jogosult által folytatott egészségügyi tevékenységgel.

A Gyftv. szerint csekély értékű az ajándék, ha értéke nem haladja meg a mindenkori minimálbér havi összegének 5%-át (ami 2012-ben 93.000 forint, ennek 5%-a 4.650 forint, hozzávetőleg 16 Euro). Csekély értékű ajándék (pl. jegyzettömb, toll, kisebb értékű könyv) adható tehát a gyógyszerek/gyógyászati segédeszközök rendelésére és forgalmazására jogosultaknak. Az ajándéktárgyakon feltüntethető a társaság logója is. A Reklámtörvény alapján azonban a vállalkozás logóját viselő valamennyi tárgyat úgy kell tekinteni, hogy reklám céljából adták.

Az ismertetést végző pénzbeli juttatást vagy előnyt semmilyen módon nem adhat, nem ajánlhat fel és nem ígérhet.

A magyar szabályozás az európai irányelvekhez képest szigorúbb rendelkezéseket tartalmaz a promóciós és szakmai rendezvények, valamint a tudományos konferenciák támogatása tekintetében.

A Gyftv. szerint gyógyszerek és gyógyászati segédeszközök bemutatását, ismertetését segítő rendezvények kizárólag szakmai, tudományos vagy oktatási céllal szervezhetőek. Az ilyen típusú rendezvényeken az ismertető tevékenységet végző által biztosított egy napra eső vendéglátás összege nem haldhatja meg a csekély értékű ajándékra vonatkozó, fentiekben ismertetett értékhatárt (4.650 forint, hozzávetőleg 16 Euro). és a rendezvény fő céljához képest másodlagosnak kell lennie. A rendezvényre, illetve a bemutatóra az egészségügyben, illetve a gyógyszerellátásban vagy a gyógyászati segédeszköz ellátásban közreműködő szakembereken kívül más személy nem hívható meg.

A szakmai és tudományos célokat szolgáló rendezvények és programok közvetett vagy közvetlen formában történő támogatásának mindenkor ésszerű mértékűnek és a rendezvény fő tudományos célkitűzéseihez képest alárendeltnek kell lennie.

A Gyftv. szerint az “ésszerű mértékű támogatást” úgy kell értelmezni, hogy a támogatás egy főre eső összege nem haladhatja meg a mindenkori minimálbér havi összegének 5%-át (tehát ugyanannyi mint a csekély értékű ajándék értéke, vagyis fejenként 4.650 forint, kb. 16 Euro).

the gift. However, any item bearing the company logo is deemed by the Advertising Act to be given for the purpose of advertising.

The advertiser may in no case give, offer or promise a monetary benefit.

Hungarian legislation contains rules stricter than comparable EU directives concerning sponsorship of promotional and professional meetings.

According to the Gyftv., events enhancing the promotion of medicinal products or therapeutic medical devices may only be organized for professional, scientific or educational purposes. The hospitality provided at such events should may not exceed the threshold limit regarding inexpensive gifts as detailed above (HUF4,650, approximately EUR16), per day, and such hospitality must be subordinate to the main purpose of the event. Only professionals active in the health care system or in the supply of medicinal products or therapeutic medical devices may be invited to these events.

Sponsorship offered, directly or indirectly, at events for purely professional and scientific purposes must always be reasonable in degree and remain subordinate to the main scientific objective of the meeting.

According to the Gyftv., the amount of "reasonable sponsorship" of scientific conferences for one participant shall be five percent of the monthly amount of the statutory minimum income (i.e., the same amount as the threshold for gift-giving: HUF4,650 or approximately EUR16 per person).

The promotional purpose must always remain subordinate to the scientific purpose of the conference. According to the Gyftv., promotional activities are only allowed at scientific events if the direct or indirect promotion (e.g., the presentation of the application of a particular product, the hiring of exhibition stands, and the purchasing of advertising space in the conference materials) is well separated in the conference program.

According to the Gyftv., in-kind sponsorship may be granted to persons who are engaged in medical or scientific activities in order to make it possible for them to attend professional conferences and courses. The in-kind sponsorship may only cover the costs directly associated with the conference (e.g. travel and accommodation expenses, and registration fee).

A tudományos rendezvények támogatása esetében a promóciós cél háttérben kell, hogy maradjon. Ezt szolgálja a Gyftv. azon rendelkezése is, miszerint a szakmai és tudományos programokon ismertető tevékenység csak abban az esetben folytatható, ha a közvetett és a közvetlen formában történő ismertető tevékenység (konkrét termék alkalmazásával kapcsolatos előadás, kiállítóhely bérlése, hirdetések közzététele a konferencia anyagokban) a szakmai, tudományos rendezvény programjában jól elkülönül.

A Gyftv. szerint természetbeni támogatás nyújtható az egészségügyi vagy tudományos tevékenységet folytató személy számára szakmai rendezvényeken, tanfolyamokon történő részvételre. A természetbeni támogatás kizárólag a rendezvényeken történő részvétellel közvetlen összefüggésben felmerülő kiadások (így különösen utazási költség, szállásköltség, részvételi díj) fedezetére szolgálhat.

A promóciós eseményekre, illetve a tudományos konferenciákra meghívható személyek köre meglehetősen tág, lényegében lefedi az egészségügyben, gyógyszer-és gyógyászati segédeszköz ellátásban tevékenykedő személyek teljes körét (pl. orvosok, gyógyszerészek, nővérek, laborasszisztensek, gyógyszer nagykereskedők, stb).

A támogatás kizárólag természetbeni lehet. Ez a gyakorlatban azt jelenti, hogy a gyógyszercégek / gyógyászati segédeszköz forgalmazók pénzbeli támogatást nem nyújthatnak az orvosnak, hanem erre szakosodott részlegük, vagy egy megbízott utazásszervező segítségével kell megszervezniük az orvos konferencián való részvételét (regisztráció, szállás, utazás, étkezés) és az orvosnak csak a már megvásárolt repülőjegyet, szállásfoglalás igazolását stb. adhatják át. A korábbi szabályokkal ellentétben a Gyftv. nem ír elő pályáztatási kötelezettséget a konferenciára utaztatással kapcsolatban.

A Gyftv. szerint egy adott helyszínen rendezvényt támogatni, illetve egy adott helyszínhez kötött rendezvényen való részvételt támogatni csak akkor lehet, ha a rendezvény tárgyát képező vagy céljához szükséges erőforrások vagy szakértelem kizárólag e helyszínen állnak rendelkezésre, vagy azok más, a résztvevők munkahelyéhez közelebbi helyszínen való biztosítása aránytalan többletköltséggel járna.

Továbbá, társadalombiztosítási támogatással gyógyszerek, illetve gyógyászati segédeszközök rendelésére és forgalmazására jogosult résztvevők számára megrendezett szakmai-tudományos rendezvény

The group of persons who may be invited to promotional and scientific events is rather broad as it is includes all healthcare professionals engaged in healthcare activities in the distribution and supply of medical products or therapeutic medical devices (such as doctors, pharmacists, nurses, laboratory assistants and distributors of medical products).

Only in-kind sponsorship may be granted to healthcare professionals. In practice, this means that pharmaceutical companies and the distributors of therapeutic medical devices may not transfer money to individual healthcare professionals , but they are required to organize, either through their internal department or a travel agent, the attendance of the medical doctor at the conference (registration fee, accommodation, travel and meals); i.e., companies may only provide the plane ticket, the confirmation of hotel booking, to the medical doctor.

Contrary to previous legislation, the Gyftv. does not require that sponsorship to attend scientific events be provided through a public tender.

Pursuant to the Gyftv., participation of a healthcare professional in a conference or the organization of an event at a given location may only be sponsored by a pharmaceutical company if the necessary means or proficiency can be ensured at such location, or if the organization of the conference at a closer location to the participants' workplace would cause unreasonable additional costs.

In addition, the organization of supplementary scientific programs for those healthcare professionals who are entitled to prescribe medicinal products or therapeutic medical devices with reimbursement is only allowed and the healthcare professionals' participation in such supplementary scientific programs may only be sponsored by a pharmaceutical company if such supplementary scientific program takes place during the scientific event.

The Gyftv. clearly states that persons entitled to prescribe or supply medicinal products and therapeutic medical devices may not solicit or accept any inducement, which is not compliant with those described above.

The Gyftv. requires that pharmaceutical companies must notify the GYEMSZI-OGYI of any direct or indirect sponsorship of professional events and training courses by submitting to the authority the data listed in the Gyftv. no later than 30 days before the date of the event or training course.

helyszínén a rendezvényhez kapcsolódó, kiegészítő szakmai vagy tudományos program, vagy az azon való részvétel csak akkor támogatható, ha arra a szakmai-tudományos rendezvény idején kerül sor.

A Gyftv. egyértelműen rögzíti, hogy a gyógyszerek és gyógyászati segédeszközök rendelésére és forgalmazására jogosult személy nem kérhet és nem fogadhat el a fentiekben részletezett szabályokkal ellentétes ösztönzést.

A Gyftv. szerint a gyógyszercégek kötelesek az általuk vagy általuk juttatott forrásból támogatott szakmai rendezvényre, tanfolyamra vonatkozó, a Gyftv.-ben meghatározott adatokat bejelenteni a GYEMSZI-OGYI részére legkésőbb a rendezvény vagy tanfolyam kezdő időpontját megelőzően 30 nappal.

A Gyftv. szerint az egészségügyi szakemberek szakmai rendezvényken való részvételéhez nyújtott támogatást szintén be kell jelenteni a GYEMSZI-OGYI részére (a Gyftv.-ben meghatározott adatok benyújtásával).

Gyógyszerismertetői tevékenység

A Gyftv. szerint a gyógyszer és gyógyászati segédeszköz ismertetése olyan, a gyógyszerekre és gyógyászati segédeszközökre, a gyógyszer összetételére, hatására, illetve a gyógyszer és a gyógyászati segédeszköz alkalmazására vonatkozó kereskedelmi gyakorlat, amely kizárólag a gyógyszerek és a gyógyászati segédeszközök rendelésére, használatának betanítására és forgalmazására jogosult egészségügyi szakképesítéssel rendelkezőknek (orvos, gyógyszerész, gyógyszer-előállító és kereskedő és a gyógyászati segédeszköz-előállító és kereskedő) szól, vagy amelyet velük szemben alkalmaznak.

Amennyiben a gyógyszer forgalomba hozatali engedélyének jogosultja, a gyógyszer forgalmazására engedéllyel rendelkező, valamint a gyógyászati segédeszköz gyártója vagy forgalmazója vagy a fentiek megbízása alapján más gazdálkodó szervezet (ismertetési tevékenységet folytató) ismertető tevékenységet kíván folytatni, köteles az erre irányuló szándékát a GYEMSZI-OGYI-nak bejelenteni. Az ismertetési tevékenységet folytató ismertetési tevékenységet csak az általa munkaviszonyban vagy munkavégzésre irányuló egyéb jogviszonyban foglalkoztatott, a Promóciós Rendeletben meghatározott képzettségi követelményeknek megfelelő, a GYEMSZI-OGYI által nyilvántartásba vett, ismertetői igazolvánnyal rendelkező természetes személy útján folytathat.

Pursuant to the Gyftv., pharmaceutical companies must also notify the GYEMSZI-OGYI (by submitting data listed in the Gyftv.) of the sponsorship of healthcare professionals' participation in professional events.

Promotion of Medicinal Products to Healthcare Professionals

Pursuant to the Gyftv. Act, the promotion of medicinal products and therapeutic medical devices shall comprise commercial practices pertaining to the composition, efficacy or application of medicinal products and therapeutic medical devices targeted solely at healthcare professionals entitled to prescribe, supply or teach the use of medicinal products and therapeutic medical devices (i.e., doctors, pharmacists, manufacturers and distributors of medicinal products or therapeutic medical devices).

A marketing authorization holder of a medicinal product, a person licensed to engage in pharmaceutical wholesale, a manufacturer or distributor of a therapeutic medical device or the authorized representative of such companies (company engaged in medicine promotion) may only promote the products subject to prior notification filed at the GYEMSZI-OGYI.

The companies engaged in medicine promotion may only perform promotional activities through a natural person employee or contractor who complies with the qualification requirements provided for in the Promotion Decree, who has been registered by the GYEMSZI-OGYI, and who has obtained an ID card from the GYEMSZI-OGYI.

The position of a medical sales representative for medicines may only be held by a person who is employed/contracted by the company engaged in medicine promotion or by the GYEMSZI-OGYI and who is professionally qualified as a medical doctor, a dental surgeon, a pharmacist, a biologist, a chemist or a graduate of the college for healthcare workers, or who has been exempt from the above qualification requirements before 14 March 2007. The applicable laws do not provide for any qualification requirements concerning sales representatives engaged in the promotion of therapeutic medical devices.

Pharmaceutical companies engaged in promotion must pay a special tax of HUF832,000 (approximately EUR2,800) for each medical sales representative ("MSR") employed by them on a monthly basis. This payment obligation is less for medical device companies: HUF83,000 (approximately EUR280) per month per MSR. If the MSR is admitted to or removed from

A Promóciós Rendelet szerint gyógyszerismertetést a GYEMSZI-OGYI-val vagy az ismertetési tevékenységet folytatóval munkaviszonyban vagy munkavégzésre irányuló egyéb jogviszonyban álló orvos, fogorvos, gyógyszerész, biológus, vegyész, egészségügyi főiskolát végzett személy, továbbá olyan személy folytathat, aki a gyógyszerismertetési tevékenység végzéséhez előírt feltételek teljesítése alól 2007. március 14-ét megelőzően felmentést kapott.

A vonatkozó jogszabályok nem írnak elő speciális képesítési követelményeket a gyógyászati segédeszköz ismertetést végző személy vonatkozásában.

Az ismertető tevékenység végzésére vonatkozó engedéllyel rendelkezőt minden általa munkavégzésre irányuló jogviszony keretében foglalkoztatott ismertető személy tevékenysége után havonta gyógyszerismertetés esetén 832,000 forint (kb. 2.800 Euro), gyógyászati segédeszköz ismertetése esetén 83.000 forint (kb. 280 Euro) összegű befizetési kötelezettség terheli. Ha a bejelentés alapján az ismertető személy hóközben kerül bejegyzésre vagy törlésre, a fizetési kötelezettséget a fenti összegnek a jogviszony napokban meghatározott fennállásának a hónap naptári napjai arányos része figyelembevételével kell teljesíteni. A Gyftv. tételesen felsorolja azokat az eseteket, amikor az ismertetési tevékenységet folytatót nem terheli befizetési kötelezettség az általa munkavégzésre irányuló jogviszony keretében foglalkoztatott ismertető személy után (például amennyiben az ismertető személy táppénzen van, gyermekgondozási segélyt kap vagy fizetés nélküli szabadságát tölti).

Amennyiben a gyártó egy marketing céget bíz meg az ismertető tevékenység folytatásával, és az orvoslátogatók a megbízott alkalmazásában állnak, a megbízott lesz köteles az ismertetők után megfizetni a fenti adót. A fizetési kötelezettséget azonban a megbízott szerződésben tovább háríthatja a gyógyszercégre/ gyógyászati segédeszköz gyártóra, forgalmazóra, mint a termékek tényleges reklámozójára.

Az ismertetést végző személy az orvost kizárólag előre egyeztetett időpontban keresheti fel. Az ismertetés megkezdése előtt az igazolványát fel kell mutatni. Az ismertetést végző személy az ismertetői tevékenység folytatása során a rendelést nem zavarhatja, illetve nem akadályozhatja az orvos egészségügyi szolgáltató tevékenységét. A Promóciós Rendelet szerint az ismertetést végző személy az orvost csak olyan időpontban látogathatja, amikor az gyógyító-megelőző tevékenységet nem végez.

the register during the month, the company's payment obligation shall be proportionate to the number of days during which the MSR was engaged in promotional activities in the given month.

The Gyftv. contains a list of periods during which the company will be exempt from the payment of the sales rep tax (e.g., the duration of sick leave, maternity leave or the period of unpaid vacation).

If the manufacturer gives a mandate to a marketing company to engage in promotional activities and the MSRs are also employed by the marketing company, the mandated person will be obliged to pay the tax in respect of the MSRs. However, the mandated marketing company will very likely pass the payment obligation onto the pharmaceutical / medical device manufacturer in their contract for services as it is in the pharmaceutical / medical device manufacturer's interest that the products be promoted.

MSRs may only promote the medicinal products to medical doctors during a previously scheduled appointment. The medical representative may not in any case disturb the consulting hours or hinder the activities of a doctor engaged in providing healthcare. According to the Promotion Decree, MSRs may only visit medical doctors when the medical doctor is not engaged in providing healthcare or preventive care.

Pursuant to the Gyftv. and the Promotion Decree, the promotion of medicinal products must always be in compliance with the summary of product characteristics of the medicinal product or the instructions for use of the therapeutic medical device in question.

The Industry Code states that promotional information presented to healthcare professionals must include, clearly and legibly, essential information consistent with the summary of product characteristics (specifying the date on which such essential information was generated or last revised) with special regard to the conditions of safe use (counter indications). Furthermore, promotional materials distributed by MSRs must call for a detailed study of the summary of product characteristics of a given product.

All the information given, including written documentation provided, by the MSRs must be precise, accessible, verifiable and up-to-date, and must be presented in such detail that enables the person qualified to prescribe or supply medicine or medical device to form an opinion about the product's

A Gyftv. és a Promóciós Rendelet szerint az ismertetés során átadott információ tartalmának összhangban kell állnia az ismertetett gyógyszer alkalmazási előírásában, illetve az ismertetett gyógyászati segédeszköz használati útmutatójában foglaltakkal.

Továbbá, az Ágazati Kódex szerint a promóciós anyagoknak tisztán és olvasható módon kell tartalmazniuk az alkalmazási előirat alapján összefoglalt ún. alapvető információkat (az alkalmazási előirat dátumával együtt), különös tekintettel a biztonságos alkalmazás feltételeire (ellenjavallatok), valamint fel kell hívniuk a figyelmet az alkalmazási előirat részletes tanulmányozására.

A fentieken túl, az ismertetés során a gyógyszerre/gyógyászati segédeszközre vonatkozó valamennyi információnak és átadott írásos anyagnak pontosnak, hozzáférhetőnek, ellenőrizhetőnek és naprakésznek kell lennie annak érdekében hogy a gyógyszerek, illetve gyógyászati segédeszközök rendelésére és forgalmazására jogosultak véleményt alkothassanak az ismertetett termékek alkalmazásáról, előnyeiről és hátrányairól. A tudományos forrásból származó idézeteket az eredetihez hű formában kell visszaadni és a pontos forrást fel kell tüntetni. A Promóciós Rendelet szerint minden írott dokumentumnak tartalmaznia kell a dokumentum lezárásának vagy utolsó aktualizálásának időpontját. Amennyiben a gyógyszer/gyógyászati segédeszköz társadalombiztosítási támogatásban részesül, a gyógyszerismertetés során átadott információnak tartalmaznia kell a közfinanszírozás alapjául szolgáló árat, a támogatás összegét és a gyógyszer térítési díját.

A MOK Kódex előírja, hogy az orvos csak szakszerű, tudományosan megalapozott, statisztikai adatokkal alátámasztott tájékoztatást fogadhat el az orvoslátogatótól.

Az orvosnak ragaszkodnia kell a tájékoztató anyagok forrásának megjelöléséhez és a gyógyszer alkalmazásával kapcsolatos teljes körű ismertetéshez.

Gyógyszerminta

Minden ismertetést végző személy az általa ajánlott gyógyszerből, egyszer használatos gyógyászati segédeszközből a gyógyszerek, illetve gyógyászati segédeszközök rendelésére és forgalmazására jogosultak aláírt és keltezéssel ellátott írásbeli kérésére, az adott gyógyszer, illetve egyszer használatos

application, advantages and disadvantages. Quotations taken from medical journals or other scientific works for use in promotional documents must be faithfully reproduced and the precise source refernced. According to the Promotion Decree, each written document must state the date on which it was finalized or last revised. If the medicinal product or therapeutic medical device is reimbursed, the information provided by MSRs during their visits must include the price serving as the basis for reimbursement, the amount of reimbursement and the consumer price of the product.

The HCMP Code provides that a medical doctor may consider only information communicated by an MSR, that is professional, scientifically-grounded and based on proper statistical data. The doctor must insist on a full-scope representation and require the MSR to indicate the scientific sources of all the information communicated.

Free Medical Samples

Each MSR may supply a limited number of free samples of medicines and disposable medical devices to persons qualified to prescribe or supply medicine or therapeutic medical devices until the end of the year following the year in which the product was been placed on the Hungarian market, to enable people to familiarize themselves with the product, in response to a written request signed by the recipient. Free samples may be given:

- in case of a healthcare service provider offering inpatient care, through the chief institutional pharmacist (in which case, the supply of samples must be recorded in the registry of the institution's pharmacy); or
- in case of any other healthcare service providers, directly to the person qualified to prescribe medicine or therapeutic medical devices.

The sample must include a summary of product characteristics for medicines and the instructions for use of therapeutic medical devices.

Pursuant to the Promotion Decree, two packaging units may be provided per year per medicinal product or per disposable therapeutic medical device for those who are authorized to prescribe and distribute medicinal products, provided that the two-packaging units not exceed the amount sufficient for a one-month treatment.

Furthermore, a protocol must be prepared for each delivery of samples. The protocols must be retained for five years and - in case of reimbursed

gyógyászati segédeszköz magyarországi értékesítésének megkezdését követő év végéig térítésmentes mintát adhat annak érdekében, hogy a termék megismerését elősegítse. Ingyenes minta adható:

- a fekvőbeteg-ellátást biztosító egészségügyi szolgáltató esetén az intézeti főgyógyszerész útján (ebben az esetben a minta átadását az intézeti gyógyszertár nyilvántartásában rögzíteni kell);
- más egészségügyi szolgáltatók esetében közvetlenül a gyógyszerek, gyógyászati segédeszközök rendelésére és forgalmazására jogosultnak.

A mintával együtt át kell adni a gyógyszerre vonatkozó alkalmazási előírást, illetve a gyógyászati segédeszközre vonatkozó használati útmutatót.

A Promóciós Rendelet szerint gyógyszerből és egyszer használatos gyógyászati segédeszközből gyógyszerenként, illetve gyógyászati segédeszközönként, valamint a gyógyszerek rendelésére és forgalmazására jogosultanként térítésmentes mintaként évente legfeljebb két csomagolási egység adható azzal, hogy a gyógyászati segédeszköz esetén a két csomagolási egység az egy havi kezelésre alkalmas mennyiséget nem haladhatja meg.

Minden egyes mintaátadást jegyzőkönyvvel dokumentálni kell. A jegyzőkönyvet öt évig meg kell őrizni, illetve - társadalombiztosítási támogatásba befogadott gyógyszer valamint társadalombiztosítási támogatással rendelhető gyógyászati segédeszköz esetén - negyedévente megküldeni a GYEMSZI-OGYI részére. Az átadott minta kiszerelése nem lehet nagyobb mint a gyógyszer, illetve az egyszer használatos gyógyászati segédeszköz legkisebb forgalmazott kiszerelési formája. A csomagoláson fel kell tüntetni az alábbi figyelmeztetést: "*Ingyenes orvosi minta, kereskedelmi forgalomba nem hozható!*", illetve egyszer használatos gyógyászati segédeszköz esetén: "*Ingyenes minta, kereskedelmi forgalomba nem hozható!*" feliratot.

Kábítószernek vagy pszichotrop anyagnak minősülő gyógyszerből gyógyszerminta nem adható.

Közvetlenül a betegek részére kizárólag az orvos által terápiás vagy rehabilitációs célból juttatott gyógyszer vagy gyógyászati segédeszköz minta adható.

medicinal products or therapeutic medical devices - they must be submitted to GYEMSZI-OGYI quarterly. Each sample must be identical with the smallest presentation in the market of the medicine or disposable medical device. The packaging must contain the words: “free medical sample, not for sale”: In the case of disposable therapeutic medical device, the packaging must contain the words: “free therapeutic medical device sample, not for sale.”

Samples of medicinal products containing psychotropic or narcotic substances may not be provided.

A medical sample or therapeutic medical device sample may only be given directly to patients for therapeutic or rehabilitation purposes.

Besides the provision of a medical sample for therapeutic purpose, doctors, pharmacists or suppliers of medical devices may not give or offer directly to patients any gift, sample or coupon enabling the purchase of the product which aims to enhance the consumption or use of a medical product or products of a given pharmaceutical manufacturer, or a reimbursed therapeutic medical device. Furthermore, pharmaceutical or medical device companies may not make the provision of the above benefits conditional upon the use of the product.

Moreover, any reduction, refund or reimbursement of the price the patient is required to pay for reimbursed medical products, is also prohibited in any direct or indirect way or form (by means of, e.g., offering gifts, samples, vouchers, coupons, discounts that are contingent upon the collection of points or by other similar means).

Any benefit provided in connection with dispensing any medicinal products which is not reimbursed - other than price discounts - may solely be used for pharmaceutical consultation services offered by the pharmacist in the pharmacy.

The dispensing of medical products, or any other products that may be sold in pharmacies or consultation services offered by the pharmacists, may not serve as a basis for granting any discount or any other advantage to the patient by the pharmacy or any other entity.

A terápiás célból adott gyógyszer / gyógyászati segédeszköz mintán kívül tilos a betegnek olyan ajándék, minta, vásárlásra jogosító utalvány (kupon) közvetlenül az orvos, gyógyszerész, illetve a gyógyászati segédeszközt kiszolgáltató által történő adása, felajánlása, amely egy adott gyógyszer, vagy egy adott gyógyszergyár termékei, vagy a társadalombiztosítás által támogatott gyógyászati segédeszköz fogyasztására, használatára ösztönöz vagy azt feltételül szabja.

Tilos továbbá a társadalombiztosítási támogatással rendelhető gyógyszerek, tápszerek és gyógyászati segédeszközök beteg által fizetendő térítési díjától bármilyen közvetlen vagy közvetett formában (pl. ajándék, minta, vásárlásra jogosító utalvány, kupon, pontgyűjtésalapú kedvezmény, vagy más hasonló módon) történő eltérés.

A társadalombiztosítási támogatással nem rendelhető gyógyszerek kiszolgáltatása esetén adott bármilyen kedvezmény - az árkedvezmény kivételével - kizárólag a gyógyszertárban nyújtott gyógyszerészi gondozás igénybevételére használható fel.

A gyógyszertárban gyógyszer, tápszer, gyógyászati segédeszköz, gyógyszertárban forgalmazható egyéb termékek kiszolgálása, továbbá a gyógyszerészi gondozás igénybevétele nem adhat alapot saját, vagy más gazdálkodó szervezettől igénybe vehető kedvezményre, ajándékozásra.

Az anyatej-helyettesítő tápszert árusító helyeken nem szabad népszerűsíteni a terméket sem minta adásával, sem más módon (így például: speciális közszemlére tétellel, árengedményes vásárral, ráadásként adott termékként, különleges ajánlatként, csalogató vagy kapcsolt áruként) a tápszer eladás növelése céljából. Az anyatej-helyettesítő tápszert előállító és forgalmazó a nyilvánosságnak, várandós anyának, szoptató anyának vagy családtagjainak ingyenes vagy csökkentett áru készítményt vagy bármely más népszerűsítő ajándékot egészségügyi szolgáltató vagy egészségügyi szolgáltató alkalmazottja útján sem adhat. A tájékoztatáshoz és képzéshez szükséges eszköz és anyag adományozását a tápszer előállítónak és forgalmazónak az Országos Élelmezés- és Táplálkozástudományi Intézethez be kell jelentenie.

Gyógyszer és gyógyászati segédeszköz adomány

Gyógyszer, illetve gyógyászati segédeszköz karitatív célra térítésmentesen csak olyan egészségügyi vagy szociális intézmény, illetve karitatív szervezet

In the case of infant formulae, the product may not be advertised at the sales point either by the giving of samples or any other promotional device aimed at inducing the sale of infant formulae directly to the consumer at the retail level (e.g., special displays, discount coupons, premiums, special sales and tie-in sales). Manufacturers and distributors of infant formulae may not provide to the general public, to pregnant or breastfeeding women or to members of their families, free or low-priced products, samples or any other promotional gifts, even if via healthcare institutions or employees of healthcare institutions. The National Institute for Nutrition and Food Hygiene must be notified when manufacturers or distributors of infant formulae donate informational or educational equipment or materials.

Medicine and Medical Device Donations

Medicinal products and therapeutic medical devices may only be donated for charitable purposes to healthcare or social institutions, or charitable organizations if the professional conditions and the control of the application of the medicine and the use of the medical device are ensured.

The Decree on the Establishment and Operation of the Charity Council (Decree 65/2000. (V. 9.) of the Government) provides the definition of "charitable activity." Pursuant to this definition, charitable activity covers the humanitarian, non-pecuniary aid granted to socially deprived people (e.g., elderly, children, handicapped and homeless people) if the assistance is: offered without discrimination as to race, gender, nationality, belief or religious belief; necessary for the fulfillment of basic needs; not related to political aims; and granted solely on the basis of a means test. In our view, the definition of "charitable activity" determines also the scope and limits the charitable purposes for which medicine and medical device donations may be granted.

According to the Healthcare Act (Act CLIV of 1997), healthcare institutions are: hospitals engaged in inpatient care and outpatient clinics; the National Ambulance Service; institutions of the national blood bank; and the national institutes of the Ministry of Health that provide healthcare. Based on the Social Allowances Act (Act III of 1993), a social institution is an institution providing personal social care, particularly, social basic care (e.g., provision of meals and family care) and specialized care (e.g., nursing homes). The law does not define the notion of charitable organization; however, organizations which engage in charitable activities (e.g., public interest companies and foundations) are likely to qualify as charitable organizations.

számára adható, ahol a gyógyszerek felhasználásának szakmai feltételei, illetve a felhasználás ellenőrzése biztosított.

A karitatív tevékenység fogalmát a Karitatív Tanács megalakításáról és működéséről szóló rendelet (65/2000. (V. 9.) Korm. rendelet) határozza meg. E szerint karitatív tevékenység a szociálisan hátrányos helyzetben lévők (így különösen az idősek, a gyermekek, a fogyatékosok, a hajléktalanok) ellátásához természetben nyújtott humanitárius segélyezési tevékenység, amelyek során a segélyezés, illetve a segítségnyújtás (i) fajra, nemre, nemzetiségre, meggyőződésre, felekezeti hovatartozásra tekintet nélkül történik; továbbá (ii) alapvető szükségletek kielégítésére szolgál; valamint (iii) nem támogat politikai célokat; és (iv) prioritását kizárólag a rászorultság mértéke határozza meg. Ezért a karitatív tevékenység fenti definíciója feltehetően meghatározza azokat a karitatív célokat is, amelyekre hivatkozással gyógyszer, illetve gyógyászati segédeszköz adományozható.

Az egészségügyi intézmény az Egészségügyi Törvény (1997. évi CLIV. törvény) szerint (i) a gyógyintézet (a rendelőintézeti járóbeteg-szakellátást vagy fekvőbeteg- szakellátást nyújtó szolgáltatók); (ii) az Országos Mentőszolgálat; (iii) a vérellátó szolgálat állami szervezetei; valamint (iv) az egészségügyi hatóság intézetei, ha egészségügyi szolgáltatást is nyújtanak. A Szociális Törvény (1993. évi III. törvény) szerint szociális intézmény a személyes szociális gondoskodást nyújtó szervezet. Ilyen különösen a szociális alapellátást (pl. étkeztetés, családsegítés), illetve szakosított ellátást nyújtó intézmények (pl. ápolást, gondozást nyújtó intézmény, lakóotthon). A karitatív szervezet fogalmát jogszabály nem határozza meg, azonban az igazolhatóan karitatív tevékenységet folytató szervezetek (pl. közhasznú szervezetek, alapítványok) valószínűleg karitatív szervezetnek tekinthetők.

A gyógyszer és gyógyászati segédeszköz adomány átadásáról jegyzőkönyvet kell készíteni, amelynek egy példányát a gyógyszer és gyógyászati segédeszköz rendelésére és forgalmazására jogosult személyek és ismertetést végző cég köteles a kiállítástól számított öt évig megőrizni, illetve - társadalombiztosítási támogatásba befogadott gyógyszer valamint társadalombiztosítási támogatással rendelhető gyógyászati segédeszköz esetén - negyedévente megküldeni a GYEMSZI-OGYI részére.

Csak olyan lejárati idejű gyógyszer, vagy gyógyászati segédeszköz adományozható, amelynek felhasználása még a lejárati időn belül biztosítható. Az adomány minden egyes kiszerelési egységén fel kell

A protocol must be prepared upon the delivery of donated medicine and medical devices. The persons authorized to prescribe or supply medicinal products and medical devices as well as the company promoting the products must keep the protocols for five years after the delivery of the donation and - in the case of reimbursed medicinal products or therapeutic medical devices - they must be submitted to the GYEMSZI-OGYI quarterly.

Medicines and therapeutic medical devices may only be donated if the expiry date allows the donee to use the donation for a reasonable time prior to expiration. The following statement must be indicated on each presentation of the donation: “Medicine donation, not for sale!” or “Therapeutic medical device donation, not for sale!”

Other Donations

Pharmaceutical or medical device companies may also grant donations other than medicine or medical devices (e.g., money and equipment). In the case of donations other than medicinal products, there is no statutory requirement that such donation may only be granted to healthcare institutions. However, we suggest providing donations only to healthcare or social institutions or foundations. Companies should not grant donations to individual healthcare professionals (or companies of individual professionals, i.e., partnerships or limited companies of medical doctors) in order to mitigate the risk that the donations may be regarded as unlawful gifts/benefits offered to them.

Further recommendations are as follows:

- Donations should only be granted upon written request of the institution / foundation in question. The request should clearly state the reason why the institution/foundation needs the donation granted by the pharmaceutical or medical device company.
- A written donation agreement should be signed in each case. The agreement may only be executed by the authorized representatives of both parties.
- Monetary donations must not be made in the form of cash.

feltüntetni: „*Gyógyszeradomány, kereskedelmi forgalomba nem hozható!*”, illetve “*Gyógyászati segédeszköz adomány, kereskedelmi forgalomba nem hozható!*”.

Egyéb adomány

A gyógyszer, illetve gyógyászati segédeszköz gyártó, illetve forgalmazó cégek gyógyszeren, gyógyászati segédeszközön kívül más jellegű adományokat is adhatnak (pl. pénzadomány, eszközadomány). Az ilyen adományok esetében nincs speciális jogszabályi előírás a tekintetben, hogy ki lehet az adományozott. Mindazonáltal azt javasoljuk, hogy egyéb adományokat is elsősorban egészségügyi, szociális intézményeknek, illetve alapítványoknak adjanak. Kerülni kell a magánszemély egészségügyi szakembereknek (vagy az általuk működtetett vállalkozásoknak, pl. Bt., Kft.) juttatott támogatást, annak érdekében, hogy az ne minősüljön a gyógyszer, gyógyászati segédeszköz rendelésére, illetve forgalmazására jogosultnak adott ajándéknak.További javaslatok:

- adomány csak az intézmény / alapítvány írásbeli kérése alapján adható.A kérelem egyértelműen tartalmazza, hogy miért van szüksége az intézménynek / alapítványnak az adományra;
- az adományozásról készüljön írásbeli szerződés. A szerződést minden esetben a szerződő felek törvényes képviselői írják alá;
- a pénzadományt nem lehet készpénz formájában átadni.

A jogszabályok megszegésének következményei

Hatósági eljárások

Reklámfelügyeleti eljárás

Az OTC gyógyszerekre, illetve a támogatással nem rendelhető gyógyászati segédeszközökre vonatkozó reklámozási szabályok megsértése esetén a fogyasztóvédelmi felügyelőségek (“NFH”) vagy a Gazdasági Versenyhivatal (“GVH”) jogosult eljárni az alábbiak szerint.

Főszabály szerint az NFH jár el fogyasztók /betegek felé irányuló jogsértő reklámozás esetén, kivéve, amennyiben a kereskedelmi gyakorlat (reklám) a gazdasági verseny érdemi befolyásolására alkalmas, mely esetben a GVH jár el. A gazdasági verseny érdemi érintettsége minden egyéb körülményre tekintet nélkül fennáll többek között, ha a reklám közzétételére országos

Consequences of Breach

Administrative Proceedings

Advertising Supervisory Proceedings

The Consumer Protection Inspectorates ("NFH") or the Competition Authority ("GVH") may issue proceedings in cases of infringing advertising of OTC medicines or non-reimbursed therapeutic medical devices, in accordance with the following.

As a general rule, the NFH may issue proceedings in cases of infringing advertising activities directed to consumers/patients, except if the commercial practice (advertisement) is capable of restricting the economic competition, in which case the GVH may issue proceedings.

Advertisement is capable of restricting the economic competition without any further consideration if, e.g., the advertisement was broadcasted nationally or if it was published in a nationally-circulated newspaper or in a daily paper circulated in at least three counties.

In certain cases as defined by the Gyftv. (e.g., illegal advertising of a prescription-only or reimbursed medicinal product or therapeutic medical device to patients) regardless of the commercial practice's capability of restricting the economic competition the NFH may issue proceedings.

The GVH (or in certain cases, the court) may issue proceedings in case of infringing comparative advertising activities.

The GYEMSZI-OGYI can act as an expert authority in the procedures of the NFH regarding certain professional question defined by law. An administrative procedure may not be initiated more than three years after the publication of the illegal advertisement. In the case of continuous illegal advertising, the three-year limitation period is counted from the date of the last publication of the advertisement.

An advertising supervisory proceeding may be initiated not only *ex officio* but also upon request. Anyone may request the commencement of an advertising supervisory proceeding if the person's right, legal interest or legal status may be affected by the illegal advertising. Consequently, competitors of advertisers may also turn to the above authorities.

médiaszolgáltatón keresztül, országos terjesztésű időszakos lapban vagy legalább három megyében terjesztett napilapban kerül sor.

A Gyftv.-ben meghatározott bizonyos esetekben, így például vényköteles vagy társadalombiztosítési támogatásba befogadott gyógyszer, illetve társadalombiztosítási támogatással rendelhető gyógyászati segédeszköz jogszabályi tilalom ellenére betegek irányába történő reklámozása esetén - a gazdasági versenyre való érdemi érintettség esetén is - az NFH jogosult eljárni.

A Gazdasági Versenyhivatal (illetve bizonyos esetekben a bíróság) jogosult eljárni jogsértő összehasonlító reklám közzététele esetén.

Az NFH által indított eljárásban gyógyszer-reklámok esetében a GYEMSZI-OGYI a jogszabályban meghatározott kérdéskörökben szakhatóságként jár el. Eljárás a jogsértő reklám közzétételét követő három éven túl nem indítható meg. Amennyiben folyamatosan elkövetett jogsértésről van szó, a három év a reklám legutolsó közzétételétől számítandó.

Reklámfelügyeleti eljárás nem csak hivatalból indítható, hanem kérelemre is. Az eljárás megindítását az kérheti, akinek a promóciós rendelkezések megsértése jogát vagy jogos érdekét sérti vagy jogi helyzetét érinti. Ebből következően a reklámozók versenytársai is fordulhatnak a fenti hatóságokhoz.

Amennyiben az NFH a jogsértést megállapítja, határozatával elrendelheti a jogsértő állapot megszüntetését és egyben megtiltja a jogsértő magatartás további folytatását, illetve bírságot is kiszabhat.

A bírság összege 15 ezer forinttól (hozzávetőleg 50 Euro)

- a számvitelről szóló 2000. évi C. törvény (a továbbiakban: Szt.) hatálya alá tartozó, 100 millió forintot (hozzávetőleg 340,000 Euro) meghaladó éves nettó árbevétellel rendelkező, a kis- és középvállalkozásokról, fejlődésük támogatásáról szóló törvény hatálya alá nem tartozó vállalkozás esetében a vállalkozás éves nettó árbevételének 5%-áig, de legfeljebb 100 millió forintig (hozzávetőleg 340,000 Euro), illetve a fogyasztók széles körének testi épségét, egészségét sértő vagy veszélyeztető, továbbá a fogyasztók széles körének jelentős vagyoni hátrányt okozó jogsértés esetén legfeljebb 2 milliárd forintig (hozzávetőleg 6,800,000 Euro),

If the NFH establishes an infringement of the law, the authority may *inter alia* issue a cease-and-desist order or impose a fine on the infringing company, etc. The amount of the fine that can be imposed ranges from HUF15,000 (approximately EUR50) to:

- Five percent of the annual net sales revenue, up to a maximum of HUF100 million (approximately EUR340,000), of business entities falling under Act C of 2000 on Accounting, (and not falling under Act XXXIV of 2004 on Small and Medium-sized Enterprises), whose annual net sales revenue is in excess of HUF100 million (approximately EUR340,000); up to a maximum of HUF2 billion (approximately EUR6,800,000) if the infringement concerns the lives, health, physical integrity of a broad range of consumers, or if it results in substantial financial injury to a broad range of consumers;
- HUF500,000 (approximately EUR1,700) for business entities not included above: or up to five percent of the annual net sales revenue of the business entity if the infringement concerns the lives, health, physical integrity of a broad range of consumers; or if it results in substantial financial injury to a broad range of consumers; or up to HUF5 million (approximately EUR17,000) for business entities to whom the Accounting Act does not apply.

The decision of the NFH may be appealed before the head of the NFH. Judicial review is available against the decision of the head of the NFH.

If the GVH establishes an infringement of the law, the authority may *inter alia* issue a cease-and-desist order or impose a fine that may amount to 10 percent of the group net turnover obtained in the preceding year by the companies involved in the infringement. The GVH's practice regarding misleading advertising activities has become more and more stringent in the past few years. For instance, it imposes increasingly higher fines due to misleading medicine advertising (e.g., in the case Vj-68/2004, the Competition Office imposed a fine of HUF100,000,000, approximately EUR340,000).

There is no appeal against the GVH's decision; however, a court review of such decision may be requested.

- az a) pont hatálya alá nem tartozó vállalkozás esetében 500 ezer forintig (hozzávetőleg 1,700 Euro), illetve a fogyasztók széles körének testi épségét, egészségét sértő vagy veszélyeztető, továbbá a fogyasztók széles körének jelentős vagyoni hátrányt okozó jogsértés esetén a vállalkozás éves nettó árbevételének 5%-áig, az Szt. hatálya alá nem tartozó vállalkozás esetén 5 millió forintig (hozzávetőleg 17,000 Euro) terjedhet.

Az NFH határozata ellen fellebbezésel lehet élni, amelyet az NFH Főigazgatója bírál el. A Főigazgató határozatával szemben bírósági felülvizsgálatra van lehetőség.

Amennyiben a GVH a jogsértést megállapítja, az eljárás alá vontat eltilthatja a jogsértő magatartás további folytatásától és bírságot szabhat ki, amelynek maximális összege elérheti a jogsértéssel érintett vállalkozáscsoport előző évi nettó árbevételének 10%-át. A GVH az utóbbi években egyre szigorúbban ítéli meg a fogyasztók megtévesztésének eseteit, így megtévesztő gyógyszer-reklámok esetében is egyre magasabb bírságot szab ki (például a Vj-86/2004 számú ügyben 100 millió forintos bírságot szabott ki; kb. 340.000 Euro).

A GVH határozatával szemben nincs fellebbezésre lehetőség, azonban a határozat bírósági felülvizsgálatát lehet kérni.

Az ismertetés szabályainak megsértése - a GYEMSZI-OGYI eljárása

A vényköteles, illetve támogogatásba befogadott gyógyszerek valamint a támogatott gyógyászati segédeszközök ismertetésére vonatkozó szabályok megsértése esetén az eljárást a GYEMSZI-OGYI folytatja le.

A jogsértés megállapítása esetén a GYEMSZI-OGYI a következő szankciókat alkalmazhatja:

- etikai eljárást kezdeményezhet a szakmailag illetékes etikai szervnél, ha ennek feltételei fennállnak;
- a jogsértést elkövető személyt határozatában határidővel felhívhatja a hiányosságok megszüntetésére és ennek megszüntetéséig a tevékenység folytatását felfüggesztheti;
- határozattal megállapítja a jogsértés tényét, elrendelheti a jogsértő állapot megszüntetését és egyben megtilthatja a jogsértő állapot további folytatását;

Illegal Promotional Activities - Proceedings of the GYEMSZI-OGYI

The GYEMSZI-OGYI has authority to proceed against cases of illegal promotion of prescription-only or reimbursed medicines or reimbursed therapeutic medical devices to healthcare professionals. If the GYEMSZi-OGYI establishes infringement of the applicable laws on medicine promotion, the GYEMSZI-OGYI may:

- initiate ethics proceedings at the competent ethics committee;
- call upon the person in breach (by indicating the deadline for correction) to correct the deficiencies and to suspend its activities;
- issue a cease-and-desist order;
- impose a fine the amount of which ranges between HUF500,000 (approximately EUR1,700) and HUF25 million (approximately EUR86,000) in case of authorized distributors, while in case of marketing authorization holders and manufacturers the amount of the fine that can be imposed on the company ranges between HUF500,000 (approximately EUR1,700) and HUF 500 million (approximately EUR1,700,000), and in case of MSRs, between HUF500,000 (approximately EUR1,700) and HUF5 million (approximately EUR17,000,000);
- if in case of a repeated or grave breach:
    - prohibit the company from promoting the medicinal product for a definitive period of time (from six months up to three years); or
    - initiate at the Health Insurance Fund Administration the suspension of the agreement that entitles the infringing company to dispense medicinal products with reimbursement, or the suspension of the agreement that entitles the infringing healthcare professional to order medicinal products with reimbursement for no longer than one month.
- for reimbursed medicinal products, if the competent authority established the infringement of the applicable laws on medicine promotion by a marketing authorization holder or its representative twice within one year, and the amount of the fines imposed on such company reaches HUF5 million (approximately EUR17,000), the Health Insurance Fund Administration shall exclude the medicinal product concerned from the reimbursement if there is another reimbursed medicinal product with the same indication that can be purchased by patients for a price not more than 50 percent higher than the medicinal product concerned.

- pénzbírságot szabhat ki, melynek mértéke
    - a forgalmazásra jogosult esetén ötszázezer forinttól (hozzávetőleg 1.700 Euro) huszonötmillió forintig (hozzávetőleg EUR 86,000);
    - az ismertetési tevékenységet folytató, a forgalombahozatali engedélyének jogosultja és a gyártó esetén ötszázezer forinttól (hozzávetőleg 1.700 Euro) ötszázmillió forintig (hozzávetőleg 1.700.000 Euro);
    - az ismertető személy esetén ötszázezer forinttól (hozzávetőleg 1.700 Euro) ötmillió forintig terjedhet (hozzávetőleg 17.000 Euro).
- ismételt vagy súlyos jogszabálysértés esetén
    - a jogsértéstért felelős ismertetési tevékenységet folytatónak az ismertetési tevékenység folytatását a határozatában meghatározott időtartamra - legalább fél évre, legfeljebb három évre - megtiltja;
    - megkeresi az egészségbiztosítási szervet és kezdeményezi a jogsértést elkövető, társadalombiztosítási támogatással történő kiszolgálásra jogosító szerződéssel rendelkező szolgáltató szerződésének a felfüggesztését, vagy a társadalombiztosítási támogatással történő rendelésre jogosult jogsértése esetén a rendelési jogosultságának legfeljebb egy hónapra történő felfüggesztését.
- Ha támogatott gyógyszer tekintetében a forgalombahozatali engedély jogosultját vagy meghatalmazottját egy éven belül két esetben - a Gyftv. és a Promóciós Rendelet gyógyszer- vagy gyógyászatisegédeszköz-ismertetésre vonatkozó előírásai megsértése miatt az arra hatáskörrel és illetékességgel rendelkező hatóság jogerősen elmarasztalta, és vele szemben e jogsértések miatt összesen legalább 5 millió forint (hozzávetőleg 17,000 Euro) mértékű bírságot szabott ki, az egészségbiztosítási szerv kizárja a társadalombiztosítási támogatásból az eljárással érintett gyógyszert, ha az adott indikációban rendelkezésre áll más olyan gyógyszer, amelyhez a beteg a támogatásból kizárt gyógyszer térítési díjánál legfeljebb 50%-kal magasabb térítési díj ellenében juthat hozzá.

Ismételt jogszabálysértésnek minősül, amennyiben az elkövetőt két éven belül a promóciós szabályok megsértése miatt jogerősen elmarasztalták. Súlyos jogszabálysértésnek minősül, ha az ismertetés szokásos piaci

A repeated breach is a breach that was at least twice as determined in final and enforceable decisions of the competent authorities within the past two years. A seroius breach is when the usual market value of the unlawful promotion of the medicinal products or medical devices exceeds HUF25,000,000 (approximately EUR85,000) for repeated breaches. A fine may be imposed cumulatively.

In pharmacies already existing on 1 January 2011, and in pharmacies established after the entry into force of the Gyftv. in which a healthcare professional entitled to prescribe medicinal products with reimbursement has an ownership share, the government body in charge of the healthcare system shall control whether any agreement exists among pharmacies marketing medicinal products with reimbursement under a contract with the Health Insurance Fund Administration, manufacturers and distributors of medicinal products, and healthcare professionals entitled to prescribe medicinal products with reimbursement that may jeopardize or endanger the safe and efficient supply of medicinal products to patients. If it can be established that the existence of such agreement endangers the efficient and safe supply of medicines, the government body in charge of the healthcare system shall approach the Health Insurance Fund Administration to terminate the contract which entitles the pharmacy to supply products with reimbursement.

Special Supervisory Powers of the GYEMSZI-OGYI

The Gyftv. conferred significant powers on the Inspectorate to investigate breaches of the rules on gift-giving, promotional hospitality and the sponsorship of scientific events.

In order to discover the relevant facts of the case, the GYEMSZI-OGYI may request that any person or organization provide the Inspectorate with the documents handled or possessed by the person or organization. The GYEMSZI-OGYI may make a forensic copy of computer databases and may inspect the stored data. The GYEMSZI-OGYI is entitled to obtain and process the personal data of the person under investigation or any person related to it. However, the GYEMSZI-OGYI may not have access to, and may not use as evidence, attorney-client privileged information. The GYEMSZI-OGYI may inspect any premises where evidence is suspected to be located: it may enter the business premises of the company under investigation, may search business premises, and may also search private

ellenértéke a huszonöt millió forintot meghaladta. Ismételt jogszabálysértés esetén a bírság halmozottan is kiszabható.

A 2011. január 1-jén már működő gyógyszertárban, illetve e törvény hatálybalépését követően létesült olyan gyógyszertárban, melyben támogatással történő gyógyszerrendelésre jogosult orvosnak tulajdoni hányada van, az egészségügyi államigazgatási szerv ellenőrzi, hogy a közfinanszírozásban részesülő gyógyszer támogatással történő forgalmazására szerződött gyógyszertár, valamint a gyógyszergyártó, -forgalmazó, illetve a támogatással történő gyógyszerrendelésre jogosult orvos között létezik-e olyan megállapodás, amely a betegek hatékony és biztonságos gyógyszerellátását sérti vagy veszélyezteti. Amennyiben ez a betegek hatékony és biztonságos gyógyszerellátását sérti vagy veszélyezteti, az egészségügyi államigazgatási szerv kezdeményezi az egészségbiztosítási szervnél a támogatással történő forgalmazási jogot biztosító szerződés felmondását.

Az ajándékozás, a promóciós vendéglátás, a konferencia támogatás és az utaztatás szabályainak megsértése miatt indított eljárásban a GYEMSZI-OGYI speciális ellenőrzési jogköre

A Gyftv. rendkívül komoly nyomozati jogköröket biztosít aGYEMSZI-OGYI részére az ajándékozás, promóciós vendéglátás, konferencia támogatás és utaztatás ellenőrzésére.

A tényállás tisztázása érdekében a GYEMSZI-OGYI kérheti, hogy bármely személy vagy szervezet a kezelésében vagy birtokában lévő iratok másolatát adja át. A GYEMSZI-OGYI jogosult bármely adathordozóról fizikai tükörmásolatot készíteni és a tárolt adatokat átvizsgálni. A GYEMSZI-OGYI jogosult megismerni és kezelni az ügyfél és az ügyféllel kapcsolatba hozható személyek minden személyes adatait. Az ügyvédi titkot tartalmazó iratokat, adatokat azonban a GYEMSZI-OGYI nem használhatja fel bizonyítékként. A Felügyelet vizsgálatait bármely helyszínen elvégezheti, amelyről feltehető, hogy ott bizonyíték lelhető fel; bármely helyszínt átkutathat, oda önhatalmúlag beléphet, ideértve a magáncélú helyiséget és járművet is, amennyiben az az ügyfél bármely jelenlegi vagy volt alkalmazottja birtokában van. A helyszín átvizsgálására csak előzetes bírói engedély alapján kerülhet sor, amelyet a Fővárosi Törvényszék ad ki. A végzés ellen fellebbezésnek és felülvizsgálatnak nincs helye. A Fővárosi Törvényszék akkor adja meg az engedélyt, ha a GYEMSZI-OGYI valószínűsíti, hogy más vizsgálati cselekmény nem vezetne eredményre, és ésszerű

homes and cars, provided that such private property belongs to a current or previous employee of the company. The GYEMSZI-OGYI may only conduct this sort of search if it has obtained in advance an order of the Metropolitan Court to do so. The order of the Metropolitan Court may not be challenged. The court will only approve such "raid" if the authority establishes substantiates that less intrusive investigational measures would not be successful and it is reasonable to assume that the evidence would not be voluntarily provided. The GYEMSZI-OGYI may request the police's assistance with the above investigational measures.

The Promotion Decree contains specific duties imposed on marketing authorization holders of medical product device companies, as well as their authorized representatives, to cooperate with the competent authorities. Under these provisions, the marketing authorization holder or its authorized representative carrying out promotional activities must ensure the control of by establishing a scientific organizational unit within the company.

Furthermore, the marketing authorization holder and the manufacturer of therapeutic medical devices or its authorized representative must archive samples of all advertisements and the mode of distribution and the starting date of distribution of the advertisement. They must supply the authorities with information, assist them during investigations, and verify that the medical sales representatives have been adequately trained and satisfy the relevant requirements.

Unfair Competition

A competitor may bring an action before a civil court for unfair competition if it can prove that a company gained an unlawful competitive advantage as a result of the infringement of the law or industry ethical rules on advertising and promotion among other remedies. Such action may lead to an injunction or damages. The court can also impose a fine on the defendant based on the Competition Act.

Ethics Proceedings

Furthermore, violation of the various ethical codes may also incur serious sanctions on the persons or companies whose activities fall under the scope of the codes.

megalapozottsággal feltehető, hogy a szükséges bizonyítékokat önként nem bocsátanák a rendelkezésére. A GYEMSZI-OGYI a vizsgálati cselekmények foganatosításához a rendőrség segítségét kérheti.

A Promóciós Rendelet kötelezi a gyógyszer forgalomba hozatali engedélyének jogosultját és a gyógyászati segédeszköz gyártóját, illetve ezek meghatalmazott képviselőjét a hatóságokkal való együttműködésre. Így, A forgalomba hozatali engedély jogosultja, illetve meghatalmazott képviselője köteles gondoskodni az általa forgalmazott gyógyszerekkel kapcsolatos kereskedelmi kommunikációs tevékenység irányításának saját szervezetén belüli megszervezéséről, e célból egy tudományos szervezeti egység létrehozásával. Továbbá, a gyógyszer forgalomba hozatali engedélyének jogosultja és a gyógyászati segédeszköz gyártója, illetve meghatalmazott képviselője köteles 5 évig megőrizni az összes reklám egy mintáját, terjesztésének módját és a terjesztés megkezdésének időpontját feltüntető dokumentációt. Emellett kötelesek a vizsgálatok, eljárások alatt a kért tájékoztatásokat megadni, az ellenőrzés elvégzését a lehetséges módon előmozdítani. Szintén kötelesek arról gondoskodni, hogy az általuk alkalmazott, ismertetést végző személyek megfelelő képzésben részesüljenek és megfeleljenek a vonatkozó követelményeknek.

Tisztességtelen piaci magatartás miatti per

A versenytárs a reklámozásra vonatkozó jogszabályok és iparági etikai szabályok megsértése esetén a polgári bíróság előtt tisztességtelen piaci magatartásra hivatkozással pert indíthat, amennyiben bizonyítani tudja, hogy a versenytárs vállalkozás a hivatkozott jogszabály vagy etikai szabály megsértése miatt jogosulatlan versenyelőnyhöz jutott. Az ilyen perben a bíróság többek között ideiglenes intézkedést is elrendelhet, valamint kártérítést is megítélhet. A bíróság továbbá az alperessel szemben a Versenytörvény szerinti bírságot is kiszabhatja.

Etikai eljárások

A fentieken túl, a különböző etikai kódexek megsértése is komoly szankciókat vonhat maga után az adott kódex hatálya alá tartozó vállalkozások vagy személyek esetében.

Az Ágazati Kódex jelentős mértékben harmonizált az EFPIA (*European Federation of Pharmaceutical Industries and Associations*) etikai kódexével, amely európai szinten fogja össze a gyógyszergyártók szövetségeit. Az

The Industry Code has been harmonized to a great extent with the code of ethics of the European Federation of Pharmaceutical Industries and Associations ("EFPIA"). The Industry Code establishes a Communication Ethics Committee (the "Committee") which reviews ethics complaints and disputes by applying the provisions of the Industry Code. The Industry Code permits anyone, including a competitor or a healthcare professional, to make a complaint about a member company. The Committee also may start proceedings *ex officio*. However, if the applicant turns to any authority prior to or in parallel with the complaint submitted to the Committee, the Committee will not start its proceedings until a decision is made by the competent authority because the Committee does not want to influence the regulatory actions of the relevant authorities. If the Committee concludes that a member company committed an ethical offense, its proceedings may result in temporary membership suspension or, in the most serious cases, permanent expulsion. The Committee prepares a summary report of its decisions on a yearly basis, which is sent to the official journals of the HCMP and HCP with a request of the publication of the report. Both the HCMP and HCP may conduct ethical procedures against their members.

The HAA Code establishes the primary liability of advertisers for compliance with the code's provisions. If the advertiser cannot be identified or the advertiser proves that the breach is not attributable to its improper conduct, act or omission, the advertisement provider or publisher is liable for an advertisement which constitutes a violation of ethics rules. However, application of the rules of the HAA Code is only voluntary.

Professional Codes of Conduct

The Industry Code's provisions are in line with, or in some cases, even more stringent than the relevant statutory norms of the Advertising Act and the Promotion Decree. Thus, the Code prohibits the giving of gifts, benefits or sponsorships to doctors, pharmacists or healthcare workers, unless it is inexpensive and related to the practice of medicine. The category of healthcare professionals is wider than the group of persons entitled to prescribe or supply medical products under the Gyftv. (i.e., the category of healthcare professionals comprises any healthcare workers or staff members of healthcare service providers who take part in healthcare and in the ordering, procuring or use of medicinal products, including, e.g., nurses). The Code, in line with the EFPIA Code, contains detailed rules regarding sponsorship and hospitality. No company or representative office may organize or sponsor an event that takes place outside its home country unless some of the invitees are from abroad and it makes greater sense to hold the

Ágazati Kódex létrehozta a Kommunikációs Etikai Bizottságot ("KEB"), amely az Ágazati Kódex szabályai alapján vizsgálja és értékeli az etikai panaszokat és vitákat. Az Ágazati Kódex bárki számára - beleértve a versenytársat vagy egészségügyi szakembereket is - lehetővé teszi, hogy panaszt tegyen a tagvállalat ellen. A KEB hivatalból is indíthat eljárást. Amennyiben a bejelentő KEB-hez történő bejelentést megelőzően vagy azzal egyidejűleg bármely hatósághoz is fordul, a KEB az adott ügyben a hatóságok döntésének a meghozataláig az eljárást nem indítja meg, mivel határozataival nem kívánja a hatóságok döntését befolyásolni. Ha a KEB megállapítja, hogy az egyik tag etikai vétséget követett el, akkor az eljárás akár a tagsági jogviszony átmeneti felfüggesztéséhez, vagy súlyosabb esetekben, a tag végleges kizárásához is vezethet. A KEB jogerős határozatairól évente összefoglaló jelentést készít, amelyet megküld a MOK és az MGYK hivatalos lapjainak, kérve a KEB által átadott szöveg közlését.

Mind a MOK, mind az MGYK folytathat etikai eljárást a tagjaival szemben.

A Reklámetikai Kódex szabályainak betartásáért a kódex a reklámozó elsődleges felelősségét állapítja meg. Ha a reklámozó kiléte nem állapítható meg, vagy a reklámozó bizonyítja, hogy a kódex szabályainak megsértése nem az ő magatartása vagy mulasztása miatt következett be, akkor a reklámszolgáltató és a közzétevő is felelős a Reklámetikai Kódex szabályainak megsértését eredményező reklámért. A Reklámetikai Kódex szabályainak alkalmazása azonban önkéntességen alapul.

Szakmai magatartási szabályok

Az Ágazati Kódex szabályai összhangban állnak a vonatkozó jogszabályok rendelkezéseivel, illetve bizonyos esetekben még a jogszabályokban foglaltaktól szigorúbb szabályokat is tartalmaz. Ennek megfelelően, az Ágazati Kódex tiltja az orvosoknak, gyógyszerészeknek, egészségügyi dolgozóknak ajándék vagy anyagi, illetve egyéb előny átadását, kivéve ha az csekély értékű és összefügg az egészségügyi szakma gyakorlásával. Az egészségügyi szakember kategóriája tágabb, mint a Gyftv.-ben meghatározott gyógyszerek és gyógyászati segédeszközök rendelésére és forgalmazására jogosult személyek köre (egészségügyi szakembernek minősül lényegében minden olyan egészségügyi dolgozó vagy az egészségügyi szolgáltató személyzetének tagja, aki a gyógyszerek rendelésében, beszerzésében vagy alkalmazásában és a betegellátásban szerepet játszik, ideértve például az ápolónőket is). A Kódex az EFPIA Kódexszel összhangban részletesen szabályozza a rendezvény támogatást és üzleti vendéglátást. Eszerint például

event in another country. Hospitality may not include entertainment programs. Companies should avoid using venues that are renowned for their entertainment facilities.

The HCMP Code currently contains the primary ethical rules governing the work of medical doctors, and seeks to set a high standard of ethics and professional responsibility to maintain confidence in the healthcare industry. A doctor shall not accept any gift or other promised material benefit that is provided with a condition that a particular product should be prescribed, used or recommended to patients. Infringement of such rules is an ethical offense. It is an ethical offense if a doctor recommends similar products of different companies as their first choice product within a short period of time. It is also an ethical offense to favor medicines, medical devices or other products as opposed to other similar products in exchange for any support or gift. The HCMP Code declares as unethical any relationship between a doctor and a pharmacist which would be aimed at gaining profits or increasing turnover.

Similarly, the HCP Code prohibits pharmacists from engaging in any kind of advertising activity that would conflict with the rules of professional conduct or ethics, or result in unfair competition among pharmacies. A pharmacist shall not conclude any agreement or accept any benefit which would endanger or infringe his/her professional independence and the independence of his/her decisions or the effective and safe pharmaceutical supply of patients. Contracts and agreements are in particular considered as capable of endangering professional independence if the pharmacist becomes interested in or seems as such that he/she offers a particular, medical product or the products of a particular pharmaceutical or food supplement company, in exchange for any fee, gift or other benefit or remuneration. The above does not apply to contracts between the pharmacist as the manager of the pharmacy and a pharmaceutical wholesaler or other supplier, under which agreement the pharmacy will be entitled to certain benefits depending on contractual volume or value.

The provisions of the HCMP and HCP Code may be amended in the future to bring the internal ethics rules of the chambers in compliance with the Ethics Regulation to be prepared by the NEC and the Minister of Health.

egyetlen cég vagy képviselet sem szervezhet, illetve támogathat olyan rendezvényt, amely a cég működési országán kívül kerül megrendezésre, kivéve, ha a meghívottak egy része külföldi és indokolható a rendezvény külföldi megrendezése. A vendéglátás nem foglalhat magában szórakozás céljából szervezett eseményeket. A cég köteles kerülni a szórakozóhelyeiről híres helyszíneket.

Az orvosok munkája során alkalmazandó legfontosabb etikai szabályokat jelenleg a MOK Kódex tartalmazza. Az MOK Kódex célja a magas szintű etikai és szakmai felelősség megteremtése és az egészségügyi ágazatba vetett bizalom fenntartása. Az orvos nem fogadhat el olyan ajándékot vagy más, számára kilátásba helyezett anyagi előnyt, amelynek feltétele egy bizonyos gyógyszer / termék felírása, használata, ajánlása betegei felé. A gyógyszer, gyógyászati segédeszköz rendelésre vonatkozó jogszabályi rendelkezések megszegése egyben etikai vétségnek minősül. Etikai vétség, ha személyes haszon reményében az orvos rövid időn belül különböző cég hasonló készítményét ajánlja elsőként választandó szerként. Etikai vétség bármely támogatásért vagy ajándék fejében gyógyszerek, műszerek vagy egyéb termékek előnyben részesítése más, hasonló készítmény színvonalával szemben. A MOK Kódex etikátlannak tekinti az orvos és a gyógyszerész közötti minden olyan kapcsolatot, amelynek célja a haszonszerzés, illetve a forgalom növelése.

Az MGYK Kódex a fentiekhez hasonlóan tiltja a gyógyszerész számára, hogy olyan reklámtevékenységben vegyen részt, amely a szakmai magatartási vagy etikai szabályokba ütközik vagy a gyógyszertárak közötti tisztességtelen verseny kialakulását eredményezi. A gyógyszerész nem köthet olyan megállapodást vagy szerződést, nem fogadhat el olyan előnyt, amely szakmai függetlenségét és döntéseinek önállóságát, továbbá a betegek hatékony és biztonságos gyógyszerellátását sérti vagy veszélyezteti. A szakmai függetlenséget különösen veszélyeztetőnek tekinthető minden olyan megállapodás vagy szerződés, amely alapján a gyógyszerész érdekeltté válik abban vagy annak látszatát kelti, hogy a hozzá forduló betegek számára egy adott gyógyszert, gyógyászati célú terméket, vagy egy adott gyógyszergyár vagy gyógytermék-/étrendkiegészítő-elıállító termékét kínálja, ajánlja, akár jutalék, ajándék, bármilyen más előny vagy ellenszolgáltatás elérése érdekében. Nem tekinthetı azonban e rendelkezésbe ütközınek az olyan szerződés, amelyet a gyógyszertári vállalkozás vezetőjeként köt a gyógyszerész a gyógyszer-nagykereskedővel vagy más gyógyászati termék

Liability Under Criminal (and Civil) Law

Regulatory Framework

In Hungary, Act No IV of 1978 on the Criminal Code (the "Criminal Code") contains the rules on bribery. These rules apply to crimes committed by natural persons. Act CIV of 2001 on the Applicable Criminal Sanctions against Legal Persons ("Criminal Sanctions against Legal Persons Act") states that in certain cases, legal persons may also be liable for criminal offenses (including bribery).

Permitted and Prohibited Practices and Sanctions

The Criminal Code differentiates between active and passive, as well as official and economic bribery. The subjects of official bribery are "public officials." The Criminal Code gives a detailed definition of public officials as follows: members of Parliament, the president of the Republic, members of government, judges of the Constitutional Court, judges and public prosecutors, the ombudsmen of fundamental rights, members of the local municipality bodies, public notaries, persons on official duty at the Constitutional Court, courts, public prosecutor's offices, administrative bodies, local municipality administrative bodies, whose activity belong to the normal functioning of the body in question, as well as persons engaged in administrative, public executive tasks at bodies which are entrusted by law with administrative or public executive powers (e.g., civil servants who have the authority to make decisions in administrative proceedings).

It is questionable whether doctors, pharmacists or other healthcare workers (for example, nurses) may qualify as public officials. As a general rule, such persons do not fall under the term 'public official'. However, in certain cases, if a doctor acts with administrative authority (e.g., a doctor certifies a person's incapability to work or issues a health certificate) he/she can be considered as a public official. Nevertheless, doctors / healthcare workers may be the subject of economic bribery since they are usually employed by a government or local municipality body (e.g., hospital, outpatient surgery) or a company (e.g., Ltd., limited partnership).

Active official bribery is when a person promises or gives an unlawful benefit to a public official or to any other person on account of such public official's actions. Such a person shall be punished for a felony and can be imprisoned for up to three years. The person may be imprisoned for a

szállítójával, és amely szerint a szerződésben meghatározott termékek rendelésével – a szerződéses összmennyiség vagy érték függvényében – a vállalkozás különféle kedvezményekre válik jogosulttá.

Büntetőjogi (és polgári jogi) felelősség

Jogszabályi keretek

Magyarországon a vesztegetés szabályait a Büntető Törvénykönyvről szóló 1978. évi IV. törvény ("Btk.") tartalmazza. Ezek a szabályok a természetes személy által elkövetett bűncselekményekre vonatkoznak. A jogi személlyel szemben alkalmazható büntetőjogi intézkedésekről szóló 2001. évi CIV. törvény ("Jogi Személyekkel Szembeni Büntetőjogi Intézkedésekről Szóló Törvény") alapján lehetőség van bizonyos esetekben, így például vesztegetés elkövetése esetén is, a jogi személyekkel szemben bizonyos büntetőjogi intézkedések alkalmazására.

Megengedett és tiltott magatartások és szankciók

A Btk. különbséget tesz aktív és passzív, hivatali és gazdasági vesztegetés között az alábbiak szerint:

A hivatali vesztegetés alanya hivatalos személy lehet. A hivatalos személy fogalmát a Btk. határozza meg. Eszerint, hivatalos személy például a köztársasági elnök, az országgyűlési képviselők, a kormány tagjai, az alkotmánybírák, a bírók, az ügyészek, az állampolgári jogok biztosai, a helyi önkormányzati testületek tagjai, a közjegyzők, az Alkotmánybíróságnál, bíróságnál, ügyészségnél, önkormányzati igazgatási szervnél, államigazgatási szervnél, stb., szolgálatot teljesítő személyek, akinek a tevékenysége a szerv rendeltetésszerű működéséhez tartozik továbbá, a jogszabály alapján közhatalmi, államigazgatási feladatokkal megbízott szervnél, testületnél az a személy, aki közhatalmi, államigazgatási feladatot lát el (például az államigazgatási ügyben határozatot hozó köztisztviselő).

Kérdésként merülhet fel, hogy az orvosok, gyógyszerészek, illetve más egészségügyi dolgozók (például nővérek) hivatalos személynek minősülnek-e. ABtk. definíciójából látható, hogy ezek a személyek főszabály szerint nem minősülnek hivatalos személynek. Bizonyos esetekben azonban az orvos is végezhet hatósági aktust (például a keresőképtelenség igazolása, vagy egészségügyi bizonyítvány kiállítása) és az ilyen feladat ellátása során hivatalos személynek minősül. Mindazonáltal az orvosok/egészségügyi

duration from one year up to five years if the person induces the public official to breach his official duty, exceed his competence or abuse his official position in any way.

Passive official bribery is if a public official requests, demands or accepts any unlawful benefit related to the performance of the public official's duties. Passive official bribery is a crime punishable by imprisonment for a duration from one to five years. Passive bribery is more strictly punishable if the public official is in a leading position or has the power to act in more substantial matters; or the crime is committed habitually, as part of a conspiracy or in a business-like manner; or the public official actually breaches his official duties, or exceeds his authority or abuses his position in any other ways.

The Criminal Code states that active economic bribery is where any person gives or promises unlawful advantage to an employee or member of a budgetary institution, business organization or social organization, or to another person on account of such employee or member, to induce him/her to breach his/her duties. Such action is punishable by imprisonment for up to three years. This form of bribery is more strictly punishable if the unlawful advantage is given or promised to an employee or member who is authorized to act in the name and on behalf of a budgetary agency, business organization or social organization.

Under the provisions on passive economic bribery, it is prohibited for an employee or member of a budgetary institution, business organization or social organization to request any unlawful benefit or to accept such benefit or the promise thereof in return for the breach of his/her duties. This crime is punishable by imprisonment for up to three years. It is more strictly punishable if the breach of duty is actually committed or it is committed in a more substantial matter, as part of a conspiracy or in a business-like manner, or the employee breaches his/her duties for the benefit, or the employee or member requesting the benefit is empowered to act on behalf of the budgetary institution, business organization or social organization.

Pursuant to the Criminal Sanctions against Legal Persons Act, various sanctions can be applied against a legal person if the crime has been committed: intentionally; for the purpose of achieving a material advantage for the benefit of the legal person, or the crime has resulted in such a benefit; and by a duly authorized representative of the legal person, a member of the supervisory board or a person authorized by them within the scope of activity

dolgozók gazdasági vesztegetés alanyai lehetnek, mivel rendszerint valamely önkormányzati vagy állami költségvetési szerv (pl. kórház, rendelőintézet), vagy gazdasági társaság (pl. Kft., Bt.) alkalmazásában állnak.

Aktív hivatali vesztegetés, amikor valaki a hivatalos személy működésével kapcsolatban, vagy reá tekintettel másnak jogtalan előnyt ad vagy ígér. Ez bűntettnek minősül és három évig terjedő szabadságvesztéssel büntetendő. A cselekmény egy évtől öt évig terjedő szabadságvesztéssel büntetendő, ha az előnyt azért adják vagy ígérik, hogy a hivatalos személy a hivatali kötelességét megszegje, a hatáskörét túllépje vagy a hivatali helyzetével egyébként visszaéljen.

Passzív hivatali vesztegetés ha a hivatalos személy működésével kapcsolatban jogtalan előnyt kér, avagy jogtalan előnyt, vagy annak ígéretét elfogadja, illetőleg a jogtalan előny kérőjével vagy elfogadójával egyetért. A passzív hivatali vesztegetés bűntett, ami egy évtől öt évig terjedő szabadságvesztéssel büntethető. A passzív hivatali vesztegetés súlyosabban büntetendő, ha a bűncselekményt vezető beosztású vagy fontosabb ügyekben intézkedésre hivatott hivatalos személy, vagy más hivatalos személy fontosabb ügyben követi el. Még súlyosabban büntetendők a fenti esetek, ha a hivatalos személy a jogtalan előnyért hivatali kötelességét megszegi, hatáskörét túllépi, vagy hivatali helyzetével egyébként visszaél, illetőleg ha a cselekményt bűnszövetségben vagy üzletszerűen követi el.

A Btk. szerint aktív gazdasági vesztegetésnek minősül, ha valaki költségvetési szerv, gazdálkodó szervezet vagy társadalmi szervezet dolgozójának, illetve tagjának, vagy reá tekintettel másnak azért ad, vagy ígér jogtalan előnyt, hogy az a kötelességét megszegje.A bűncselekmény három évig terjedő szabadságvesztéssel büntetendő. A cselekmény súlyosabban büntetendő, ha a jogtalan előnyt költségvetési szerv, gazdálkodó szervezet vagy társadalmi szervezet önálló intézkedésre jogosult dolgozójának, illetve tagjának adják vagy ígérik.

Passzív gazdasági vesztegetés az, amikor egy költségvetési szerv, gazdálkodó szervezet vagy egy társadalmi szervezet dolgozója, illetőleg tagja a működésével kapcsolatban jogtalan előnyt kér, vagy a kötelessége megszegéséért az ilyen előnyt, illetve annak ígéretét elfogadja, vagy a jogtalan előny kérőjével, vagy elfogadójával egyetért. Az ilyen cselekmény háromévig terjedő szabadságvesztéssel büntethető. Súlyosabban büntetendő a cselekmény, ha fontosabb ügyben történt a kötelességszegés, illetve ha a

of the legal person; or the crime has been committed by a member or employee within the scope of activity of the legal person if the person entitled to supervise such persons could have prevented such an act.

The criminal sanctions that may be applied against legal persons include: the termination of the legal person's activity; the restriction of the activity; and a fine (ranging from HUF500,000 or approximately EUR1,700) of up to three times the material advantage / benefit which was intended to be gained or was actually gained by the crime.

As a general rule, Hungarian anti-bribery rules prohibit any kind of "unlawful benefit." The Criminal Code does not define what constitutes a benefit. The Commentaries of the Criminal Code indicate that a benefit may be either material or personal in nature, and that the term "benefit" should be interpreted broadly. Furthermore, there is no significant jurisprudence interpreting the relevant Criminal Code provisions, and the Hungarian Supreme Court has not yet issued any interpretative rulings on this subject. As a result, whether an advantage or benefit given or promised comes within the scope of the bribery provisions of the Criminal Code must be decided on a case by case basis, taking into account the relevant facts and circumstances.

Regarding the gifts and benefits granted to persons entitled to prescribe or supply medicinal products and medical devices, in our view, the distinction between "lawful" and "unlawful" advantage may be made according to the statutory thresholds. According to the Gyftv., only inexpensive gifts may be granted to such persons. Inexpensive means five percent of the statutory monthly minimum income (in 2012, HUF4,650 or EUR16). If a pharmaceutical company provides a medical doctor a benefit, the value of which exceeds the above threshold (e.g., the doctor is provided with a more expensive gift or with expensive hospitality), it can be considered as an unlawful benefit, and – provided the other elements of the Criminal Code's provisions, such as an inducement to breach the person's duties, are also fulfilled – the crime of bribery may be established.

Public Procurement and Fraud

Any fraud committed in relation to public procurement proceedings can be sanctioned by civil or criminal laws. No special regulations apply to public

cselekményt bűnszövetségben, vagy üzletszerűen követik el, illetve ha az elkövető az előnyért kötelességét megszegi vagy a jogtalan előnyt költségvetési szerv, gazdálkodó szervezet vagy társadalmi szervezet önálló intézkedésre jogosult dolgozója, illetve tagja kéri.

A Jogi Személyekkel Szembeni Büntetőjogi Intézkedésekről Szóló Törvény rendelkezései szerint az alábbi feltételek együttes teljesülése esetén lehet jogi személlyel szemben büntetőjogi intézkedéseket alkalmazni: (i) szándékos bűncselekmény elkövetéséről van szó; (ii) a bűncselekmény elkövetése a jogi személy javára vagyoni előny szerzését célozza vagy eredményezi; (iii) a bűncselekményt a jogi személy ügyvezetésre vagy képviseletre feljogosított tagja vagy tisztségviselője, felügyelő bizottságának a tagja, illetőleg ezek megbízottja a jogi személy tevékenységi körében követte el; vagy tagja vagy alkalmazottja a jogi személy tevékenységi körében követte el, és azt a vezető tisztségviselő felügyeleti vagy ellenőrzési kötelezettségének teljesítése megakadályozta volna.

A jogi személyekkel szemben alkalmazható büntetőjogi szankciók a következők:

(i) a jogi személy működésének megszüntetése; (ii) a működés korlátozása; és (iii) bírság (a bírság összege minimum 500.000 forint (kb. 1.700 Euro), a bírság maximuma a bűncselekménnyel szerzett, vagy megszerezni kívánt anyagi előny háromszorosa).

A magyar korrupciós jogszabályok általában tiltják a “jogtalan előny” átadását. Sem a Btk., sem annak magyarázata nem határozza azonban meg a “jogtalan előny” fogalmát. Ugyanakkor a Btk. Kommentár szerint a “jogtalan előny” fogalmát szélesen kell értelmezni: az lehet anyagi vagy személyi jellegű is. Nem alakult ki a Btk. e rendelkezéseit mélységében értelmező joggyakorlat sem, továbbá a Legfelsőbb Bíróság sem adott ki jogegységi határozatot e kérdéskörben. Ennek megfelelően tehát azt, hogy az előny adása a Btk. hatálya alá esik-e, esetről esetre kell megvizsgálni a releváns tények és körülmények figyelembe vételével.

A gyógyszerek és gyógyászati segédeszközök rendelésére és forgalmazására jogosult személyeknek adott ajándékok és egyéb juttatások tekintetében, álláspontunk szerint a “jogos” és “jogtalan” előny elhatárolását a jogszabályok által megállapított értékhatárok szabják meg. A Gyftv. szerint ezeknek a személyeknek csak csekély értékű ajándék adható. A csekély

procurement by healthcare institutions and fraud committed by healthcare professionals.

Contracts with Healthcare Professionals and Medical Institutions

The general rules of Act No. IV of 1959 on the Civil Code (the "Civil Code") apply to all contracts between healthcare professionals and medical institutions in the same way as those general rules apply to contracts in any other industry.

The general rules on contracts for services are regulated in Sections 474-483 of the Civil Code. Pursuant to the Civil Code, the person entrusted with a mandate to provide services must duly provide the services in accordance with the principal's instructions and interests, and the principal must pay a fee for the services. Pursuant to Section 479 (1) of the Civil Code, the costs incurred by the person entrusted to provide services must be reimbursed by the principal.

With regard to contracts concluded with doctors, the most important issue is that under the agreement, the doctor must provide real services/activities proportionate with the remuneration offered for the service under the agreement. An agreement reached with a medical doctor must not disguise any provision of gifts or benefits to the doctor. In the latter case, the contract may be regarded as a hidden contract aimed at circumventing the laws on gifts and benefits that are allowed to be offered to healthcare professionals. According to the Civil Code, such contracts are null and void. Anyone can challenge an invalid contract without a time limit (Section 234 of the Civil Code). Thus, the competent authorities (the GYEMSZI-OGYI, the GVH or the tax authorities) may also initiate proceedings against disguised contracts aimed at circumventing the applicable laws on medicine promotion (or in certain cases, the rules on taxation). Hidden contracts may also be considered bribery under the Criminal Code.

In order to avoid a contract being classified as a hidden contract, the following are recommended:

- The contracts should precisely define what kind of services the doctor must provide (such as delivering a presentation, writing an article or conducting a study).

értékű ajándék a mindenkori minimálbér havi összegének 5%-a (ez 2012-ben 4.650 forint; 16 Euro). Amennyiben tehát egy orvos ennél magasabb értékű ajándékot kap (tehát például ennél drágább ajándékot kap, drága vendéglátásban részesül, stb.), az jogellenesnek tekinthető, és akár vesztegetésnek is minősülhet, amennyiben a Btk. többi tényállási eleme is teljesül (pl. a kötelességszegésre rábírás).

Közbeszerzés és csalás

Bármely, a közbeszerzési eljárás keretein belül vagy azon kívül elkövetett csalás mind büntető, mind polgári jogi jogkövetkezményeket is maga után vonhat. Az egészségügyi szakemberek, illetve intézmények vonatkozásában nincsen speciális szabályozás a közbeszerzésre, illetve a csalás megítélésére vonatkozóan.

Szerződések egészségügyi szakemberekkel és egészségügyi intézményekkel

A Polgári Törvénykönyvről szóló 1959. évi IV. törvény ("Ptk.") általános rendelkezéseit kell alkalmazni minden egészségügyi szakemberrel és egészségügyi intézménnyel kötött szerződés vonatkozásában, éppen úgy, mint a bármely más üzleti területen megkötött szerződésre.

A Ptk. 474-483. §-ai tartalmazzák a megbízási szerződésekre vonatkozó rendelkezéseket. Eszerint a megbízott köteles a rábízott ügyet a megbízó utasításai szerint és érdekeinek megfelelően ellátni, a megbízó pedig köteles ezért díjat fizetni. A Ptk. 479. § (1) bekezdése szerint az ügy ellátásával felmerült költségek a megbízót terhelik.

Az orvosokkal kötendő szerződések kapcsán ügyelni kell arra, hogy az orvos/egészségügyi szakember tényleges szolgáltatást teljesítsen, amely a kapott díjazással arányos. Az orvosokkal kötött szerződéseknek nem lehet céljuk, hogy ajándékok vagy egyéb előnyök juttatását palástolják. Ilyen esetben ugyanis a szerződés színlelt szerződésnek minősül, amely az orvosoknak/egészségügyi szakembereknek jogszerűen adható ajándékokra és egyéb juttatásokra vonatkozó jogszabályok megkerülését célozza. A Ptk. szerint a színlelt szerződések semmisek. A semmis szerződés érvénytelenségére bárki határidő nélkül hivatkozhat (Ptk. 234. § (1) bekezdés), így a hatáskörrel rendelkező hatóságok (a GYEMSZI-OGYI, a GVH, a NAV) is felléphetnek az olyan színlelt szerződésekkel szemben,

- If the contract is concluded with a company, the name of the person who will personally deliver the service (e.g., hold a lecture) should be indicated in the contract. In this a case, this person should also sign (or countersign) the contract.
- Conditions for the completion of the services should be determined in the contract (such as the deadline and manner).The completion of the services should be documented (such as a prepared study, slides of a lecture, summary report, conference material, signed minutes taken from an advisory board meeting), and the relevant documentation regarding the completion of services should be archived.
- The fee may only be paid via bank transfer and only if the fulfillment of the contract is properly documented.
- The fees paid to the healthcare professional under the contract must be commensurate with the services rendered under the contracts.

Should the medical professional incur any expenses as a result of the performance under the contract (e.g., the doctor had to participate in meetings, conferences or trainings in connection with the contract), it has to be clear from the contract that these extra costs were necessary for the proper completion of the services under the contract. Reimbursement of extra costs (travel, accommodation, meal) must be reasonable. No luxury costs may be reimbursed.

In case of contracts with healthcare professionals, pharmaceutical companies must take into account that in certain cases, the healthcare professional's employer must be notified in advance of the establishment of the contractual relationship, or the doctor must seek the prior approval of his/her employer. The duty of notification or the obtaining of prior approval depends on the legal relationship of the healthcare professional, i.e., whether he/she is an employee, a civil servant or a public employee. Therefore, before entering into a contract with a healthcare professional, a pharmaceutical company should check the laws regulating the legal relationship between the doctor and his/her employer, and the internal regulations/by laws of the institution (e.g., internal rules of a hospital). If it is practically possible, it is also advisable to request the employer of the healthcare professional to countersign the contract to verify that the employer is aware of the healthcare professional's additional contractual relationship and approves it.

amelyeknek a célja a gyógyszer-promócióra (esetleg adózásra) vonatkozó szabályok egyértelmű kijátszása. A színlelt szerződések a Btk. értelmében akár vesztegetésnek is minősülhetnek.

Annak érdekében tehát, hogy egy szerződés ne minősüljön színlelt szerződésnek a következők javasolhatóak:

- a szerződés írásban pontosan rögzítse, hogy az orvosnak milyen szolgáltatást kell teljesítenie (pl. előadást tartani, cikket írni, kutatást végezni);
- amennyiben a gyógyszercég a szerződést egy vállalkozással köti meg, a szerződésben szerepeljen annak a személynek a neve, aki a szolgáltatást személyesen teljesíteni fogja (vagyis pl. megtartja az előadást). Ebben az esetben a személyesen közreműködő fél is lehetőleg írja alá a szerződést;
- a szolgáltatás teljesítésének körülményei (pl. határideje, módja) a szerződésben legyenek egyértelműen rendezve, illetve a teljesítést dokumentálni kell (pl. az elkészített tanulmány, előadás vázlat, összefoglaló, konferencia anyag, tanácsadó tesület üléséről készített aláírt jegyzőkönyv). A teljesítést igazoló dokumentációt meg kell őrizni;
- a megbízási díj kizárólag banki átutalással kerülhet kifizetésre és csak akkor, ha a szolgáltatás teljesítése a fentiek szerint megfelelően igazolt;
- a megbízási díjnak az elvégzett szolgáltatással arányosnak kell lennie.

Amennyiben az orvosnak a szolgáltatás teljesítése következtében költségei merülnek fel (például a szerződéssel összefüggő tárgyaláson, konferencián vagy továbbképzésen kellett részt vennie), a szerződésből egyértelműen derüljön ki, hogy a többletköltségek szükségesek voltak a szerződésből folyó kötelezettségek teljesítéséhez és azokhoz szervesen kapcsolódnak. Ebben az esetben is azonban a megtérített költségek (utazás, szállás, étkezés) mértékének ésszerűnek kell lennie, a "luxus-szintű" költségtérítés nem lehet indokolt.

Az egészségügyi szakemberekkel kötött szerződések esetében figyelemmel kell lenni arra is, hogy bizonyos esetekben a szerződés megkötését be kell jelenteni az egészségügyi szakember munkáltatójának vagy a munkáltató hozzájárulását kell kérni a további jogviszony létesítéséhez. A bejelentési, illetve a hozzájárulás beszerzésének a kötelezettsége függ attól, hogy az egészségügyi szakember munkaviszonyban, közalkalmazotti vagy közszolgálati jogviszonyban dolgozik-e. Szerződéskötés esetében tehát

It is in any case recommended to include in the contract with the healthcare professional the following or similar provision: “the healthcare professional represents and warrants that he/she has the ability under his/her current employment relationship to enter into, and to perform under, the contract; and further, that he/she has made the notifications and has obtained all the approvals required by law and the internal by laws of the institution to enter into, and to perform under, the contract with the company.”

Recommendations

The legislation on pharmaceutical promotion has changed several times recently. The Gyftv. will likely be a decisive piece of legislation in the long term. Stringent rules apply to the promotional activities of pharmaceutical and medical device companies, and the failure to comply with these rules may entail significant authority actions and sanctions. Therefore, it is of the utmost importance to properly comply with the relevant laws and ethical rules.

As a general recommendation, always try to comply with the applicable promotional thresholds (e.g., for gifts, sponsorship). Exceeding the thresholds may bring about sanctions and might also be considered as bribery. Benefits granted to healthcare professionals may not be of a personal nature and may in no case relate to the turnover of a particular product (e.g., to the number of prescriptions). It is advisable to keep detailed records on promotional activities (e.g., contracts, certificates of performance, invoices). Regarding contracts concluded with healthcare professionals, the remuneration provided to healthcare professionals must be proportionate to the value of the service provided, and performance must be properly documented. Where possible, it should be ensured that the relevant institution’s management is aware of the agreement with an individual healthcare professional.

mindig meg kell vizsgálni az egészségügyi szakember alap-jogviszonyára vonatkozó jogszabályokat, valamint az egészségügyi szakembert foglalkoztató intézmény (pl. kórház) belső szabályzatait.Amennyiben ez lehetséges, javasolt a megbízási szerződést a munkáltatóval "ellenjegyeztetni", amely igazolja, hogy a munkáltatónak tudomása van a további jogviszony létesítéséről és hozzájárul ahhoz.

Minden esetben javasolt a megbízási szerződés rendelkezései közé beiktatni egy olyan klauzulát, mi szerint az egészségügyi szakember szavatol azért, hogy jogosult a megbízási szerződés megkötésére és teljesített a munkáltatója irányában minden, a vonatkozó jogszabályok, előírások, illetve intézményi belső szabályzatok által megkövetelt bejelentési, illetve engedélykérési kötelezettséget.

Javaslatok

A gyógyszerpromócióra vonatkozó szabályok az elmúlt időszakban többször is változtak. A Gyftv.-vel fémjelzett jogi környezet feltehetően hosszabb távon meghatározó lesz. A gyógyszer és gyógyászati segédeszköz cégeknek a promóciós tevékenységére szigorú szabályok vonatkoznak, a szabályok be nem tartása pedig komoly hatósági intézkedéseket és szankciókat vonhat maga után. Ezért kiemelten fontos a vonatkozó jogszabályoknak és etikai normáknak való megfelelés (compliance).

Általános javaslat, hogy ügyelni kell a mindenkori promóciós értékhatárok betartására (ajándékok, szponzoráció esetében). Az értékhatárok átlépése ugyanis szankciókat von maga után és akár vesztegetésnek is minősülhet. A juttatások nem lehetnek személyes jellegűek és semmiképpen nem lehetnek kapcsolatban egy adott termék üzleti forgalmával (például a felírt vények számával). Javasolt a promóciós tevékenységre vonatkozó dokumentációt a legnagyobb részletességgel megőrizni (pl. szerződések, igazolások, számlák). Az egészségügyi szakemberekkel kötött megbízási jellegű szerződésekkel kapcsolatban figyelni kell az értékarányosságra és a tényleges teljesítés dokumentálására. Ahol lehetséges, biztosítani kell, hogy az adott intézet vezetésének tudomása legyen az egészségügyi szakképesítéssel rendelkező személlyel történő megállapodás megkötéséről.

Italia

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Introduzione

La promozione di farmaci e dispositivi medici in Italia è disciplinata, innanzitutto, dalla legislazione nazionale (che, molto spesso, attua Direttive comunitarie), ma trovano applicazione anche vari regolamenti, linee guida, codici di condotta emanati da Autorità regolatorie e dalle associazioni di categoria, nazionali e sovranazionali. Per quanto riguarda i dispositivi medici, qualora le questioni non fossero regolate dalla specifica normativa agli stessi applicabile, la prassi è quella di applicare i principi relativi alla legislazione farmaceutica.

In generale, la promozione di farmaci e dispositivi medici destinata agli operatori sanitari è particolarmente attenta alla accuratezza delle informazioni, all'adeguatezza della formazione, e alla prevenzione dell'indebita ingerenza nel processo decisionale dell'operatore sanitario (comprese le decisioni di acquisto di prodotti farmaceutici e biomedicali da parte degli enti pubblici). A tal fine, è prevista una rigorosa regolamentazione dell'informazione scientifica, nonché una serie di restrizioni in ordine ai rapporti tra aziende farmaceutiche e biomedicali ed operatori sanitari per seminari, tavole rotonde, ed eventi promozionali.

Per quanto concerne la pubblicità rivolta al pubblico, è vietata la promozione di farmaci e dispositivi medici per i quali è necessaria la prescrizione medica o che devono essere utilizzati con l'assistenza di un professionista. I messaggi promozionali indirizzati al pubblico, laddove consentiti dalla normativa applicabile, devono essere in ogni caso preventivamente approvate da una Commissione consultiva operante presso il Ministero della Salute.

Aspetti regolatori relativi alla pubblicità di farmaci e dispositivi medici.

Disposizioni normative regolano la pubblicità di farmaci e dispositivi medici

Diverse disposizioni normative regolano la pubblicità di farmaci e dispositivi

Italy

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Introduction

The promotion of medicines and medical devices in Italy is controlled, in the first instance, by national legislation (implementing, in many instances, Community Directives), but also involves the application of various regulations, guidelines, and codes of conduct issued by the regulatory authorities and national and international industry associations. When issues arise not specifically provided for in the materials pertaining to medical devices, the trend is to apply principles found in rules and codes developed for medicines and medicinal products.

Broadly speaking, the promotion of medicines and of medical devices to healthcare professionals ("HCPs") is governed by concerns for accuracy in information, adequacy in education and training, and the avoidance of undue influence over HCP decision-making (including purchasing decisions by public entities). To this end, there are a number of restrictions on how information may be presented to HCPs with respect to seminars, panel discussions, promotional events and the like.

With regard to advertising to the public, it is forbidden to promote medicines and medical devices that require an HCP's prescription or that must be used with the assistance of an HCP. Advertising messages addressed to the public, if allowed by relevant legislation, must in any case be approved in advance by an Advisory Board operating at the Ministry of Health ("MoH").

Regulatory Framework

Laws Governing the Promotion of Medicines and Medical Devices

Various pieces of legislation apply to the advertising of medicines and medical devices in Italy, in particular:

- Legislative Decree No. 219 of 24 April 2006 ("LD 219"), implementing Directive 2001/83/EC, as amended, on the Community Code on medicinal products for human use;
- Section 21 of Legislative Decree of 24 February 1997, No. 46 ("LD 46"), implementing Directive 93/42/EEC;
- Ministerial Decree of February 23, 2006 on medical devices advertising ("MD");

medici in Italia, in particolare: (a) il Decreto Legislativo 24 aprile 2006, n. 219 ("D.Lgs. 219"), in attuazione della Direttiva 2001/83/CE, così come modificata, relativa ad un codice comunitario concernente i medicinali per uso umano, (b) l'articolo 21 del Decreto Legislativo 24 febbraio 1997, n. 46 ("D.Lgs. 46"), in attuazione della direttiva 93/42/CEE, (c) il Decreto del Ministro della Salute 23 febbraio 2006 sulla pubblicità dei dispositivi medici ("DM"), (d) l'articolo 2598, che disciplina le pratiche di concorrenza sleale (un aspetto che potrebbe essere rilevante nella definizione delle strategie pubblicitarie nel settore dei dispositivi medici), (e) il Decreto Legislativo 6 settembre 2005, n. 206, in attuazione della Direttiva 84/450/CEE, relativa alla pubblicità ingannevole e della Direttiva 97/55/CE relativa alla pubblicità comparativa e, (f) a livello regionale, le "Linee Guida di regolamento regionale dell'informazione scientifica sul farmaco" adottate il 24 aprile 2006 prevedono norme dettagliate in materia di informazione scientifica e pubblicità dei farmaci a medici e farmacisti da parte degli informatori scientifici. Sulla base di tali linee guida le singole Regioni italiane hanno già adottato propri regolamenti in merito.

Più in particolare:

a) Il D.Lgs 219 prevede una dettagliata disciplina in materia di pubblicità diretta al pubblico ed agli operatori sanitari.

In linea generale, è vietata qualsiasi pubblicità di un medicinale per cui non è stata rilasciata un'autorizzazione all'immissione in commercio (AIC). La pubblicità di un medicinale deve, inoltre, favorirne l'uso razionale, presentandolo in modo obiettivo e senza esagerarne le proprietà e non può essere ingannevole.

La promozione di medicinali di un'impresa farmaceutica straniera, titolare di AIC, può essere effettuata anche da un'altra impresa farmaceutica che abbia sede in Italia e sia stata investita della legale rappresentanza dell'impresa straniera in Italia. Inoltre, L'attuazione della pubblicità presso gli operatori sanitari può essere realizzata, anche in forma congiunta con il titolare dell'AIC del medicinale, ma comunque in base ad uno specifico accordo con questo, da altra impresa. Cio significa che in Italia sono consentite sia il co-marketing che la co-promotion.

Come detto, è vietata la pubblicità presso il pubblico dei medicinali che possono essere forniti soltanto dietro presentazione di ricetta medica o che contengono sostanze psicotrope o stupefacenti; in deroga a tale divieto il Ministero della salute può autorizzare campagne di vaccinazione promosse

- Section 2598 dealing with unfair competition practices (an aspect which may be relevant in medical devices advertising strategies);
- Legislative Decree of September 6, 2005, No. 206, implementing Directives 84/450/EEC on misleading advertising and 97/55/EC on comparative advertising, and
- with respect to the regional level, the "Guidelines for regional regulations regarding scientific information relevant to medicines" issued on April 26, 2006, providing detailed rules regarding scientific information and advertising of medicines and medical devices to doctors and pharmacists by scientific informers. Based on said Guidelines, the Regions adopted their regulations.

In more detail:

LD 219 sets forth a detailed discipline on advertising to the public and to HCPs. In general terms, it prohibits any advertising of a medicinal product for which a marketing authorization has not been granted. The advertising of a medicinal product must encourage the rational use of the medicinal product, by presenting it objectively and without exaggerating its properties, and must not be misleading.

Advertising to health professionals may be made by another pharmaceutical company jointly with the marketing authorization holder by a company that, on the basis of a specific agreement with the holder of the marketing authorization, actually distributes the products in the entire national territory. This means that in Italy, both co-marketing and co-promotion agreements are allowed.

Advertising to the general public of medicinal products, which are available on medical prescription only or contain psychotropic or narcotic substances, is prohibited. Notwithstanding this prohibition, the MoH may authorize vaccination campaigns promoted by the industry. Moreover, the distribution of medicines to the public for promotional purposes is prohibited.

In publications, radio or television broadcasting, or in any non-promotional messages to the general public, it is prohibited to mention the name of a medicinal product in a context where this results in the promotion of the consumption of the product.

da imprese farmaceutiche. È, inoltre, vietata la distribuzione al pubblico di medicinali a scopo promozionale.

In pubblicazioni a stampa, trasmissioni radio-televisive e in messaggi non a carattere pubblicitario comunque diffusi al pubblico, è vietato mostrare in immagini un medicinale o la sua denominazione in un contesto che può favorire il consumo del prodotto.

Per quanto concerne la pubblicità presso operatori sanitari, questa deve sempre includere il riassunto delle caratteristiche del prodotto che risulta autorizzato al momento della diffusione della pubblicità, specificare la classificazione del medicinale ai fini della fornitura e indicare il prezzo di vendita e le condizioni dell'eventuale dispensazione del medicinale con onere a carico del Servizio sanitario nazionale.

La documentazione oggetto della campagna pubblicitaria presso gli operatori sanitari, deve essere preventivamente depositata depositata presso l'Agenzia Italiana del Farmaco ("AIFA"), prima dell'inizio della campagna pubblicitaria e può essere fornita al medico dall'impresa farmaceutica se sono trascorsi dieci giorni dalla data di deposito.

Secondo quanto previsto dall'articolo 118, comma 14, del D.Lgs 219 alcune disposizioni normative concernenti la pubblicità di medicinali si applicano anche ai medicinali (in tal senso si veda sopra il punto a) relativamente alla procedura di silenzio-assenso). Inoltre, i principi generali e le regole relative alla pubblicità di prodotti medicinali presso i professionisti sanitari sono considerati applicabili anche ai dispositivi medici, confermando la tendenza a regolare in maniera omogenea la materia della promozione dei medicinali e dei dispositivi medici.

b) In materia di dispositivi medici, ai sensi dell'articolo 21 del D.Lgs. 24 febbraio 1997, n. 46 "D.Lgs. 46"), è vietata la pubblicità verso il pubblico dei dispositivi medici che possono essere venduti soltanto su prescrizione medica o essere impiegati eventualmente con l'assistenza di un medico o di un professionista sanitario.

Per contro, la pubblicità di dispositivi medici che non necessita di prescrizione medica o dell'assistenza di un professionista sanitario deve essere autorizzata dal Ministero della Salute. In questo caso, se il Ministero della Salute non comunica alcuna risposta al richiedente entro 45 giorni dalla richiesta la pubblicità del dispositivo medico deve considerarsi implicitamente approvata.

As to promotion to HCPs, any advertising of a medicinal product to persons qualified to prescribe or supply such products shall always include the essential information contained in the summary of product characteristics of the product authorized at the time the advertising is disseminated; specify the supply classification of the medicinal product; and specify the sale price and the conditions for reimbursability by the National Health Care Service.

The documentation on the medicinal product must be filed before the advertisement with the Agenzia Italiana del Farmaco, i.e., the Italian Pharmaceutical Agency at the MoH, and can be supplied after the expiration of a term of 10 days from the filing.

Pursuant to Section 118, paragraph 14 of LD 219, certain provisions on advertising medicinal products also apply to medical devices (please see above). Furthermore, the general principles and rules on advertising medicinal products to HCPs are deemed applicable also to medical devices in line with the trend to regulate the promotion of medicinal products and medical devices to HCPs in the same manner.

With regard to medical devices, pursuant to Section 21 of LD46, it is prohibited to advertise to the general public medical devices that must be ordered by, chosen by or ultimately used with the assistance of an HCP.

Instead, the advertising of medical devices that do not need an HCP's prescription or assistance must be authorized by MoH. In this case, if the MoH does not send any response to the applicant within 45 days from the application, the advertising of the medical device must be considered as implicitly approved.

According to the MD, the categories of medical devices which shall not be advertised to the general public are the following: custom-made medical devices, medical devices that must be ordered by or chosen by an HCP, and medical devices which must be used with the assistance of an HCP.

Section 3 of the MD states that advertising by a company that intends to promote only its own image without referring to a specific product (institutional advertising) must be subject to the general regime for advertising and not to the specific restrictions provided by Italian law on promotion of medical devices.

c) Secondo le disposizioni contenute nel DM, le categorie di dispositivi medici che non possono essere pubblicizzate verso il pubblico sono le seguenti: (i) dispositivi medici su misura (ii) dispositivi medici che possono essere venduti soltanto su prescrizione medica, e (iii) dispositivi che possono essere impiegati con l'assistenza di un medico o di un professionista sanitario.

L'articolo 3 del DM prevede che la pubblicità di un'azienda che intenda esclusivamente promuovere la propria immagine senza riferimento ad uno specifico prodotto (pubblicità istituzionale) è soggetta alle regole generali sulla pubblicità e non alle specifiche restrizioni previste dalla normativa italiana in materia di pubblicità di dispositivi medici.

d) L'articolo 2598 del codice civile stabilisce che è vietato: (i) danneggiare una società concorrente, agendo in violazione dei principi di correttezza professionale e (ii) pubblicare informazioni relative ad aziende concorrenti o ai loro prodotti, che possano cagionare danni alle medesime aziende.

e) L'articolo 2d del Decreto Legislativo 2 agosto 2007, n. 145, definisce "pubblicità comparativa" qualsiasi pubblicità che identifica in modo esplicito o implicito un concorrente o beni o servizi offerti da un concorrente.

Ai sensi dell'articolo 4 dello stesso decreto, la pubblicità comparativa è lecita se sono soddisfatte le seguenti condizioni: (i) la pubblicità comparativa proposta non è ingannevole, (ii) confronta beni o servizi che soddisfano gli stessi bisogni o si propongono gli stessi obiettivi, (iii) confronta oggettivamente una o più caratteristiche essenziali, pertinenti, verificabili e rappresentative, compreso eventualmente il prezzo, (iv) non ingenera confusione sul mercato tra i professionisti, (v) non causa discredito o denigrazione di marchi, denominazioni commerciali, altri segni distintivi, beni, servizi, attività o posizione di un concorrente, (vi) per i prodotti recanti denominazione di origine, si riferisce in ogni caso a prodotti aventi la stessa denominazione, (vii) non trae indebitamente vantaggio dalla notorietà connessa al marchio, alla denominazione commerciale ovvero ad altro segno distintivo di un concorrente o alle denominazioni di origine di prodotti concorrenti, e (viii) non presenta un bene o un servizio come imitazione o contraffazione di beni o servizi protetti da un marchio o da una denominazione commerciale depositati.

Section 2598 of the Civil Code states that it is illegal to: damage a competing company, acting in violation of the principles of professional fairness; and to publish information related to competing companies or their products, which may cause damage to the same companies.

Section 2. d of Legislative Decree dated August 2, 2007, No. 145 defines "comparative advertising" as "any advertising which explicitly or by implication identifies a competitor, or goods or services offered by a competitor."

According to Section 4 of the same decree, comparative advertising is permitted when the following conditions are met: the proposed comparative advertising is not misleading; it compares goods or services with the same needs or intended for the same purpose; it compares objectively one or more material, relevant, verifiable and representative characteristics of goods and services, which may include their price; it does not create confusion among traders; it does not discredit or denigrate trademarks, trade names, or other distinguishing marks, goods, services, activities, or circumstances of a competitor; for products with designation of origin, it relates in each case to products with the same designation; it does not take unfair advantage of the reputation of a trademark, trade name or other distinguishing marks of a competitor or of the designation of origin of competing products; and it does not present products or services as imitations or replicas of products or services bearing a protected trademark or trade name.

Codes of Conduct and Regulatory Provisions

Further provisions and codes of conduct governing advertising of medicines and medical devices are the Circular of the Ministry of Health of 17 February 2010 ("Circular"), for which Guidelines were issued on the use of new means of dissemination of advertising of medicines and medical devices; the Code of Ethics of Farmindustria - association of the Italian pharmaceutical industries ("Farmindustria Code") - and the Code of Ethics ("ABM Code") issued by Assobiomedica - Italian Association of Medical Device Companies - which sets forth ethical guidelines regarding the organization of events held by companies for promotional purposes.

The Circular lays down rules on the use of "toll-free numbers" in advertisements. The operators of the toll-free numbers are only authorized to provide technical product information and promotional messages. If pre-recorded promotional messages are addressed to clients, such messages should be approved by the MoH.

Codici di condotta e disposizioni regolamentari in materia di pubblicità di farmaci e dispositivi medici.

Ulteriori disposizioni e codici di condotta che regolano la pubblicità di farmaci e dispositivi medici sono (i) la Circolare del Ministero della Salute del 17 febbraio 2010 ("Circolare"), con la quale sono state diramate Linee Guida in merito all'utilizzo di nuovi mezzi di diffusione nella pubblicità sanitaria concernente farmaci e dispositivi medici, (ii) il Codice Etico di Farmindustria – associazione di aziende italiane che operano nel settore dei medicinali – (Codice Farmindustria), e (iii) il Codice Etico ("Codice ABM") adottato da Assobiomedica – associazione di aziende italiane che operano nel settore dei dispositivi medici –, che detta dei principi di carattere etico relativamente all'organizzazione di eventi organizzati dalle aziende per scopi promozionali.

(i) In primo luogo, la Circolare detta norme in merito all'uso numeri verdi in messaggi promozionali. Gli operatori dei numeri verdi sono autorizzati a fornire solo informazioni tecniche sul prodotto e non messaggi promozionali. Qualora messaggi promozionali pre-registrati fossero indirizzati ai clienti, tali messaggi dovrebbero essere preventivamente autorizzati dal Ministero della Salute.

La diffusione tramite internet di informazioni su farmaci e dispositivi medici ad operatori sanitari è permessa senza autorizzazione del Ministero della Salute. Tuttavia, la diffusione di tali informazioni deve avvenire in aree criptate del sito, protette da password.

Secondo la Circolare, i messaggi pubblicitari autorizzati dal Ministero della Salute non possono essere automaticamente pubblicati su internet. A tal fine è necessaria un'ulteriore autorizzazione.

Infine, secondo la Circolare è ammessa la diffusione di messaggi pubblicitari tramite e-mail o tramite MMS, previa autorizzazione, esclusivamente nel caso in cui l'Azienda che commercializza dispositivi medici abbia ricevuto una richiesta dal cliente. Non è ammessa la diffusione di pubblicità tramite SMS.

(ii) Secondo il Codice ABM ed il codice Farmindustria alle aziende è permesso promuovere i propri prodotti invitando i professionisti sanitari a corsi e conferenze, per la partecipazione ai quali le aziende coprono ogni ragionevole spesa di viaggio. Tuttavia, se i professionisti che partecipano all'evento formativo organizzato da un'azienda (o in ogni caso ad eventi organizzati per la promozione dei prodotti di un'azienda) sono dipendenti del Servizio Sanitario Nazionale,

The dissemination of information about medicines and medical devices to healthcare professionals via the internet is permitted without MoH's authorization, however, the spread of this information must be in an encrypted area of the sites, protected by a password. According to the Circular, advertisements authorized by the MoH can not be automatically published on the internet further approval is necessary.

Finally, the Circular allows the dissemination of information by email or MMS, with prior permission, only if the company selling medical devices has received a request from the client. It is not permissible to disseminate advertising via SMS.

Under the ABM Code and the Farmindustria Code, companies are allowed to promote their products by inviting HCPs to workshops and conferences, for which the companies pay any reasonable travel costs incurred by the HCPs. However, if the HCPs attending the company's events (or in any case events organized to promote the company's products) are employed with the National Health Care Service, the company should send communication to their employee to communicate the initiative.

It is forbidden to pay the lodging costs for the HCPs' guests.

Marketing Authorization of Products to be Advertised

Pursuant to LD 219, medicines can be placed on the market only once the marketing authorization has been obtained.

The marketing authorization, according to the national procedure, is granted by the AIFA.

Under LD 46, a medical device bearing the CE mark can be placed in the market or put into use, without any further authorization given by the local authorities.

In order to obtain the CE mark, the manufacturer must file an application to determine the quality of the medical device's system with a Notified Body ("NB"), a technical auditing organization authorized by the MoH and by the Ministry of Industry, which will examine the file.

If the product complies with the relevant provisions of LD 46, the NB will release a CE declaration of conformity, which is the legal basis for the attachment of the CE mark. Decisions taken by the NB will be valid for a maximum of five years and may be extended for further periods of five years.

l'azienda deve inviare una comunicazione al loro datore di lavoro per informarlo dell'iniziativa.

Inoltre, è proibito pagare i costi relativi all'alloggio per gli ospiti dei professionisti sanitari.

Autorizzazioni all'immissione in commercio dei prodotti da promuovere.

In base al D.lgs 219, un farmaco può essere immesso in commercio solo dopo aver ottenuto un'AIC.

Secondo quanto previsto dal D.Lgs. 46 un dispositivo medico recante il marchio CE può essere immesso in commercio o messo in servizio senza alcuna ulteriore autorizzazione rilasciata dalle autorità locali.

Per quanto concerne i farmaci l'AIC, in base alla procedura nazionale, è rilasciata dall'AIFA. Per quanto concerne i dispositivi medici, al fine di ottenere il marchio CE per un dispositivo medico, il fabbricante deve presentare una domanda ad un Organismo designato ad attestare la conformità ("Organismo notificato") – un'organizzazione tecnica di controllo – autorizzato dal Ministero della Salute e dal Ministero dell'Industria, che esaminerà la richiesta.

Se il prodotto si conforma alle rilevanti disposizioni del D.Lgs 46, l'Organismo notificato rilascia una dichiarazione di conformità CE, che dal punto di vista legale rappresenta la base per l'apposizione del marchio CE. Le decisioni prese dall'Organismo notificato avranno validità per cinque anni e potranno essere prorogate per un ulteriore periodo di cinque anni.

Solo i dispositivi medici di classe I, con i più bassi requisiti di sicurezza, non richiedono la presentazione di una domanda all'Organismo notificato. Questi dispositivi medici possono essere immessi in commercio sotto la sola responsabilità del fabbricante.

Come regola generale, un dispositivo medico e un farmaco possono essere immessi in commercio o messo in servizio solo se autorizzati o se recanti il marchio CE.

In deroga alla predetta regola generale, i seguenti dispositivi medici non recano il marchio CE: (i) dispositivi per indagini cliniche e (ii) dispositivi su misura, a condizione che il fabbricante sia iscritto nel Registro dei fabbricanti

Only “class I” medical devices with the lowest safety requirements do not require an application to be filed with an NB. These devices can be placed on the market under the sole responsibility of the manufacturer.

As a general rule, medicines and medical devices can be placed on the market or put into use only if the marketing authorization for the CE mark has been obtained.

As derogation to the above rule, the following medical devices shall not bear the CE mark: devices intended for clinical investigation; and custom-made devices, provided that the manufacturer is enrolled in the Roster of Manufacturers kept by the MoH, and has communicated to the MoH a list of custom-made devices which have been put into service.

With regard to medicines, same can be administered to patients - if not authorized - only for compassionate use, provided that they have passed at least phase II of the clinical experimentation. In restricted cases, the administration of medicines not authorized in Italy is allowed provided that they are imported from the country in which an authorization has been granted to the same.

Permitted and Prohibited Practices

Pursuant to Italian legislation, an HCP is a physician or other professional enrolled in the professional association recognized by the MoH (e.g., physiotherapist, nurse, or podiatrist). We indicate below some of the general rules which pharmaceutical and biomedical companies must follow in relations with HCPs or institutions operating in the healthcare sector, with respect to gifts, sample products, hospitality, entertainment and sponsorship for training, research, employee positions or events.

Gifts

According to Section 123 of LD 219 on advertising of pharmaceutical products, the principles of which are also applied to medical devices, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to physicians or pharmacists unless they are of irrelevant value and are in any case instrumental to the practice of medicine or pharmacy.

Furthermore, pursuant to Section 170 of the Consolidated Text of Health Laws (Royal Decree No. 1265 of July 27, 1934 as amended), the physician who inappropriately receives money or other benefits to inflate the number of drug prescriptions or other medical products for pharmaceutical use is punishable by imprisonment of up to one year and with a fine of up to EUR520.

tenuto dal Ministero della Salute ed abbia comunicato al Ministero della Salute una lista di dispositivi su misura che sono stati messi in servizio. Per quanto riguarda i farmaci, possono essere somministrati a pazienti farmaci non autorizzati solo per uso compassionevole, purchè tali farmaci abbiano superato almeno la fase II di una sperimentazione clinica. In ristretti casi è concessa anche la somministrazione di farmaci non autorizzati in Italia, se importati da Paesi in cui agli stessi è stata concessa un'AIC.

Rapporti tra operatori sanitari e aziende farmaceutiche e biomedicali

Secondo la normativa italiana, un professionista sanitario è un medico o altro professionista sanitario non medico iscritto ad un'associazione professionale riconosciuta dal Ministero della Salute (ad esempio, Fisioterapista, infermiere, podologo, etc.). Indichiamo di seguito alcune delle regole generali cui le aziende che commercializzano farmaci e dispositivi medici si devono attenere nelle interazioni con operatori sanitari o istituzioni operanti nel settore sanitario in materia di doni, campioni gratuiti, ospitalità, intrattenimento e sponsorizzazione per attività di formazione, ricerca, borse di studio o eventi.

Doni

Secondo l'articolo 123 del D.Lgs. 219, relativo alla pubblicità dei farmaci, i cui principi si applicano anche ai dispositivi medici, nessun dono, vantaggio pecuniario o altri benefici in natura possono essere concessi, offerti o promessi a medici o farmacisti, salvo che siano di valore trascurabile e siano comunque collegabili all'attività espletata dal medico.

Inoltre, secondo quanto disposto dall'art. 170 del Testo Unico delle leggi sanitarie (Regio Decreto 27 luglio 1934, n. 1265, così come modificato), il medico o il veterinario che ricevano denaro o altra utilità allo scopo di aumentare il numero di prescrizioni mediche di specialità medicinali a uso farmaceutico, sono puniti con l'arresto fino a un anno e con l'ammenda fino ad Euro 520.

Se il vantaggio pecuniario è offerto ad un operatore sanitario che presta servizio presso ospedali o enti pubblici, troverebbero applicazione le norme in materia di corruzione dei pubblici ufficiali.

Inoltre, secondo il Codice Farmindustria ed il Codice ABM doni a pubblici ufficiali sono autorizzati solo se hanno un valore nominale o modesto e rivestono la funzione effettivamente formativa o possono recare beneficio ai

If the pecuniary advantage is offered to HCPs working for public hospitals or entities, the general rules regarding bribery of public officials would apply.

Moreover, according to the Farmindustria Code and the ABM Code, gifts to public officials are authorized if the gifts have a nominal or modest value, and either serve a genuine educational function or are to the benefit of patients. Please note that under Italian law, there is no statutory definition or quantification of "nominal or modest value."

Sample Products

Medicine sample products may be supplied only to physicians authorized to prescribe the same, and must be handed over only by scientific informers. Samples can not be delivered without a written request bearing the date, stamp and signature of the consignee.

Scientific informers can deliver to each HCP, in any visit, two samples of each dosage or pharmaceutical form of a medicine only in the first 18 months following the first marketing of the same and within a maximum amount of eight samples.

As regards sample products offered to medical institutions, it is worth noting that the tender regulations published by the awarding authorities usually request to supply a certain number of free samples.

Hospitality

Under the Farmindustria Code and the ABM Code, hospitality is allowed subject to the following requirements: if the HCP works for a public hospital or entity, a prior written notification should be sent to the employer; the company shall not bear the expenses related to hospitality for accompanying spouses or other guests; and travel, lodging, hospitality, and meals must be reasonable and can be offered only for the duration of the scientific event attended by the HCP invited.

Hotel services must be in hotels with a maximum rating of four stars, and air travel must be in economy class only, excluding intercontinental flights. The Competition Authority, in its communication of May 2011, noted the illegitimacy of the ABM Code in so far as it prohibits the organization of conferences in five-star hotels on a basis other than the prices they may charge. This provision is detrimental to competition, to the benefit of lower-category hotels. The ABM

pazienti. Si noti che secondo la legge italiana non c'è una specifica definizione o una quantificazione di valore nominale o modesto.

Campioni gratuiti

I campioni gratuiti di un medicinali possono essere forniti solo ai medici autorizzati a prescriverlo e devono essere consegnati soltanto per il tramite di informatori scientifici. I campioni non possono essere consegnati senza una richiesta scritta, recante data, timbro e firma del destinatario.

Gli informatori scientifici possono consegnare a ciascun sanitario due campioni a visita per ogni dosaggio o forma farmaceutica di un medicinale esclusivamente nei diciotto mesi successivi alla data di prima commercializzazione del prodotto ed entro il limite massimo di otto campioni annui

Per quanto riguarda campioni gratuiti offerti ad istituzioni operanti nel settore medico, è bene notare che le disposizioni regolamentari relative a gare d'appalto, pubblicate dalle Autorità aggiudicatici richiedono spesso la fornitura di un certo numero di campioni gratuiti.

Ospitalità

Secondo il Codice Farmindustria e il Codice ABM l'ospitalità è consentita a condizione che siano rispettate le seguenti condizioni: (i) se il professionista sanitario presta servizio per un ospedale o un ente pubblico, una preventiva comunicazione scritta dovrebbe essere inviata al datore di lavoro, (ii) l'azienda non deve coprire le spese relative all'ospitalità per coniugi o altri ospiti, e (iii) le spese di viaggio, di alloggio, di ospitalità e di pasti debbono essere ragionevoli e possono essere offerte solo per la durata dell'evento scientifico cui partecipa il professionista sanitario invitato.

Il servizio alberghiero dovrà avvenire in alberghi con un massimo di quattro stelle e gli eventuali viaggi aerei dovranno essere esclusivamente in classe economica, ad esclusione dei voli intercontinentali.

L'Autorità Garante per la Concorrenza ed il Mercato, in una propria comunicazione del maggio 2011, ha rilevato l'illegittimità delle norme del Codice ABM e del Codice Farmindustria nella parte in cui vietano l'organizzazione di convegni in alberghi a cinque stelle, al di là dei prezzi dagli stessi praticati. Tale disposizioni sarebbero lesive della concorrenza a beneficio degli alberghi di categoria inferiore.

Code of 2011 ignores the communication of the Competition Authority, and persists in maintaining the prohibition, since the luxurious image given by five-star hotels is against the principle of moderation on which the ABM Code is based.

Entertainment

No specific laws or regulations regulate this aspect, apart from the abovementioned rules regarding bribery of public officials and the pecuniary advantage offered to HCPs. However, under the Farmindustria Code and the ABM Code, on the occasion of conferences and workshops,recreational activities should not prevail over the content of the technical-scientific event and must be characterized by moderation.

Sponsorship for Training, Research, Employee Positions or Events

The Eucomed Code sets forth the following principles concerning sponsorship for training, research, employee positions or events:

- Training - Medical device companies are encouraged to make product education and training available to facilitate the safe and effective use of medical technology.
- Research - Companies may provide funds to support genuine independent medical research, provided: it is not viewed as a price concession, reward or incitement to commit acts contrary to law; that appropriate documentation is maintained; and that the recipients are entitled to receive grants under local rules. Research grants to support customer-initiated studies may be permitted for programs involving clinical or non-clinical research in areas of legitimate interest to the company in question. All requests for research grants must be in writing from the requestor stating the nature and objective of the research activity, and no support should be provided until a written agreement providing for adverse event reporting is signed by both parties. Full disclosure of the award should be made to the healthcare professional's hospital, superior or employer, and the recipient of the grant must acknowledge the sponsorship of the research in all oral or written presentations of the results.
- Employee Positions - Companies may also provide educational grants to training or healthcare institutions or professional societies for medical education programs by providing financial support for fellowships and similar scholarship awards. However, the selection of the grantee should be within the discretion of the institution at which they are enrolled or the teaching institution at which they will be

Il Codice ABM ed il Codice Farmindustria più recenti disattendono la comunicazione dell'Autorità Garante ed insistono nel mantenimento del divieto, dal momento che l'immagine di lusso che viene data dagli alberghi a cinque stelle contrasta con il principio di sobrietà.

Intrattenimento

Nessuna specifica disposizione di legge o di regolamento disciplina questo aspetto, salvo le sopra menzionate norme relative alla corruzione dei pubblici ufficiali e i vantaggi pecuniari offerti ai professionisti sanitari.

Tuttavia, secondo il Codice ABM ed il Codice Farmindustria, in occasione di conferenze o *workshops*, le attività ricreative non debbono prevalere sul contenuto tecnico-scientifico dell'evento e devono essere improntate alla sobrietà.

Sponsorizzazione per attività di formazione, ricerca, borse di studio o eventi

Il Codice Eucomed detta i seguenti principi in materia di sponsorizzazione per attività di formazione, ricerca, assunzione di personale o eventi:

- Attività di formazione – le aziende produttrici di dispositivi medici sono incoraggiate a svolgere attività di formazione ed insegnamento al fine di facilitare un uso corretto e sicuro della tecnologia medica;
- Ricerca – le aziende possono finanziare la ricerca medica seria e indipendente, ferma restando la necessità che (i) tale finanziamento non possa essere considerato come una concessione di denaro, una ricompensa o un'induzione volta a commettere atti contrari alla legge, (ii) che la documentazione rilevante sia conservata e (iii) che i professionisti sanitari siano autorizzati a ricevere i finanziamenti secondo le leggi locali. I finanziamenti per la ricerca in favore di studi iniziati da parte dei clienti sono consentiti per lo sviluppo di programmi relativi alla ricerca clinica e non clinica nelle aree di interesse dell'azienda sponsor. Tutte le richieste per i finanziamenti alla ricerca debbono essere predisposte per iscritto dal richiedente, precisando la natura e l'obiettivo dell'attività di ricerca, e nessun finanziamento può essere erogato fino al momento in cui le parti stipulino un accordo scritto volto a garantire una corretta informazione in caso di eventi avversi. E' necessario comunicare all'Ospedale, al superiore del professionista sanitario o al proprio datore di lavoro ogni notizia relativa al finanziamento ricevuto.

trained, rather than the company sponsor. Grants must be provided to the teaching or professional institution, not to individual fellows, save for the prior written request of the institution. In no way should the funding be tied to an institution's purchase of a company's products, or otherwise based on an institution's past or potential future use of the company's products or services.

- Events - Medical device companies are entitled to provide financial support to cover the cost of third-party educational conference attendance by individual healthcare professionals. Such financial support must be limited to the conference registration fee andreasonable travel, meals and accommodation costs relating to the attendance of the event. Companies must ensure they comply with local rules surrounding such sponsorship, such as disclosure requirements. Where there are no prescribed rules for disclosure, companies must nevertheless maintain appropriate transparency, for example, by requiring that prior written notification of the sponsorship is made to the healthcare professional's hospital, superior or employer.

The Farmindustria Code repeats substantially the same principles above.

Equipment

The Companies marketing medicines and medical devices are authorized to provide equipment to hospitals free of charge if permissible under tender regulations.

Medical device companies are also allowed to enter into charitable donations with hospitals. However, according to the ABM Code, charitable donations entered into with public hospitals and entities should be documented in writing.

Contracts with Healthcare Professionals and Medical Institutions

According to Section 53 of Legislative Decree of March 30 2001, No. 165, HCPs who work for a public hospital or entity must be authorized by their employer before entering into contracts with private companies (e.g., consulting agreements or research and development agreements). The authorization of the employer is not required for agreements concerning attendance at conferences and seminars (e.g., speaking agreements) and for articles to be published in scientific reviews.

Il soggetto che riceve il finanziamento deve dare atto del finanziamento ricevuto in tutte le presentazioni dei risultati dello studio finanziato dallo sponsor, sia orali che scritte.

- Borse di studio – Le aziende possono anche fornire finanziamenti per borse di studio o programma di formazione presso società di formazione o istituzioni sanitarie specializzate in programmi di formazione medica. Tuttavia, la scelta del beneficiario del finanziamento deve essere compiuta dall'istituzione sanitaria presso cui il beneficiario presta servizio o dall'istituto di formazione nel quale lo stesso è iscritto, piuttosto che direttamente dall'azienda sponsor. I finanziamenti debbono essere erogati nei confronti degli istituti di formazione o professionali e non direttamente agli individui, a meno che non vi sia una preventiva autorizzazione dell'istituzione presso la quale il beneficiario presta servizio. In nessun caso il finanziamento può essere collegato all'acquisto di prodotti aziendali o basato sul fatto che l'istituzione in passato o nel futuro abbia fatto o farà uso dei prodotti o dei servizi dell'azienda sponsor.
- Eventi – Le aziende produttrici di dispositivi medici possono concedere finanziamenti a copertura del costo di partecipazione di professionisti sanitari. Tali finanziamenti debbono essere limitati alle spese di registrazione alla conferenza ed alle ragionevoli spese di viaggio, pasti e pernottamento relative alla partecipazione all'evento. Le aziende debbono assicurare il rispetto della legge locale concernente gli obblighi di pubblicità/comunicazione del finanziamento. Se non è previsto alcun obbligo di pubblicità/comunicazione, le aziende debbono comunque garantire la trasparenza, inviando, ad esempio, una preventiva comunicazione concernente il finanziamento del professionista sanitario all'ospedale, al superiore o al datore di lavoro dello stesso.

Il Codice Farmindustria ripropone, in sostanza, principi assimilabili a quelli menzionati.

Le aziende che commercializzano farmaci e dispositivi medici sono autorizzate a fornire gratuitamente attrezzatura ad ospedali?

Le aziende che commercializzano farmaci e dispositivi medici sono autorizzate ad offrire gratuitamente attrezzatura medica ad ospedali se è stabilito dai regolamenti delle gare d'appalto.

According to Section 6 of Law No. 240, dated December 12, 2010, as amended by Law Decree February 9, 2012, No. 5, university professors and university researchers (a rank below full professors) are no longer requested to obtain the employer's authorization to sign agreements related to occasional lessons and seminars, scientific and consultancy activities, and dissemination of scientific material.

According to the ABM Code, consulting agreements entered into between medical device companies and HCPs who work for public hospitals and entities must meet the following conditions: the agreement must be documented in writing; the fees paid to HCPs must be reasonable and closely connected to the service performed by the HCPs; the agreement must be entered into only if bearing a legitimate purpose for performing the services; the consultant must be chosen for his qualification and expertise; and if the consultant is engaged for research and development, a research protocol must be approved by the public hospital or entity where the HCP works.

Promotional Practices

As already underlined, according to the applicable laws and regulations on advertising of medical devices, advertising to the general public of categories of medicines and medical devices sold only after a physician's prescription or requiring a physician or other medical professional intervention is forbidden.

As a general rule, the advertising of medicines and medical devices, with very few exceptions, is authorized by the MoH. For that purpose, a specific Advisory Board has been established within the MoH with the aim of evaluating all advertising requests and ensuring full compliance with all applicable laws governing the advertising of medicines and medical devices. In applying for such authorization from the MoH, the manufacturing company or the party responsible for placing the medicine or the device on the market must file all the relevant information regarding the product, the kind of advertising and the relevant means of communication chosen.

Supply of Scientific Data and Literature

In Italy, applicable regulations on medical device advertising do not provide any specific provisions regarding the supply of scientific data and relevant scientific literature. However, the general principles and rules on advertising medicinal products to HCPs are deemed applicable also to medical devices in line with the trend to regulate the promotion of medicinal products and medical devices to HCPs in the same manner.

Le aziende che commercializzano dispositivi medici sono, altresì, autorizzate ad effettuare donazioni nei confronti di ospedali. Tuttavia, secondo il Codice ABM ed il Codice Farmindustria le donazioni ad ospedali e ad enti pubblici debbono essere documentate in forma scritta.

Contratti stipulati con professionisti sanitari e con istituzioni sanitarie.

Le aziende produttrici dispositivi medici e le aziende farmaceutiche possono stipulare accordi con professionisti sanitari per partecipazione a convegni o altri servizi?

Secondo quanto previsto dall'articolo 53 del Decreto Legislativo 30 marzo 2001, n. 165, i professionisti sanitari che lavorano per un ospedale o ente pubblico debbono essere autorizzati dai propri datori di lavoro prima di stipulare contratti con aziende private (ad esempio, contratti di consulenza o di ricerca e sviluppo). L'autorizzazione del datore di lavoro non è richiesta per accordi concernenti la partecipazione a conferenze o seminari e per articoli da pubblicarsi su riviste scientifiche.

Secondo quanto previsto dall'art. 6 della legge 12 dicembre 2010, n. 240, come modificata dal decreto-legge 9 febbraio 2012, n.5., non è più richiesto a professori universitari e ricercatori l'ottenimento dell'autorizzazione del datore di lavoro al fine di stipulare accordi relativi a lezioni e seminari di carattere occasionale, attività di collaborazione scientifica e di consulenza e pubblicazione di materiali scientifici.

In base alle disposizioni del Codice ABM, i contratti di consulenza stipulati tra l'azienda di dispositivi medici ed il professionista sanitario che lavora per ospedali o enti pubblici è soggetto al rispetto delle seguenti condizioni: (i) gli accordi debbono essere documentati in forma scritta, (ii) il corrispettivo pagato ai professionisti sanitari deve essere ragionevole e strettamente connesso al servizio svolto dal medesimo, (iii) l'accordo deve essere stipulato solo laddove venga individuato uno scopo legittimo per la prestazione dei servizi, (iv) il consulente deve essere scelto per la sua qualificazione ed esperienza, e (v) se il consulente è impegnato in attività di ricerca e sviluppo, un protocollo di ricerca deve essere approvato dall'ospedale o dall'ente pubblico per cui il professionista sanitario presta servizio.

Pursuant to Article 120, paragraph 3 of LD 219, all the information contained in the promotional documentation shall be accurate, up-to-date, verifiable and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the medicinal product concerned. According to paragraph 4 of the abovementioned article, quotations as well as tables and other illustrative matters taken from medical journals or other scientific works for use in the documentation shall be faithfully reproduced and the precise sources indicated.

Promotional Messages Addressed to the Public

Direct advertising to the general public of medical devices for which a medical prescription is required, or for which a physician or other medical assistance is necessary, is forbidden. It is only permissible to advertise to the public those medicines and medical devices for which a physician's prescription or other medical assistance is not required, provided that the promotional messages were authorized by MoH.

There are no specific legal provisions with regard to the kind of language to be used in the advertising of medicines or medical devices with the general public for example, regarding the use of expert terminology. For the categories of medical devices that need to be authorized, the claims need to be approved by the Advisory Board of the MoH.

In Italy, there are no specific provisions forbidding the display of prices in advertising materials.

According to the guidelines provided on the MoH website regarding the application for advertising authorization, in addition to other information, the company must indicate the means of communication chosen for the advertising campaign. The listed means of communication include TV and movie shorts; radio communications; general press and newspapers; advertising materials for retail shops (such as flyers, brochures, displays and shop windows) and others. Furthermore, on 17 February 2010, the Circular's new guidelines were issued containing clarifications on the permitted contents and methods for the dissemination of advertisements relating to medical devices through new means of delivery (toll-free numbers, web, SMS, MMS, email).

Pratiche promozionali permesse e proibite

Come abbiamo avuto modo di sottolineare in precedenza, secondo le vigenti disposizioni di legge in materia, la promozione di farmaci e dispositivi medici presso il pubblico è vietata per quelle categorie di dispositivi che possono essere venduti solo su prescrizione di un medico o possono essere impiegati eventualmente con l'assistenza di un medico o di un altro professionista sanitario.

Come principio generale, la promozione di farmaci e dispositivi medici, tranne alcune eccezioni, è soggetta ad autorizzazione del Ministero della Salute. A tale proposito è stata istituita una specifica Commissione Consultiva all'interno del Ministero stesso, con lo scopo di valutare tutte le richieste di autorizzazione alla promozione di farmaci e dispostivi medici ed assicurare la conformità di tali materiali pubblicitari alle vigenti disposizioni di legge in materia. All'atto della presentazione della domanda di autorizzazione ad effettuare una pubblicità sanitaria, l'azienda fabbricante o responsabile dell'immissione in commercio del farmaco e del dispositivo, dovrà fornire tutte le informazioni inerenti il prodotto, il tipo di pubblicità e il relativo mezzo di diffusione scelto.

La divulgazione di dati e letteratura scientifica da parte delle aziende farmaceutiche e biomedicali è attività promozionale?

In Italia le disposizioni di legge vigenti in materia di promozione di dispositivi medici non forniscono alcuna specifica indicazione circa la divulgazione di dati e letteratura scientifica come forma di promozione di dispostivi medici.

Ad ogni modo, i principi generali e le regole relative alla pubblicità di prodotti medicinali presso i professionisti sanitari sono considerati applicabili anche ai dispositivi medici, confermando la tendenza a regolare in maniera omogenea la materia della promozione dei medicinali e dei dispositivi medici.

Secondo l'art. 120, comma 3, del D.Lgs. 219 tutte le informazioni contenute nella documentazione promozionale devono essere esatte, aggiornate, verificabili e sufficientemente complete per permettere al destinatario di essere adeguatamente informato sull'effetto terapeutico e sulle caratteristiche del medicinale.

In Italy, there are no specific regulations regarding the use of testimonials to promote medical products. However, according to Section 114 of Legislative Decree 219/2006 on advertising of pharmaceutical products, the principles of which also apply to medical devices, advertising of medicinal products must encourage the rational use of the medicinal product by presenting it objectively and without exaggerating its properties. Moreover, in publications, radio or television broadcasting, or in any non-promotional messages to the general public, it is prohibited to mention the name of a medicinal product in a context where this results in the promotion of the consumption of the product.

With regard to the permission to offer contests, raffles or other procedures where results are determined by chance to consumers who purchase medical devices, the applicable laws and regulations on medical device advertising do not provide for any specific provision. However, considering the general trend of regulating the promotion of medicinal products and medical devices in the same manner, Article 5, paragraph 3 of the Legislative Decree No. 223/2006, which forbids the organization of contests and competition concerning medicines, may apply.

According to Article 3, paragraph 2 of MD, the advertising of medical device manufacturing or distribution companies is allowed if no additional information regarding the characteristics of such devices is provided. This type of advertising is referred to as “institutional” and in accordance with the abovementioned dispositions. No authorization of the MoH is required for it. Same conclusions must be reached with respect to “institutional” advertisement of pharmaceutical companies.

Section 113 of LD 219, defines “advertising” as any form of information, activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products. In light of such broad definition, a patient information session organized to inform patients about the characteristics and the properties of company’s medical devices would be considered as a way to promote such products.

Liability Under Criminal and Civil Law and the Applicable Codes of Conduct

Companies which violate the provisions of Italian law regarding the promotion of medical devices are punished with administrative fines ranging between EUR2,582.28 and EUR15,493.71. Moreover, unless the MoH decides to proceed by its own initiative, the MoH can order the immediate

Il comma 4 del medesimo art. 120 del D.Lgs. 219 stabilisce che gli articoli, le tabelle e le altre illustrazioni tratte da riviste mediche o da opere scientifiche devono essere riprodotti integralmente e fedelmente, con l'indicazione esatta della fonte. Non sono consentite citazioni che, avulse dal contesto da cui sono tratte, possono risultare parziali o distorsive.

Messaggi promozionali diretti al pubblico.

E' permesso:

(a) promuovere farmaci o dispositivi medici direttamente ai consumatori/pazienti; e

E' vietata la pubblicità verso il pubblico dei dispositivi medici e dei farmaci che possono essere venduti soltanto su prescrizione medica o essere impiegati eventualmente con l'assistenza di un medico o di un altro professionista sanitario.

E' permessa la pubblicità al pubblico solo di quei farmaci e dispositivi medici per i quali non è richiesta la prescrizione di un medico o altro tipo di assistenza medica per l'uso, purchè il messaggio promozionale sia autorizzato dal Ministero della Salute.

Le aziende di farmaci e dispositivi medici possono usare terminologia specialistica nelle promozioni destinate ai consumatori/pazienti?

In Italia le vigenti disposizione di legge in materia di pubblicità di farmaci e dispostivi medici non contengono alcuna disposizione specifica riguardo l'uso di terminologia specialistica nelle promozioni dirette al pubblico. Per le categorie di farmaci e dispositivi medici la cui pubblicità necessita dell'approvazione del Ministero della Sanità, la terminologia del *claim* pubblicitario dovrà essere approvata dalla Commissione Consultiva.

Le aziende di dispositivi medici possono usare i prezzi nelle promozioni di dispositivi medici?

In Italia le vigenti disposizioni di legge in materia di pubblicità di dispositivi medici non forniscono alcuna indicazione specifica riguardo la possibilità di indicare il prezzo nelle promozioni.

Sono permesse le seguenti tipologie di promozione per i dispositivi medici:

(a) e-mail;
(b) TV / radio?

cessation of the advertising and the dissemination, at the expense of the infringing party, or a notice to rectify or clarify the advertising in accordance with the instructions provided by the MoH.

In the case of misleading advertising, the Italian Antitrust Authority: may order the infringing party to stop any illegal activity; order rectifying statements to be published at the expense of the infringing party; and issue administrative fines ranging between EUR5,000 and EUR500,000.

As to pharmaceutical products, in case of any violation of the rules on advertising to the general public, Article 118 of the Code provides that the MoH can order the immediate cessation of the advertising and the dissemination, at the expense of the violator, or a notice to rectify or clarify the advertising in accordance with the instructions provided by the Ministry, unless the Ministry decides to proceed by its initiative; the company is also subject to a pecuniary fine ranging from EUR2,700 to EUR15,600 pursuant to Article 148 of the Code.

Same sanctions apply, pursuant to Articles 127 and 148 of the Code in case of a violation of the requirements set forth for the advertising to persons qualified to prescribe or supply medicinal products. For products that are reimbursed by the National Health Care Service, the violation shall also be punished with the suspension of the medicinal product from the reimbursement regime for a period ranging from 10 days to two years. The suspension is adopted after the notification of the violation to the holder of the marketing authorization that has the right to file its observations within 15 days from the notification.

Article 148 of the Code provides for other penalties in case of violation of the requirements for publications, radio and television broadcasting, and messages that do not have promotional content (administrative fine from EUR10,000 to EUR60,000), for free samples of medicinal products (for instance, an administrative fines from EUR5,000 to EUR30,000 for samples that do not bear the “not for sale” marking) and for the scientific service (administrative fine from EUR50,000 to EUR300,000).

A further potential area of liability for pharmaceutical and biomedical companies stems from Legislative Decree no. 231 of 2001, under which companies will be criminally liable for crimes committed, for the benefit or the advantage of the company, by its representatives (i.e., directors, managers, and other employees). Companies may avoid this liability by implementing an internal organizational model (“231 Model”) that: introduces specific procedures to be followed by managers and employees in order to avoid, or to reduce the risk

Secondo delle prime linee guida pubblicate sul sito internet del Ministero della Salute, concernenti la domanda per l'autorizzazione alla pubblicità di dispositivi medici, l'azienda interessata, tra le altre informazioni dovrà indicare il mezzo di comunicazione scelto per la campagna promozionale. La lista pubblicata su tale sito internet, include: cortometraggio televisivo o cinematografico; radio comunicato; stampa quotidiana o periodica; stampa punto vendita (cartello vetrina, espositore, volantino, opuscolo); cartellonistica stradale, affissioni; altro. Inoltre, il 17 febbraio 2010 è stata emanata la Circolare, contenente nuove linee guida contenenti chiarimenti sui contenuti e sulle modalità consentite per la diffusione attraverso i nuovi mezzi di diffusione (numeri verdi, web, SMS, MMS, posta elettronica) di messaggi pubblicitari relativi ai dispositivi medici.

E' permesso alle aziende di dispositivi medici l'uso di *testimonials* per promuovere i loro prodotti?

In Italia le vigenti disposizioni di legge in materia di pubblicità di dispositivi medici non forniscono alcuna indicazione specifica riguardo la possibilità di impiegare *testimonials* per promuovere i propri prodotti.

In ogni caso, secondo quanto previsto dall'art. 114 del D.Lgs 219, i cui principi generali si applicano anche ai dispositivi medici, la pubblicità di farmaci deve favorire l'uso razionale del medicinale presntandolo in modo obiettivo e senza esagerarne le proprietà. Inoltre, in trasmissioni radio-televisive e in messaggi non a carattere pubblicitario comunque diffusi al pubblico, è vietato menzionare il medicinale in un contesto che possa favorire il consumo del prodotto.

Le aziende farmaceutiche e quelle produttrici di dispostivi medici possono organizzare concorsi a premio, lotterie o altre operazioni a premio, per i consumatori di farmaci e dispositivi medici?

Le vigenti norme di legge applicabili in materia di pubblicità di dispositivi medici non forniscono alcuna disposizione specifica circa la possibilità di organizzare concorsi od operazioni a premio per i consumatori di dispositivi medici.

A tale riguardo, considerando la generale tendenza a rendere omogenee le discipline del farmaco e dei dispositivi medici, potrebbe trovare applicazione l'art. 5, comma 2, del Decreto Legislativo n. 223/2006 secondo il quale sono vietati i concorsi e le manifestazioni a premi aventi ad oggetto farmaci.

of, committing crimes; appoints referents to be informed with regard to the activities carried out by the company; and appoints an independent supervisory body having the task of ensuring the enforcement of the 231 Model.

Recommendations

Stringent laws apply to the promotional activities of medicines and medical devices, and in case of infringement of such rules, the MoH may institute an administrative proceeding and impose sanctions.

Strict compliance with the above-explained administrative rules and self-regulation is surely the most effective way a company may minimize the risk of any infringements of the laws governing direct advertising with the general public of medicines and medical devices in Italy.

In Italy, stringent laws and regulations govern the promotion of medicines and medical devices to HCPs and even more so to consumers. These requirements are enforced by MoH, and by the AIFA which have the power to initiate administrative proceedings and impose sanctions in case of noncompliance. Companies wishing to promote medicines and medical devices in Italy need to be aware of existing and proposed rules, as well as the industry's best practices like those promulgated by Farmindustria Eucomed and Assobiomedica, and implement a regime that ensures the compliance of their employees and their contractors to avoid the risk of serious penalties.

Finally, it is recommended to adopt and implement the abovementioned 231 Model, including the appointment of a supervisory body with the task of ensuring the enforcement of the 231 Model, to avoid the risk of criminal liability in case of crimes committed by directors, managers or other employees.

Esistono delle restrizioni alla promozione del solo nome dell'azienda (e non dei suoi prodotti) farmaceutica o biomedicale?

Secondo l'art. 3, comma 2, del DM non è sottoposta ad autorizzazione sanitaria la pubblicità istituzionale che richiama la denominazione o il campo di attività di un'azienda produttrice o distributrice di dispostivi medici, a condizione che non vanti specifiche proprietà di tali dispositivi, richiamati singolarmente o nel loro complesso. Alle medesime conclusioni deve giungersi per quanto riguarda la pubblicità istituzionale di aziende farmaceutiche.

Le aziende operanti nel settore farmaceutico e biomedicale possono organizzare riunioni informative con i pazienti relativamente a: prodotti; una malattia; o un'operazione chirurgica?

L'art. 113 del D.Lgs. 219, che è considerato applicabile anche alla pubblicità di dispositivi medici, definisce "pubblicità" qualsiasi azione d'informazione, di ricerca della clientela o di esortazione, intesa a promuovere la prescrizione, la fornitura, la vendita o il consumo di medicinali.

Alla luce di tale ampia definizione, riunioni organizzate al fine di informare i pazienti circa le caratteristiche e le proprietà dei dispositivi medici commercializzati da un'azienda sarebbe considerata come una forma di pubblicità di tali prodotti. Pertanto, in tal caso troverebbero applicazione le disposizioni normative italiane in materia di pubblicità di dispositivi medici (si veda sopra la domanda 1).

Responsabilità secondo la normativa penale, civile e secondo i codici di condotta applicabili.

Alle aziende che violano le disposizioni normative italiane in materia di pubblicità di dispositivi medici viene irrogata una sanzione amministrativa da 2.582, 28 fino a 15493, 71 Euro.

Inoltre, a meno che il Ministero della Salute non decida di agire di propria iniziativa, lo stesso Ministero può ordinare l'immediata cessazione della pubblicità e la pubblicazione a spese del trasgressore di un comunicato di

rettifica e di precisazione, secondo le modalità stabilite dal medesimo Ministero.

In caso di pubblicità ingannevole (si veda sopra la domanda 1), l'Autorità Antitrust italiana può (i) ordinare al trasgressore la cessazione qualsiasi attività illegale, (ii) ordinare una dichiarazione di rettifica da pubblicarsi a spese del trasgressore e (iii) irrogare una sanzione amministrativa da 5000 fino 500.000 Euro.

Per quanto concerne i farmaci, in caso di violazioni delle norme sulla pubblicità al pubblico, l'Articolo 118 del Codice consente al Ministero della Salute di ordinare l'immediata cessazione della pubblicità e di far pubblicare, a spese dell'autore delle violazioni, una rettifica o un avviso a chiarimento secondo istruzioni fornite dal Ministero stesso, e salvo che il Ministero non decida di provvedervi direttamente. L'azienda che ha commesso una violazione è punibile con una sanzione pecuniaria da 2.600,00 a 15.600,00 euro in applicazione dell'Articolo 148 del Codice.

Le medesime sanzioni si applicano, ai sensi degli Articoli 127 e 148 del Codice in caso di violazioni dei requisiti stabiliti per la pubblicità ai medici. Se si tratta poi di medicinali il cui rimborso è a carico del Servizio Sanitario Nazionale, le violazioni sono inoltre sanzionabili con la sospensione del medicinale dal regime di rimborsabilità per un periodo che va da 10 giorni a 2 anni. La sospensione è adottata dopo aver notificato la violazione al presunto autore della violazione e titolare dell'AIC il quale ha il diritto di presentare le proprie osservazioni entro 15 giorni da detta notificazione.

L'Articolo 148 del Codice commina altre sanzioni in caso di violazione dei requisiti in materia di pubblicazioni a stampa, trasmissioni radio-televisive e messaggi a carattere non pubblicitario (sanzione amministrativa da 10.000 a 60.000 euro), in materia di distribuzione di campioni gratuiti (ad esempio, una sanzione amministrativa da 5.000 a 30.000 euro per campioni che non rechino la dicitura "campione gratuito") e in materia di servizio scientifico (sanzione amministratova da 50.000 a 300.000 euro).

Un ulteriore potenziale area di responsabilità per le società farmaceutiche e biomedicali origina dal D.Lgs. 231/2001, in base al quale le società sono assoggettabili a responsabilità penale per reati commessi da propri rappresentanti (amministratori, direttori, managers ed altri dipendenti) qualora il reato sia stato commesso a beneficio o vantaggio della società. Al riguardo, le medesime società possono escludere la propria responsabilità adottando un modello organizzativo interno ("Modello 231") che (i)

stabilisca specifiche procedure che i propri managers e dipendenti sono tenuti a rispettare per evitare o quantomeno ridurre il rischio che siano commessi reati, (ii) indichi referenti da informare in merito alle attività svolte dalla società, e (iii) costituisca un organismo di vigilanza indipendente con il compito di assicurare il rispetto del Modello 231.

Raccomandazioni

Alle attività promozionali relative a farmaci e dispositivi medici, si applicano norme particolarmente severe e in caso di loro violazione, il Ministero della Salute avvia un procedimento amministrativo e impone sanzioni.

L'applicazione delle summenzionate regole e l'adozione di auto-regolamentazione interna sono indubbiamente le misure più efficaci che una società possa adottare per minimizzare il rischio di violazione delle leggi che regolano la pubblicità diretta al pubblico di farmaci e dispositivi medici in Italia.

In Italia, norme e regole severe disciplinano la promozione di farmaci e dispositivi medici presso gli operatori sanitari, ancora più che per i consumatori. Il Ministero della Salute e l'AIFA hanno il compito di accertare che i requisiti fissati dalla legge siano rispettati, ed hanno il potere di avviare procedimenti amministrativi e imporre sanzioni in caso di violazioni. Le società che vogliono promuovere farmaci e dispositivi medici in Italia devono essere consapevoli delle norme esistenti e qui indicate, così come delle norme di buona condotta (best practices) emanate da Farmindustria, Eucomed e Assobiomedica, e devono adottare un sistema che garantisca il rispetto delle regole da parte di dipendenti e fornitori, per evitare di essere seriamente sanzionati.

Infine, si raccomanda l'adozione del menzionato Modello 231 e la costituzione di un organismo di vigilanza deputato ad assicurare il rispetto del Modello 231 medesimo, evitando il rischio di incorrere in responsabilità della società per reati commessi da propri amministratori o dipendenti.

Nederland

Misha Iutje Beerenbroek, Emma Runia, Eline van Nimwegen

Inleiding

De regulering van geneesmiddelenreclame geschiedt in Nederland door middel van twee verschillende systemen die elkaar aanvullen. Naast wet- en regelgeving – de Geneesmiddelenwet – bestaat een systeem van zelfregulering waarbij gedragscodes zijn opgesteld door organisaties uit de farmaceutische sector. Geneesmiddelenreclame omvat zowel (publieks)reclame als gunstbetoon. In dit hoofdstuk zal het laatstgenoemde aspect van geneesmiddelenreclame worden behandeld.

Wet- en regelgeving

Geneesmiddelenwet

Op Europees niveau zijn de voorschriften met betrekking tot geneesmiddelenreclame opgenomen in titel VIII van de Europese Richtlijn tot vaststelling van een communautair wetboek betreffende geneesmiddelen voor menselijk gebruik (Richtlijn).[1] De betreffende titel over reclame uit deze Richtlijn is in Nederland geïmplementeerd in de Geneesmiddelenwet.

De Geneesmiddelenwet geeft algemene regels voor de gehele farmaceutische sector. Het is een kaderwet die nader wordt uitgewerkt in het Besluit Geneesmiddelenwet, de Regeling Geneesmiddelenwet, alsmede beleidsregels (zie onder “Beleidsregels”)

Beleidsregels

Zoals reeds aangegeven heeft het Ministerie van Volksgezondheid, Welzijn en Sport (VWS) tevens beleidsregels uitgevaardigd waarin het begrip gunstbetoon zoals neergelegd in de Geneesmiddelenwet nader wordt ingevuld (Beleidsregels gunstbetoon Geneesmiddelenwet).[2]

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[1] Richtlijn 2001/83/EC tot vaststelling van een communautair wetboek betreffende geneesmiddelen voor menselijk gebruik, zoals gewijzigd bij Richtlijn 2003/63/EG. Voorheen waren deze bepalingen opgenomen in Richtlijn 1992/28/EEG betreffende reclame voor geneesmiddelen voor menselijk gebruik.

[2] Beleidsregels van de Minister van Volksgezondheid, Welzijn en Sport, van 9 januari 2012, inzake gunstbetoon als bedoeld in art. 94 van de Geneesmiddelenwet, Staatscourant 2012 nr. 854, 18 januari 2012.

The Netherlands

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Introduction

Medicinal product advertising in the Netherlands is regulated by two different systems that complement each other. In addition to laws and regulations embodied in the Medicines Act, there is a system of self-regulation, based on codes of conduct prepared by organizations within the pharmaceutical industry. Medicinal products are advertised by means of public advertising and by inducement (gifts, favors and hospitality). Here, we focus on the latter form of medicinal products advertising.

The Regulatory Framework

The Medicines Act

At the European level, requirements for medicinal product advertising have been laid down in Title VIII of the directive on the Community code relating to medicinal products for human use.[1] The relevant title on advertising has been implemented in the Netherlands in the Medicines Act.

The Medicines Act provides general rules for the whole pharmaceutical sector. It is a framework act that has been developed further in the Medicines Decree, the Medicines Regulations, as well as policy rules (see below).

Policy Rules

As indicated above, the Ministry of Health, Welfare and Sports ("VWS") has also issued policy rules that contain a more elaborate description of the concept of inducement as laid down in the Medicines Act (Policy Rules Inducement Medicines Act).[2]

[1] Directive 2001/83/EC on the Community code relating to medicinal products for human use, as amended by Directive 2003/63/EC. Previously, those provisions were part of Council Directive 92/28/EEC on the advertising of medicinal products for human use.

[2] Policy rules of the Minister of Health, Welfare and Sports of 9 January 2012, regarding inducement as laid down in Article 94 of the Medicines Act, Official Gazette 2012 no. 854, 18 January 2012.

Zelfregulering

Tot slot bestaat er in Nederland in aanvulling op de wettelijke reclameregelgeving een systeem van zelfregulering met betrekking tot geneesmiddelenreclame. Dit systeem is onder meer uitgewerkt in de Gedragscode Geneesmiddelenreclame. Een belangrijk onderdeel van de Gedragscode is de Uitwerking normen gunstbetoon,[3] waarin de regels ten aanzien van gunstbetoon uit de Gedragscode nader zijn uitgewerkt. Het toezicht op de naleving van de Gedragscode is opgedragen aan twee commissies, te weten de Codecommissie en de Commissie van Beroep van de Stichting Code Geneesmiddelenreclame (CGR). De Codecommissie kan alleen over promotionele activiteiten oordelen nadat door een belanghebbende een klacht over een promotionele activiteit is ingediend.

De Koninklijke Nederlandse Maatschappij ter bevordering van de Geneeskunde (KNMG) heeft een gedragscode voor artsen opgesteld, die ook een bepaling over gunstbetoon bevat. In de Gedragsregels voor artsen (Hoofdstuk VI.I), opgesteld door de KNMG, wordt vrij algemeen bepaald dat "de arts een open en integere relatie met het bedrijfsleven onderhoudt en belangenverstrengeling die de patiënt kan schaden, voorkomt." en dat: "Het aannemen van gunsten in geringe mate aanvaardbaar is, conform de gestelde normen in de Gedragscode van de Stichting Code Geneesmiddelenreclame". Artsen die lid zijn van de KNMG zijn aan de bepalingen in de gedragscode gebonden. Daarnaast is de "Code ter voorkoming van oneigenlijke beïnvloeding door belangenverstrengeling" in januari 2012 door het KNMG aan de Minister van VWS aangeboden. Deze code vormt een aanscherping van het al bestaande beleid op het gebied van gunstbetoon en is van toepassing op alle ondertekenaars van deze code.

Medische Hulpmiddelen

De strenge Nederlandse wet- en regelgeving rond reclame en gunstbetoon op het gebied van geneesmiddelen is niet van toepassing op medische hulpmiddelen. Voor medische hulpmiddelen bestaat een aparte code, namelijk de "Code Publieksreclame Medische (zelfzorg) Hulpmiddelen".[4] Deze code is alleen van toepassing op zogenaamde zelfzorghulpmiddelen die zonder tussenkomst van een arts verkrijgbaar zijn. Publieksreclame voor andere soorten medische hulpmiddelen is verboden.

[3] Zie www.cgr.nl.
[4] Zie www.koagkag.nl.

Self-Regulation

Finally, as a supplement to statutory advertising rules, medicinal products advertising in the Netherlands is governed by a system of self-regulation, which has been laid down in the Code for the Advertising of Medicinal Products to the General Public. An important section of this code is the Elaboration on Inducement Standards.[3] The task of supervising compliance with the code is entrusted to the Code Committee and the Board of Appeal of the Pharmaceutical Advertising Code Foundation ("CGR"). The Code Committee assesses a promotional activity only when an interested party files a complaint.

The Royal Dutch Medical Association ("KNMG") has a code of conduct for doctors that also contains a provision on inducement. The code of conduct for doctors (Section VI.I), drawn up by the KNMG, stipulates in general terms that "doctors should have an open and honest relationship with the business community and should avoid a conflict of interests that may harm the patient" and that "accepting favours is allowable to a small extent, in accordance with the standards set out in the Association of Pharmaceuticals Advertising Code." Doctors who are members of the KNMG are obliged to observe the provisions of this code. In addition, in January 2012, the KNMG presented another code regarding the prevention of conflict of interest (Code as a precaution against the improper influence through conflict of interest) to the Minister of Health, Welfare and Sports. This code forms a tightening of the already existing policy regarding inducement and is applicable to all signatories of this code.

Medical Devices

The strict Dutch regulatory framework concerning advertising and inducement does not apply to medical devices. For medical devices, a separate code exists, namely the Code for the Advertising of (over-the-counter) Medical Devices to the General Public.[4] This code is only applicable to so-called over-the-counter medical devices that are available without the intervention of a doctor.

Under certain circumstances, as is the case for medicinal products, the provisions relating to bribery (to be discussed in the section on liability

[3] See www.cgr.nl.
[4] See www.koagkag.nl.

Daarnaast kunnen onder omstandigheden - evenals bij geneesmiddelen -de in het hoofdstuk over strafrechtelijke aansprakelijkheid te bespreken bepalingen rond omkoping van toepassing zijn. Wanneer een medisch hulpmiddel als vehikel wordt gebruikt om op indirecte wijze een (daarmee verbonden) geneesmiddel te promoten, kan de geneesmiddelen regelgeving alsnog van toepassing zijn.

Toegelaten en verboden handelingen

In het onderstaande zal eerst aan de orde komen welke activiteiten in het kader van de promotie van geneesmiddelen zijn toegelaten en welke activiteiten zijn verboden. Deze activiteiten worden onderverdeeld in (I) gunstbetoon en (II) het verstrekken van monsters). Vervolgens zullen de gevolgen van overtreding van de wet- en regelgeving ten aanzien van deze activiteiten worden behandeld.

Gunstbetoon

Definitie gunstbetoon

De Geneesmiddelenwet bevat in artikel 1 lid 1 onder zz de volgende definitie van gunstbetoon: “Het in het vooruitzicht stellen, aanbieden of toekennen van geld of op geld waardeerbare diensten of goederen met het kennelijke doel het voorschrijven, ter hand stellen of gebruiken van een geneesmiddel te bevorderen.”. Artikel 1 lid 2 van de Geneesmiddelenwet bepaalt dat met gunstbetoon gelijk gesteld wordt “het doen van een aanbod om het voorschrijven, ter hand stellen of gebruiken van een geneesmiddel te bevorderen met het kennelijke doel daarvoor geld of op geld waardeerbare diensten of goederen te ontvangen, dan wel het aanvaarden van zodanige gelden, diensten of goederen na een aanbod te hebben gedaan het voorschrijven, ter hand stellen of gebruiken van een geneesmiddel te bevorderen.” De Beleidsregels Gunstbetoon Geneesmiddelenwet die de Minister van VWS heeft uitgevaardigd en de toelichting bij de Uitwerking Normen Gunstbetoon van de CGR bevatten definities van gelijke strekking.

De strekking van de definitie van gunstbetoon is dat zowel het verlenen als het ontvangen van gunstbetoon de verantwoordelijkheid is van de farmaceutische industrie en de beroepsbeoefenaar. Het is immers niet de bedoeling dat beroepsbeoefenaren farmaceutische bedrijven mogen “verleiden” tot verboden handelingen.

under criminal law) may apply. If medical devices are used as a vehicle for the indirect promotion of a related medicine, the rules for medicines may apply.

Permitted and Prohibited Practices

The practices that are allowed and those that are prohibited in promoting medicinal products will be addressed below. These practices will be subdivided into inducement and supplying samples. Subsequently, the consequences of breaching the rules and regulations governing those practices will be considered.

Inducement

Definition of Inducement

The Medicines Act contains the following definition of inducement in section 1, subsection 1, under zz: "To hold out, offer or award money, or services or goods measurable in money with the apparent objective to enhance the prescription, delivery or use of a medicine."

Section 1, subsection 2 of the Medicines Act stipulates that inducement may be equated with "making an offer in order to enhance the prescription, delivery or use of a medicine with the apparent objective to receive money, or services or goods measurable in money in return, or to accept such money, services or goods following an offer to enhance the prescription, delivery or use of a medicine." The Policy Rules Inducement Medicines Act issued by the Minister of Health, Welfare and Sports, and the explanation to the Elaboration on Inducement Standards of the CGR contain similar definitions.

The purpose of the definition of inducement is that both the offer and acceptance of inducement fall under the responsibility of the pharmaceutical industry and professional practitioners. After all, practitioners should not be seen to "tempt" pharmaceutical companies to perform forbidden acts.

The following categories of inducement will be addressed below: Gifts provided and received; hospitality provided and enjoyed; sponsorship; requested and received; payment for services; offer and acceptance of discounts and bonuses.

Hierna zullen de volgende categorieën gunstbetoon aan de orde komen: het geven en ontvangen van geschenken; het verlenen en genieten van gastvrijheid; het vragen en verlenen van sponsoring; de honorering van dienstverlening; het aanbieden en aannemen van kortingen en bonussen.

Geschenken

De Geneesmiddelenwet bepaalt dat het verboden is om ter bevordering van de verkoop van geneesmiddelen, aan personen die bevoegd zijn om geneesmiddelen voor te schrijven of af te leveren, premies of voordelen in welke vorm dan ook toe te kennen, aan te bieden of in het vooruitzicht te stellen, tenzij deze een geringe waarde hebben en van betekenis zijn voor de uitoefening van de geneeskunde of de farmacie.

De Beleidsregels gunstbetoon Geneesmiddelenwet van VWS en de Uitwerking Normen Gunstbetoon van de CGR stellen een maximum bedrag per beroepsbeoefenaar per keer en per jaar voor het geven en ontvangen van geschenken. Dat betekent dat per geschenk moet worden bekeken of het maximum voor de beroepsbeoefenaar wordt overschreden. Het maximum bedrag geldt per beroepsbeoefenaar, per vergunninghouder en per therapeutische klasse, hetgeen betekent dat een bedrijf wel de mogelijkheid heeft om meerdere geneesmiddelen door middel van geschenken te promoten bij een beroepsbeoefenaar.

Gastvrijheid

Onder het verlenen van gastvrijheid kan worden verstaan de vergoeding of het niet in rekening brengen van inschrijfgeld en reis- en verblijfskosten door een farmaceutische onderneming aan een beroepsbeoefenaar. Vergoeding of het niet in rekening brengen van andere kosten is niet toegestaan.

Gastvrijheid kan worden onderverdeeld in twee vormen: gastvrijheid bij wetenschappelijke bijeenkomsten (bijeenkomsten) en gastvrijheid bij niet-wetenschappelijke bijeenkomsten (manifestaties).

Een wetenschappelijke bijeenkomst is een bijeenkomst met een uitsluitend beroepsmatig en wetenschappelijk karakter. Het begrip “bijeenkomst” staat gedefinieerd in artikel 1 lid 1 onder aaa van de Geneesmiddelenwet en is nader uitgewerkt in de Beleidsregels gunstbetoon Geneesmiddelenwet en de Uitwerking Normen Gunstbetoon.

Gifts

The Medicines Act prohibits giving, offering and/or promising premiums or advantages in any form, unless they are of minor value or are relevant for practicing medicine or pharmacy, to persons who are authorized to prescribe or deliver medicinal products.

The Policy Rules Inducement Medicines Act of the Ministry of Health, Welfare and Sports, and the Elaboration on Inducement Standards of the CGR provide for a maximum amount that may be offered to – or received by – any practitioner per time and per year. As a result, each gift must be appraised to decide whether the maximum applicable to the practitioner is exceeded. The maximum applies per practitioner, per license holder and per therapeutic class, which means that a company can offer gifts to a practitioner to promote several medicinal products.

Hospitality

Providing hospitality may consist of reimbursing or not charging for enrolment fees, and travel and accommodation expenses by a pharmaceutical company to a practitioner. Reimbursing or not charging for other costs is not allowed.

Two forms of hospitality can be distinguished: hospitality at scientific meetings (meetings) and hospitality at non-scientific meetings (manifestations).

A scientific meeting is exclusively scientific and professional in nature. The definition of "meeting" has been defined under section 1, subsection 1 aaa of the Medicines Act and has been further described in the Policy Rules Inducement Medicines Act and the Elaboration on Inducement Standards.

All other meetings are considered to be manifestations. The definition of "manifestation" has been defined under section 1, subsection 1 bbb of the Medicines Act.

- Hospitality at scientific meetings

In principle, hospitality at scientific meetings is allowed. The Medicines Act determines that hospitality must be limited to what is strictly necessary in order to be able to participate in the meeting. The Policy Rules Inducement Medicines Act and the Elaboration on Inducement Standards provide for

Alle andere bijeenkomsten vallen onder het begrip manifestaties. Het begrip "manifestatie" staat gedefinieerd in art. 1 lid 1 onder bbb van de Geneesmiddelenwet.

Gastvrijheid bij wetenschappelijke bijeenkomsten

Gastvrijheid bij wetenschappelijke bijeenkomsten is in beginsel toegestaan. De Geneesmiddelenwet bepaalt dat gastvrijheid beperkt dient te blijven tot hetgeen strikt noodzakelijk is om aan de bijeenkomst te kunnen deelnemen. De Beleidsregels gunstbetoon Geneesmiddelenwet en de Uitwerking Normen Gunstbetoon geven hiervoor eveneens algemene, doch minder stringente regels: de gastvrijheid moet binnen redelijke perken blijven, ondergeschikt zijn aan het wetenschappelijke hoofddoel van de bijeenkomst en mag zich niet uitstrekken tot anderen dan beroepsbeoefenaren/de deelnemers aan het inhoudelijke gedeelte van de bijeenkomst.

De Beleidsregels gunstbetoon Geneesmiddelenwet en de Uitwerking Normen Gunstbetoon stellen maximum bedragen per beroepsbeoefenaar, per therapeutische klasse, per jaar voor het geven en ontvangen van gastvrijheid bij wetenschappelijke bijeenkomsten. Hierbij tellen ook de bedragen mee die reeds zijn ontvangen voor andere bijeenkomsten georganiseerd door derden voor dezelfde therapeutische klassen. In plaats van de maximum bedragen, kan ook worden gekozen voor de mogelijkheid om maximaal de helft van de reis-, verblijf- en inschrijvingskosten van de beroepsbeoefenaar te vergoeden (de 50% optie).

Indien een farmaceutisch bedrijf zelf een bijeenkomst organiseert is preventieve goedkeuring door de CGR vereist. Bij goedkeuring gelden dezelfde maximum bedragen als hierboven vermeld. De 50% optie is echter niet van toepassing op dergelijke bijeenkomsten.

De Uitwerking Normen Gunstbetoon vereist bij alle soorten bijeenkomsten dat banden tussen sprekers en de farmaceutische industrie vooraf bekend worden gemaakt en dat vertegenwoordigers van de industrie als zodanig herkenbaar zijn (bijvoorbeeld door het dragen van een badge).

Gastvrijheid bij manifestaties

Ook gastvrijheid bij manifestaties is in beginsel toegestaan, mits voldaan is aan dezelfde algemene regels als bij bijeenkomsten: de gastvrijheid moet beperkt blijven tot het strikt noodzakelijke, binnen redelijke perken blijven, ondergeschikt zijn aan het hoofddoel van de bijeenkomst en mag zich niet uitstrekken tot anderen dan beroepsbeoefenaren.

general, but less strict rules: the hospitality must remain within reasonable limits, be subordinate to the main scientific objective of the meeting and may be extended only to practitioners/participants of the substantive part of the meeting.

The Policy Rules Inducement Medicines Act and the Elaboration on Inducement Standards stipulate maximum amounts per practitioner, therapeutic class and year with respect to giving and receiving hospitality at scientific meetings. Amounts already received for other meetings organized by third parties for the same therapeutic classes will also be counted. As an alternative to maximum amounts, it is also possible to reimburse half the practitioner's travel and accommodation expenses and enrolment fees (the "50% option").

If a pharmaceutical company organizes a meeting itself, the approval of the CGR is required. If approval is given, the same maximum amounts apply as referred above. However, the 50% option does not apply to such meetings.

The Elaboration on Inducement Standards requires, with regard to all meetings, that relationships between speakers and the pharmaceutical industry are made known in advance and that representatives of the industry are recognizable as such (e.g., by wearing a badge).

- Hospitality at manifestations (non-scientific meetings)

Hospitality at manifestations is in principle also allowed, provided that the same general rules as applied to meetings are observed: hospitality must be limited to what is strictly necessary, should remain within reasonable limits, be subordinate to the objective of the meeting and extended only to practitioners.

The Policy Rules Inducement Medicines Act and the Elaboration on Inducement Standards stipulate maximum amounts per practitioner, therapeutic class and year for manifestations, although those maximums are significantly lower than the maximums that apply to scientific meetings. The 50% option does not apply to manifestations.

- Abroad

These rules will also affect hospitality at international scientific congresses. If a pharmaceutical company organizes a meeting abroad, the preventive evaluation/permission of the CGR is required. Exempted from this obligation are foreign congresses that have an international character and of which a

Ook voor manifestaties stellen de Beleidsregels gunstbetoon Geneesmiddelenwet en de Uitwerking Normen Gunstbetoon maximum bedragen per beroepsbeoefenaar, per therapeutische klasse, per jaar, zij het dat deze maximum bedragen aanzienlijk lager zijn dan de maximum bedragen die gelden voor wetenschappelijke bijeenkomsten. De 50% optie is niet van toepassing op manifestaties.

Buitenland

De regelgeving is ook van invloed op de gastvrijheid bij internationale wetenschappelijke congressen. Wanneer een farmaceutisch bedrijf een bijeenkomst organiseert in het buitenland is preventieve toetsing/toestemming van de CGR vereist. Vrijgesteld van deze verplichting zijn buitenlandse bijeenkomsten die een internationaal karakter hebben en waarvan een belangrijk deel van de sprekers en deelnemers afkomstig zijn uit andere landen dan Nederland zijnen (i) georganiseerd zijn door een samenwerkingsverband van beroepsbeoefenaren, een wetenschappelijke organisatie of andere van de farmaceutische industrie onafhankelijke groeperingen of instanties; of (ii) waarvan de inhoud door een wetenschappelijke vereniging of een van de farmaceutische industrie onafhankelijke en door de betrokken beroepsgroep erkende instantie als wetenschappelijk is aangemerkt.

Op grond van een uitspraak van de Codecommissie van de CGR kan in bepaalde gevallen zelfs een Nederlandse dochteronderneming aansprakelijk gehouden worden voor overtreding van de Nederlandse regels door een buitenlandse moederonderneming.[5] De Codecommissie vindt een dergelijke vergaande toerekening gerechtvaardigd omdat anders de Nederlandse regelgeving gemakkelijk kan worden omzeild.

De CGR is van mening dat de maximumbedragen en 50% optie niet van toepassing zijn op beroepsbeoefenaren die niet in Nederland wonen of werken. Voor deze beroepsbeoefenaren geldt de wet- en regelgeving van het land waarin zij wonen of werken.

Sponsoring

Sponsoring wordt behandeld in de Uitwerking Normen Gunstbetoon en is ook nog apart geregeld in de “Gedragsregels sponsoring”, uitgevaardigd door

[5] Codecommissie CGR 6 februari 2003, JGR 2003/2, nr. 16.

considerable number of the speakers and participants are from countries other than the Netherlands and are organized by a partnership of practitioners, a scientific organization or other groups or bodies that are independent of the pharmaceutical industry; or of which the content has been qualified as scientific by a scientific association or by a body that is recognized by the associated profession and that is independent of the pharmaceutical industry.

In view of a decision by the Code Committee of the CGR, it is even possible in certain cases for a Dutch subsidiary to be held liable for breach of the Dutch rules by a foreign parent company.[5] The Code Committee believes that such far-reaching imputation is justifiable to ensure that the Dutch rules are not circumvented.

The CGR believes that the maximum amounts and the 50% option are not applicable to practitioners who do not live or work in the Netherlands. These practitioners are subject to the laws and regulations of the country where they live or work.

Sponsoring

Sponsorship is dealt with in the Elaboration on Inducement Standards and has been separately regulated in the Code of Conduct Sponsoring, issued by the CGR.[6] The former regulates sponsoring of meetings/manifestations, the latter relates to other forms of sponsorships. There are many types of sponsorship, not all of which are regarded as undesirable inducement. The basic principle is that the practitioner may not be unduly influenced with regard to his behavior in relation to prescription or delivery. To the extent that sponsoring activities lead to prohibited forms of inducement, they are to be regarded as a breach of the standards laid down in the Policy Rules Inducement Medicines Act.

Sponsorship is also governed by the principles and standards laid down in the Elaboration on Inducement Standards and the sponsorship must be laid down in an agreement prior to the sponsoring.

The main rule for other forms of sponsoring is that such sponsoring in principle is allowed, provided that the rules of the Code of Conduct Sponsoring are adhered to. These rules contain, among others, requirements

[5] Code Committee of the CGR, 6 February 2003, JGR 2003/2, no 16.
[6] See www.cgr.nl.

de CGR.[6] De eerstgenoemde regelt de sponsoring van bijeenkomsten/manifestaties, de laatste ziet op andere vormen van sponsoring.

Sponsoring kent vele varianten, die niet allemaal zijn aan te merken als ongewenste vormen van gunstbetoon. Het uitgangspunt is dat de beroepsbeoefenaar niet op onwenselijke wijze in zijn voorschrijf- of aflevergedrag wordt beïnvloed. Voor zover sponsoractiviteiten als gevolg hebben dat niet toegestane vormen van gunstbetoon langs de weg van sponsoring toch worden verleend, zijn zij te beschouwen als een inbreuk op de normen zoals neergelegd in de Beleidsregels gunstbetoon Geneesmiddelenwet.

Voor sponsoring van bijeenkomsten/manifestaties geldt voorts dat aan de voorwaarden van de Uitwerking Normen Gunstbetoon moet worden voldaan en dat de sponsoring voorafgaand aan de sponsoring schriftelijk wordt vastgelegd in een overeenkomst.

De hoofdregel voor andere vormen van sponsoring is dat deze zijn toegestaan, mits de regels van de Gedragsregels sponsoring worden nageleefd. Deze regels bevatten onder andere eisen met betrekking tot integriteit, transparantie en exclusiviteit. Het verlenen van financiële/andere op geld waardeerbare ondersteuning aan individuele beroepsbeoefenaren (anders dan de bijdragen die worden geleverd in het kader van bijeenkomsten/manifestaties die onder de Uitwerking Normen Gunstbetoon vallen) is in ieder geval niet toegestaan, tenzij het gaat om sponsoring van proefschriften.

De CGR heeft tevens regels uitgevaardigd in verband met het sponsoren van patiëntenorganisaties.[7] Dit is onder voorwaarden toegestaan, die vergelijkbaar zijn met de voorwaarden gesteld in de Gedragsregels Sponsoring.

Honorering van dienstverlening

Honorering van dienstverlening door beroepsbeoefenaren, zoals het geven van lezingen, advisering of het verrichten van geneesmiddelenonderzoek, is in beginsel toegestaan, mits de beloning in redelijke verhouding staat tot de

[6] Zie www.cgr.nl.
[7] Zie www.cgr.nl.

with regard to integrity, transparency and exclusivity. The offering of financial or other support measurable in money to individual practitioners (other than those contributions that are delivered in relation to meetings/manifestations that fall under the ambit of the Elaboration on Inducement Standards) is not allowed, unless it concerns the sponsoring of doctoral theses.

The CGR has also issued rules relating to the sponsoring of patient organizations.[7] This is allowed under certain conditions, comparable to those included in the Code of Conduct Sponsoring.

Payment for Services

Payment to practitioners for services rendered, such as giving lectures, providing advice or performing medicinal product research, is in principle allowed, provided that the payment is reasonably proportionate to the practitioner's performance and that the performance is of importance for the exercise of medicine, pharmaceutics, dentistry or midwifery.

The practitioner has the right to a reasonable payment and to be reimbursed for expenses incurred. Verification hereof needs to occur on the basis of time spent and an hourly or daily rate. In order to determine a reasonable hourly or daily rate, the rates that have been determined in accordance with the Healthcare Market Regulation Act can be followed. Based on this act, the Minister of Health, Welfare and Sports has determined hourly rates for practitioners based on the nature of the healthcare that is to be provided.

Each agreement between the company and the practitioner must be recorded in writing and must contain a clear description of the purpose of the service to be rendered and the manner in which such service will be rendered.

In addition, as of 1 January 2012, new rules of conduct regarding the publication of financial relationships between pharmaceutical companies and practitioners (Rules of Conduct Publication Financial Relationships) apply.[8] Based on these rules of conduct, financial relationships need to be registered in a central register, which is publicly accessible.

[7] See www.cgr.nl.
[8] See www.cgr.nl.

door de beroepsbeoefenaar geleverde prestatie en de prestatie van de beroepsbeoefenaar van belang is voor de uitoefening van de geneeskunst, de farmacie, de tandheelkunst of de verloskunst.

De beroepsbeoefenaar heeft recht op een redelijke beloning en op vergoeding van gemaakte onkosten. Toetsing hiervan zal dienen plaats te vinden aan de hand van de bestede tijd en een uur- of dagtarief. Voor het bepalen van een redelijk uur- of dagtarief kan worden aangesloten bij de tarieven die zijn vastgesteld krachtens de Wet marktordening gezondheidszorg. De Minister van Volksgezondheid, Welzijn en Sport heeft op basis van deze wet uurtarieven voor beroepsbeoefenaren vastgesteld op basis van de te leveren zorg.

Elke dienstverleningsovereenkomst tussen de onderneming en beroepsbeoefenaar dient schriftelijk te worden vastgelegd en de doelstelling en uitvoering van de te verlenen dienst dient helder te zijn omschreven.

Met ingang van 1 januari 2012 gelden er tevens gedragsregels over de openbaarmaking van financiële relaties tussen farmaceutische ondernemingen en beroepsbeoefenaren, de "Gedragsregels Openbaarmaking Financiële Relaties".[8] Op basis van deze gedragsregels moeten financiële relaties in een centraal register, dat voor eenieder vrij toegankelijk is, worden geregistreerd.

Een veel voorkomende vorm van dienstverlening door artsen is het verrichten van onderzoek tegen betaling. Met betrekking tot dergelijk onderzoek kan een onderscheid worden gemaakt tussen (i) onderzoek dat wordt beheerst door de Wet Medisch-wetenschappelijk Onderzoek met mensen (WMO) en (ii) onderzoek dat niet onder die wet valt.

WMO-plichtig onderzoek: Onderzoek dat valt onder de WMO dient op grond van die wet te worden goedgekeurd door een Medisch-ethische toetsingscommissie (METC) of door de Centrale Commissie Mensgebonden Onderzoek (CCMO). Bij de aanvraag tot goedkeuring van een onderzoeksprotocol dient aangegeven te worden hoe het onderzoek gefinancierd wordt en of de onderzoeker een financiële relatie heeft of heeft gehad met de financier van het onderzoek. De METC betrekt dit in haar oordeel over de toelaatbaarheid van het onderzoek.

[8] Zie www.cgr.nl.

A common service by doctors is the conduct of research for payment. With regard to such research, a distinction must be made between research governed by the Act on Scientific Medical Research on Human Beings ("WMO"), and research that falls outside the scope of that legislation.

WMO-governed research: Under the WMO, a medical ethics committee ("METC") or the Central Committee on Research Involving Human Subjects ("CCMO") must approve all WMO-governed research. The application for approval of the research protocol must specify how the research will be financed and whether the researcher has or had a financial relationship with the financier. The METC includes this in its assessment of the acceptability of the research.

Research not subject to the WMO: Research that is not subject to the WMO must satisfy the requirements of further elaboration of Article 16 of the code of conduct on non-WMO- governed research.[9] Further elaboration includes requirements for the research structure and methodology, data processing and research fees. Again, payments to the researcher must be reasonably proportionate to the work performed.

In addition, pharmaceutical companies should either request an assessment per research from the Code Committee or adopt internal procedures for performing research not governed by the WMO, and the Code Committee of the CGR must approve those procedures.

Discounts and Bonuses

Discounts and bonuses with regard to the purchase of medicinal products are in principle excluded from the prohibition on inducement in section 94 sub d of the Medicines Act. Discounts in kind (in the form of bonus supplies of the same medicine) or in money are thus allowed, provided that this has explicitly been recorded in writing (especially on the invoice).

Pharmaceutical companies sometimes supply medicines to hospitals at extreme discounts or for free in order to influence the way medical specialists prescribe medicines. A patient who has been discharged from hospital is often prescribed the same medicines as those ordered by the medical specialist earlier in the hospital. As a result, pharmaceutical companies are willing to grant hospitals substantial discounts, which are later earned back on the outside market, where prices are higher.

[9] See www.cgr.nl.

Niet-WMO-plichtig onderzoek: Onderzoek dat niet onder de WMO valt, moet voldoen aan de regels in de Nadere Uitwerking van artikel 16 Gedragscode inzake 'niet-WMO-plichtig onderzoek'.[9] Deze Uitwerking bevat onder meer criteria voor een deugdelijke opzet en methodologie van het onderzoek, de wijze van gegevensverwerking en uiteraard de vergoeding voor het onderzoek. Ook hier geldt dat de vergoeding die de onderzoeker ontvangt, in redelijke verhouding moet staan tot de verrichte werkzaamheden. Voorts dienen farmaceutische ondernemingen ofwel per onderzoek een preventief oordeel van de Codecommissie te vragen ofwel een interne procedure op te stellen voor het verrichten van niet-WMO-plichtig onderzoek, welke procedure door de Codecommissie moet worden goedgekeurd.

Kortingen en bonussen

Kortingen en bonussen met betrekking tot de inkoop van geneesmiddelen zijn uitgezonderd van het verbod op gunstbetoon in art. 94 sub d Geneesmiddelenwet. Kortingen in natura (in de vorm van bonusleveranties van hetzelfde geneesmiddel) dan wel in geld zijn dus toegestaan, mits dit uitdrukkelijk schriftelijk (met name op de factuur) is vastgelegd.

Farmaceutische bedrijven leveren soms geneesmiddelen tegen zeer hoge kortingen of zelfs gratis aan ziekenhuizen. Daarmee proberen farmaceutische bedrijven het voorschrijfgedrag van medische specialisten te beïnvloeden. Vaak krijgt een patiënt na ontslag uit het ziekenhuis door de huisarts namelijk dezelfde geneesmiddelen voorgeschreven als eerder in het ziekenhuis voorgeschreven door de medisch specialist. Dit wordt ook wel het uitstralingseffect genoemd. Vanwege dit uitstralingseffect zijn farmaceutische bedrijven bereid om voor bepaalde geneesmiddelen, waarvoor het uitstralingseffect geldt, hoge kortingen te verlenen aan ziekenhuizen. De kosten die hiermee gemoeid zijn, worden vervolgens gecompenseerd door de hogere verkoopcijfers op de rest van de markt, ook wel de extramurale markt genoemd, waarvoor hogere prijzen gelden.

Een dergelijke prijsdifferentiatie is naar Nederlands recht in beginsel toegestaan. Wel kunnen aan een dergelijke prijsdifferentiatie mededingingsrechtelijke bezwaren kleven die differentiatie ongeoorloofd maken.

[9] Zie www.cgr.nl.

In principle, Dutch law permits such price differentiation. However, there may be provisions under competition law that make such price differentiation unlawful.

Samples

According to section 92 of the Medicines Act, samples may only be provided if the following conditions are met:

- For the sampling, a dated and personally signed request is filed with the company by the practitioner (who is authorized to prescribe POM medicine).
- The sample is not bigger than the smallest packaging on the market.
- The practitioner is not provided with more than two samples of the same medicine per calendar year.
- On the sample is indicated that it is free of charge and may not be sold.
- Attached to the sample is a summary of the characteristics of the medicine.
- The party providing the sample keeps records in which it is recorded to whom, when and in which amount the sample has been provided.

Consequences of Breaching Laws and Regulations

Monitoring and Enforcement

The monitoring of compliance with the rules regarding medicinal products advertising (the "Medicines Act and the Policy Rules Inducement Medicines Act") is fulfilled by the Healthcare Inspectorate ("IGZ"). The IGZ carries out investigations in relation to medicinal products advertising on its own initiative, but also based on notifications.

The CGR monitors the compliance with advertising rules for advertising focused on practitioners based on self-regulation. This happens based on complaints that any person can file with the CGR.

Civil Law Consequences

A company or practitioner who breaches one or more statutory provision may be held liable under civil law, for example, by a competitor that brings a case for unfair competition (wrongful act). Such cases are frequently assessed in summary proceedings, provided that they are urgent enough. The plaintiff usually requests an injunction to bar the company that breaches the statutory

Monsters

Ingevolge art. 92 van de Geneesmiddelenwet mogen monsters slechts worden verstrekt als aan de volgende voorwaarden is voldaan:

- daartoe een gedateerde en persoonlijk ondertekende aanvraag door een beroepsbeoefenaar (die bevoegd is UR-geneesmiddelen voor te schrijven) is ingediend bij de betrokken ondernemer;
- het monster niet groter is dan de kleinste verpakking die in de handel is;
- aan de beroepsbeoefenaar niet meer dan twee monsters van hetzelfde geneesmiddel per kalenderjaar worden verstrekt;

- op het monster is vermeld dat het gratis is en niet verkocht mag worden;
- bij het monster een exemplaar van de samenvatting van de kenmerken van het geneesmiddel is gevoegd; en
- degene die het gratis monster verstrekt, een administratie bijhoudt waarin is vastgelegd aan wie, op welke datum en in welke hoeveelheid het is verstrekt.

Gevolgen van overtreding van de wet- en regelgeving

Toezicht en handhaving

Het toezicht op de naleving van de regels voor geneesmiddelenreclame (de Geneesmiddelenwet en de Beleidsregels gunstbetoon Geneesmiddelenwet) wordt uitgeoefend door de Inspectie voor de Gezondheidszorg (IGZ). De IGZ doet zelf onderzoek naar geneesmiddelenreclame, maar ook op basis van meldingen wordt toezicht gehouden.

De CGR ziet toe op de naleving van reclameregels voor reclame gericht op beroepsbeoefenaren op basis van zelfregulering. Dit gebeurt op basis van klachten, die eenieder kan indienen.

Civielrechtelijke gevolgen

Een onderneming kan, wanneer zij één of meerdere wettelijke bepalingen overtreedt, civielrechtelijk worden aangesproken door bijvoorbeeld een concurrerende onderneming die voor de burgerlijke rechter een zaak aanhangig maakt op basis van oneerlijke mededinging (onrechtmatige daad).

regulations from conducting the relevant activities any longer. If misleading advertising material has been distributed, then, in addition to a ban, a rectification may be sought as well as an order to recall any misleading material distributed.

In principle, damages are not claimed in summary proceedings, but have to be claimed in proceedings on the merits of the case. Only an advance on the damages may be claimed in summary proceedings, provided that it is readily evident what damage has been incurred. Claims for an advance on damages are, however, often rejected in summary proceedings.

Besides proceedings before a civil court, proceedings may be instituted before the Code Committee of the CGR. Any interested party may file a complaint with the Code Committee with respect to any acts or omissions in breach of the code of conduct. Complaints may be filed against pharmaceutical companies, medical representatives or other representatives of the company, or may be filed against a doctor. Again, if the case is urgent, summary proceedings may be conducted before the Code Committee. The measures imposed by the Code Committee, or on appeal, the Board of Appeal, are almost identical to the measures that may be imposed in civil law proceedings. In addition, the Code Committee or the Board of Appeal may reprimand a pharmaceutical company or, under certain conditions, a medical representative, and also decide to publicize its decisions in various media including the punishment or measure that has been imposed.

The decisions of the Board of Appeal are considered binding. Challenging such a decision can only occur by bringing proceedings before a normal court. Similarly to enforce the decision, one must also turn to a normal court.

In view of the similarities with civil law summary proceedings, cases are often brought before the Code Committee. The advantage is the Committee's expertise. The drawback is that its decision cannot be enforced by penalties, which sometimes means that civil law proceedings are inevitable. In those cases, the civil court often adopts the Code Committee's decision. It should be noted that civil law proceedings are conducted on the basis of a wrongful act (unfair competition). This means that a mere violation of laws and regulations without additional (distorted competition) circumstances is not always sufficient for a conviction.

Finally, the Dutch state, represented by the IGZ, may start summary proceedings, although it rarely does, based on a wrongful act if the laws and regulations are breached.

Een dergelijke procedure wordt meestal in kort geding gevoerd, mits de zaak spoedeisend genoeg is. In een dergelijke kort geding procedure wordt veelal gevorderd dat de onderneming die zich niet houdt aan de wettelijke regelgeving, een verbod krijgt opgelegd om de desbetreffende activiteiten nog langer uit te voeren. Gaat het om misleidend reclamemateriaal dat is verspreid, dan kan behalve een verbod ook een rectificatie worden gevorderd, alsmede een bevel om het verspreide misleidende materiaal terug te halen.

Schadevergoeding kan in beginsel niet in kort geding worden gevorderd. Hiervoor dient een zogenaamde bodemprocedure te worden gevoerd. Hooguit kan in kort geding een voorschot op de schade worden gevorderd, mits aannemelijk is gemaakt welke schade er is geleden. Een dergelijke vordering wordt in kort geding echter vaak afgewezen.

Behalve een procedure bij de civiele rechter, kan ook een procedure worden gestart bij de al eerder genoemde Codecommissie van de CGR. Iedere belanghebbende kan klachten met betrekking tot enig handelen of nalaten in strijd met de Gedragscode indienen bij de Commissie. Klachten kunnen worden ingediend tegen een farmaceutische onderneming, een artsenbezoeker of andere vertegenwoordiger van die onderneming, ofwel tegen de arts zelf. Ook hier geldt dat, indien de zaak spoedeisend is, een kort geding procedure bij de Codecommissie kan worden gevoerd. De maatregelen die de Codecommissie, of in hoger beroep de Commissie van Beroep, kan opleggen, zijn vrijwel gelijk aan de maatregelen die in de civiele procedure kunnen worden opgelegd. Daarnaast kan de Codecommissie, dan wel de Commissie van Beroep, aan een farmaceutische onderneming of onder bepaalde voorwaarden aan een artsenbezoeker een berisping opleggen en ook beslissen tot publicatie van haar beslissingen in verschillende media met inbegrip van de opgelegde straf of maatregel.

De uitspraken van de Commissie van Beroep gelden als bindend advies. Aantasting van een dergelijke beslissing kan uitsluitend geschieden door het binnen vier weken aanhangig te maken bij de gewone rechter. Ook voor het afdwingen van een beslissing moet bij de gewone rechter worden aangeklopt.

Gezien de overeenkomsten met de civiele procedure in kort geding wordt in de praktijk veel gebruik gemaakt van de procedure bij de Codecommissie. Groot voordeel is de deskundigheid van de Codecommissie. Nadeel is dat de beslissing van de Codecommissie niet middels dwangsommen kan worden geëffectueerd, hetgeen betekent dat in sommige gevallen alsnog een gang naar de civiele rechter onvermijdelijk is. De civiele rechter neemt in deze gevallen vaak de beslissing van de Codecommissie over. Opgemerkt dient te

It should be noted that the IGZ and the CGR have recently entered into an agreement cooperation in the field of medicinal products advertising. It has been agreed that the CGR shall develop the norms in the field of medicinal products advertising aimed at healthcare providers; the CGR shall take care of providing information and education regarding the rules in relation to the aforementioned advertising; the CGR shall adopt further preventive examination procedures; the CGR shall take care of the so-called phase 1 monitoring, while IGZ will take care of phase 2 monitoring; information exchange will take place between the agencies; and complaints will be referred to each other where necessary.

Administrative Consequences

The Medicines Act states that in the case of non-compliance with laws and regulations, no penal sanction will initially be imposed. As an alternative, the Minister of VWS, represented by IGZ, will be able to impose a maximum administrative fine of EUR450,000. The amount of the fine will depend on the seriousness of the case, the risk to public health and the size of the company. An objection may be made against the administrative fine and an appeal may be lodged. This has been provided for in the "Policy Rules Administrative Fines Medicines Act."

Consequences Under Criminal Law

Under current legislation, criminal enforcement is in principle no longer applicable. This will be further discussed in the section below on Liability Under Criminal Law.

Disciplinary and Other Consequences

Failure to comply with regulations relating to gifts, favors and hospitality on the part of a practitioner may, under certain circumstances, subject a company to the statutory disciplinary rules and may lead to a sanction for the practitioner.[10]

The KNMG has opted for association disciplinary rules for the maintenance of its rules of conduct. On the basis of the KNMG Rules of Conduct for doctors, internal disciplinary proceedings may be used in the case of disputes concerning a rule of conduct between colleagues who are both members of

[10] See Section VII of the Healthcare Professions Act [*Wet op de beroepen in de individuele gezondheidszorg – BIG*].

worden dat procedures bij de civiele rechter op basis van onrechtmatige daad (oneerlijke concurrentie) worden gevoerd. Dit betekent dat enkele overtreding van de wet- en regelgeving zonder bijkomende (concurrentie vervalsende) omstandigheden niet altijd voldoende is voor een veroordeling.

Tenslotte kan ook de Nederlandse Staat bij monde van IGZ – hoewel het niet gebruikelijk is - op grond van onrechtmatige daad een civiele procedure starten bij overtreding van de wet- en regelgeving.

Opgemerkt moet worden dat IGZ en de CGR werkafspraken hebben gemaakt, die toezien op de wijze van samenwerking op het gebied van geneesmiddelenreclame. Er is onder andere afgesproken dat (i) de CGR de normen op het terrein van geneesmiddelenreclame gericht op beroepsbeoefenaren ontwikkelt, (ii) dat de CGR zorg draagt voor voorlichting en educatie over de regels voor de laatstgenoemde reclame, (iii) dat de CGR zal doorgaan met het ontwikkelen van preventieve maatregelen, (iv) dat de CGR zorg draagt voor de zogenaamde fase 1 monitoring, terwijl de IGZ dat doet voor de fase 2 monitoring, (v) dat er informatie-uitwisseling plaatsvindt tussen beide instanties, en tot slot (vi) dat klachten waar nodig naar elkaar worden doorverwezen.

Bestuursrechtelijke gevolgen

De Geneesmiddelenwet bepaalt dat bij niet-naleving van de wet- en regelgeving de minister van VWS, vertegenwoordigd door IGZ, een bestuurlijke boete van ten hoogste EUR 450.000 kan opleggen. De hoogte van de boete hangt af van de ernst van het feit, het risico van de volksgezondheid en de grootte van de onderneming. Tegen de bestuurlijke boete kan bezwaar worden gemaakt en beroep worden ingesteld. Één en ander is geregeld in de “Beleidsregels bestuurlijke boete Geneesmiddelenwet”.

Strafrechtelijke gevolgen

Onder de huidige regelgeving is strafrechtelijke handhaving in principe niet meer van toepassing. Dit zal verder besproken worden in het hoofdstuk over strafrechtelijke aansprakelijkheid.

Tuchtrechtelijke en overige gevolgen

Niet naleving van de regelgeving rond gunstbetoon door een beroepsbeoefenaar kan onder (uitzonderlijke) omstandigheden onder het

the KNMG. Doctors who are not KNMG members are not officially bound to the rules of conduct, as these have, in principle, only an internal effect. However, the internal rules may be used by the civil court when assessing a doctor's actions with respect to the disciplinary standards applicable in the Netherlands. The rules of conduct are therefore also important for those not affiliated with the KNMG.

Liability Under Criminal Law

The preceding chapter addressed the concept of gifts, favors and hospitality, and the liability under civil law and disciplinary rules if applicable laws and regulations are breached. This chapter addresses briefly the criminal law liability of the pharmaceutical industry and practitioners.

Laws and Regulations

The Medicines Act is primarily based on a system of administrative fines, as a result of which criminal liability is in principle out of the question. It is, however, possible that a breach of the Medicines Act is qualified as a criminal offense (minor offense) if in the preceding 24 months, an administrative fine has been imposed twice for the same conduct.

The sanction for the abovementioned offense is a prison sentence of at most six months, or a fine of the third category, unless the offender is a company, in which case a maximum fine can be imposed of the fourth category (as of 1 January 2012, EUR7,800 and EUR78,000, respectively).

Lastly, certain provisions of the Criminal Code relating to bribery may apply under special circumstances. Those provisions will also be briefly discussed below.

Sanctions Under the Criminal Code: Bribery

The Criminal Code contains a number of general penalty clauses relating to bribery.[11]

Under these articles, bribing civil servants and others is punishable under certain conditions. It is unclear to what extent these articles apply to the provision of inducement. After all, the Medicines Act contains specific norms in relation to inducement.

[11] See Articles 177, 177a, 328 ter, 362 and 363 of the Criminal Code.

wettelijke tuchtrecht vallen en tot een sanctie voor de beroepsbeoefenaar leiden.[10]

De KNMG heeft voor de handhaving van haar gedragsregels gekozen voor verenigingstuchtrecht. Op grond van de KNMG Gedragsregels voor artsen kan dus, in geval van geschillen over een gedragsregel tussen collegae die beiden lid zijn van de KNMG, van interne tuchtrechtspraak gebruik worden gemaakt. Artsen die geen lid zijn van de KNMG zijn formeel niet gebonden aan de gedragsregels, omdat deze in beginsel slechts intern werken. De interne regels kunnen echter door de civiele rechter gebruikt worden bij het toetsen van het handelen van de arts aan de in Nederland geldende tuchtnormen. De gedragsregels zijn dus ook voor degenen die niet zijn aangesloten bij de KNMG van belang.

Strafrechtelijke aansprakelijkheid

Wet- en regelgeving

In de Geneesmiddelenwet wordt uitgegaan van een systeem van bestuurlijke boetes, zodat van strafrechtelijke aansprakelijkheid in principe geen sprake meer is. Wel kan een gedraging in strijd met de Geneesmiddelenwet worden gekwalificeerd als een strafbaar feit (overtreding) indien in de daaraan voorafgaande 24 maanden tweemaal een bestuurlijke boete ter zake van eenzelfde gedraging is opgelegd.

De sanctie voor bovengenoemde overtreding is een gevangenisstraf van ten hoogste zes maanden of een geldboete van de derde categorie, tenzij de overtreder een bedrijf is, dan kan een boete worden opgelegd van maximaal de vierde categorie (per 1 januari 2012 respectievelijk EUR 7.800 en EUR 78.000).

Tot slot kunnen onder bijzondere omstandigheden bepalingen inzake omkoping uit het Wetboek van Strafrecht van toepassing zijn. Deze bepalingen zullen hieronder kort worden toegelicht.

[10] Zie hoofdstuk VII van de Wet op de beroepen in de individuele gezondheidszorg (BIG).

Finally, in this respect, there are no published precedents in which action was taken against practitioners or against the pharmaceutical industry.

If the penal provisions apply, the situation will be as follows.

Bribing of Civil Servants

The term civil servant must be interpreted broadly and no high demands may be made on this term. The following definition has been established by case law: any person who has been appointed by a public authority in a public function in order to carry out a part of the task of the government or its bodies. In this regard, it is not important whether such person can also be considered a civil servant from an employment law perspective. It is possible that physicians or pharmacists working at university hospitals will be considered civil servants within the meaning of these provisions of the code.

The bribing of a civil servant is punishable both if the civil servant acts in contravention of his official duty and if he acts in accordance with his official duty. The difference is found in the sanctioning: in the former situation, the maximum punishment is higher. A failure in contravention of an official duty may arise, for example, if a doctor or a pharmacist takes a bribe to persuade the hospital in which they work to purchase more expensive medicinal products, although their duty requires them to prescribe medicinal products of a better price-quality ratio.

A person who bribes a civil servant can be punished with a prison sentence of up to four years, and a maximum fine of the fifth category or the sixth category if the offender is a company and the judge considers the fine of the fifth category insufficient punishment (as of 1 January 2012, EUR78,000 and EUR780,000, respectively). The sanction for a civil servant who is bribed consists of imprisonment of four years at most and a maximum fine of the fifth category (as of 1 January 2012, EUR78,000). In theory, the court may bar a person from exercising a certain office or profession, temporarily or permanently (for example, in the case of repeat offenders).[12]

Bribing of Others

Commercial bribery is also punishable under Dutch law, namely if (it can be reasonably assumed that) the acceptance of the gift, promise or services has been concealed form the employer contrary to good faith. Commercial

[12] See Article 28 of the Criminal Code.

Sancties onder het wetboek van strafrecht: omkoping

Het Wetboek van Strafrecht een aantal algemene strafbepalingen inzake omkoping.[11]

Deze artikelen stellen het omkopen van ambtenaren en anderen dan ambtenaren onder voorwaarden strafbaar. Het is de vraag in hoeverre deze artikelen op het verlenen van gunstbetoon van toepassing zijn. De Geneesmiddelenwet bevat immers specifieke normen ten aanzien van gunstbetoon. Tenslotte is er ook geen (gepubliceerde) rechtspraak bekend, waarin in dit verband tegen beroepsbeoefenaren of de farmaceutische industrie is opgetreden.

Indien de strafbepalingen van toepassing zijn, geldt het volgende.

Omkopen van een ambtenaar

Het begrip ambtenaar dient autonoom te worden uitgelegd en er dienen geen hoge eisen aan te worden gesteld. In vaste rechtspraak wordt uitgegaan van de volgende definitie: eenieder die door het openbaar gezag is aangesteld tot een openbare betrekking, om een deel van de taak van de staat en zijn organen te verrichten. Het doet er daarbij niet toe of de persoon ook arbeidsrechtelijk als ambtenaar kan worden aangemerkt. Het is mogelijk dat artsen of apothekers die zijn aangesteld in een academisch ziekenhuis als ambtenaar in de zin van deze artikelen worden beschouwd.
bribery is punished with a prison sentence of up to two years, and a maximum fine of the fifth category or the sixth category if the offender is a company and the judge considers the fine of the fifth category insufficient punishment (as of 1 January 2012, EUR78,000 and EUR780,000 respectively).

Therefore, if a physician is not considered a civil servant within the meaning of the code, bribing of this physician could, in theory, still be punishable on the basis of these provisions. However, as already noted, there are no published precedents in which action was taken against practitioners or against the pharmaceutical industry in such cases.

Het omkopen van een ambtenaar is zowel strafbaar als de ambtenaar handelt in strijd met zijn wettelijke plicht, als wanneer hij handelt in overeenstemming met zijn wettelijke plicht. Het verschil zit in de

[11] Zie artikelen 177, 177a, 178, 328ter, 362, 363 en 364 Wetboek van Strafrecht.

Recommendations

- When interacting with practitioners, be aware: depending on the kind of interaction different rules may apply which may result in the interaction being restricted or forbidden.
- Always keep in mind that the main principle in relation to promoting medicinal products is that the other party may not be unduly influenced in any way.
- If in doubt, obtain legal advice: non-compliance does not only potentially lead to serious civil and administrative law consequences, it may also have a negative impact on your company from a commercial perspective (e.g., its public reputation).

Conclusion

The pharmaceutical industry must be careful in promoting its medicinal products now and in the future. The statutory rules have been tightened up by the Policy Rules relating to gifts, favors and hospitality.

Administrative enforcement and also self-regulation are currently the most important ways of enforcement.

sanctionering: in de eerstgenoemde situatie zijn de maximale straffen hoger. Bij het handelen in strijd met een ambtelijke plicht kan wellicht gedacht worden aan de arts of apotheker die het ziekenhuis waar hij is aangesteld, als gevolg van het aannemen van steekpenningen, beweegt tot het aankopen van bepaalde duurdere geneesmiddelen, terwijl zijn plicht hem voorschrijft geneesmiddelen met een goedkopere prijs / kwaliteit verhouding aan te bevelen.

Degene die een ambtenaar omkoopt kan worden gestraft met hechtenis van maximaal 4 jaar en een maximale boete van de vijfde categorie of van de zesde categorie indien de overtreder een onderneming is en de rechter de boete van de vijfde categorie onvoldoende bestraffing vindt (per 1 januari 2012 respectievelijk EUR 78.000 en EUR 780.000).

De sanctie voor de ambtenaar die wordt omgekocht bestaat uit hechtenis van maximaal 4 jaar en een maximale geldboete van de vijfde categorie (per 1 januari 2012 EUR 78.000). De rechter heeft tevens (in theorie) de mogelijkheid om personen de uitoefening van een bepaald ambt of beroep (tijdelijk) te ontzeggen (bijvoorbeeld in geval van recidive).[12]

Omkopen van iemand anders dan een ambtenaar

Ook commerciële omkoping is strafbaar, namelijk wanneer (redelijkerwijs kan worden aangenomen dat) het aannemen van een gift, belofte of dienst in strijd met de goede trouw wordt verzwegen tegenover de werkgever. Commerciële omkoping kan worden gestraft met een gevangenisstraf van ten hoogste twee jaren of geldboete van de vijfde categorie of van de zesde categorie indien de overtreder een onderneming is de rechter de boete van de vijfde categorie onvoldoende bestraffing vindt (per 1 januari 2012 respectievelijk EUR 78.000 en EUR 780.000).

In het geval een arts dus niet als ambtenaar in de zin van het Wetboek van Strafrecht kan worden aangemerkt, is omkoping van deze arts in theorie dus nog steeds strafbaar middels deze bepalingen. Echter, zoals reeds opgemerkt, is er geen rechtspraak bekend waarin in dergelijke gevallen tegen beroepsbeoefenaren of de farmaceutische industrie is opgetreden.

[12] Artikel 28 Wetboek van Strafrecht.

Aanbevelingen

- Let op wanneer u interacteert met beroepsbeoefenaren: afhankelijk van de soort interactie kunnen verschillende regels van toepassing zijn die de interactie zouden kunnen beperken of verbieden.
- Hou altijd in gedachten dat het uitgangspunt in verband met de promotie van geneesmiddelen is, dat de andere partij op geen enkele wijze onwenselijk mag worden beïnvloed.
- In geval van twijfel, schakel juridische hulp in: het niet-nakomen van de regels kan potentieel niet alleen leiden tot serieuze civiele en bestuursrechtelijke consequenties, het kan op commercieel vlak ook een negatieve invloed op uw bedrijf hebben (e.g. publieke reputatie).

Conclusie

De farmaceutische industrie dient nu en in de toekomst voorzichtig zijn bij het promoten van haar geneesmiddelen; de regels worden continue aangescherpt en er komen telkens nieuwe regels bij.

Bestuursrechtelijke handhaving en voornamelijk ook zelfregulering zijn op dit moment de belangrijkste manier van handhaving.

Polska

Paulina Kieszkowska-Knapik, Magdalena Bąkowska

Wprowadzenie

Kwestie związane z reklamą produktów leczniczych w polskim systemie prawnym uregulowane zostały przede wszystkim w ustawie z dnia 6.09.01 Prawo farmaceutyczne (Dz. U. z 2008 r., nr 45, poz. 271 z późn. zm.). Przepisy prawa farmaceutycznego stanowią w tym zakresie implementację dyrektywy 2001/83/WE Parlamentu Europejskiego i Rady z dnia 6.11.2001 r. w sprawie wspólnotowego kodeksu odnoszącego się do produktów leczniczych stosowanych u ludzi. Co do zasady więc, założenia polskiego systemu prawnego w odniesieniu do reklamy leków są zgodne z wymogami prawa wspólnotowego. Prawo farmaceutyczne przewiduje m.in.:

- podział na reklamę kierowaną do publicznej wiadomości oraz do profesjonalistów,
- wymóg, aby reklama nie wprowadzała w błąd, prezentowała produkt leczniczy obiektywnie i informowała o jego racjonalnym użyciu
- zakaz kierowania do publicznej wiadomości reklamy dotyczącej produktów leczniczych wydawanych wyłącznie na podstawie recepty,
- zakaz reklamy produktów leczniczych niedopuszczonych do obrotu.

Zgodnie z polskim prawem nadzór nad reklamą leków ma charakter przede wszystkim administracyjny i jest sprawowany przez Głównego Inspektora Farmaceutycznego. W przypadku niezgodności reklamy z przepisami Prawa farmaceutycznego GIF może nakazać:

- Zaprzestanie ukazywania się lub prowadzenia reklamy
- Publikację wydanej decyzji w miejscach, w których ukazała się reklama sprzeczna z obowiązującymi przepisami, oraz publikację sprostowania błędnej reklamy
- Usunięcie stwierdzonych naruszeń (np. wycofanie publikacji zawierających błędną reklamę).

Poland

Paulina Kieszkowska-Knapik, Magdalena Bąkowska

Introduction

Issues relating to the advertising of medicinal products under the Polish legal system are regulated mainly by the act of 6 September 2001 Pharmaceutical Law (Journal of laws of 2008, no. 45, sec. 271, as amended) which implements provisions of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. Therefore, the rules for advertising medicinal products in Poland are in principle compliant with the requirements of Community Law. Pharmaceutical Law provides for, among other things:

- distinction between advertising addressed to the general public and to healthcare professionals;
- requirement that advertising cannot be misleading, shall objectively present the medicinal product and inform about its rational usage;
- prohibition to address to the general public advertising of medicinal products available only by prescription; and
- prohibition of advertising of products which have not been authorized.

In accordance with Polish law, supervision pharmaceutical advertising is mainly of administrative character and is conducted by the Chief Pharmaceutical Inspector ("CPI").

Should the advertisement fail to comply with pharmaceutical law regulations, the following sanctions may be applied:

- Prohibition of further publishing of the given advertisement
- An order to publish the decision of the CPI and/or to issue a corrective statement in places (media) in which the banned advertisement has been published (broadcast)
- An order to remove the ascertained breaches (e.g., withdrawal of publications including the prohibited advertisement)

Podstawy prawne

Reklama produktów leczniczych została uregulowana w następujących aktach prawnych:

- Ustawa z dnia 06.09.2001 r. Prawo farmaceutyczne (Dz. U. z 2008 r., nr 45, poz. 271 z późn. zm.);
- Rozporządzenie Ministra Zdrowia z dnia 21.11.2008 r. w sprawie reklamy produktów leczniczych (Dz. U. nr 210, poz. 1327).

Oprócz powyższych aktów prawnych do reklamy leków mają zastosowanie także przepisy o charakterze ogólnym, m.in. Ustawa z dnia 16.04.1993 r. o zwalczaniu nieuczciwej konkurencji (Dz. U. z 2003 r. Nr 153, poz. 1503, z późn. zm.), Kodeks cywilny oraz Kodeks karny.

Reklama produktów leczniczych regulowana jest również kodeksami postępowania przyjętymi przez przedsiębiorców bądź organizacje zawodowe. Kodeksy te nie stanowią powszechnie obowiązujących przepisów prawa i ich przestrzeganie nie może być egzekwowane przez organy państwowe, jednak przewidują one wobec swoich członków sankcje, które mogą być stosowane przez stowarzyszenia. Zastosowanie mają następujące kodeksy:

- Kodeks Dobrych Praktyk Marketingowych Przemysłu Farmaceutycznego, Współpracy z Przedstawicielami Ochrony Zdrowia i Organizacjami Pacjentów przyjęty przez Związek Pracodawców Innowacyjnych Firm Farmaceutycznych INFARMA.[1] Jako że INFARMA jest członkiem EFPIA (European Federation of Pharmaceutical Industries and Associations), Kodeks INFARMA oparty jest na „Code of Practice on the promotion of prescriptions-only medicines to, and interactions with, healthcare Professional" przyjętym przez EFPIA. Postanowienia Kodeksu INFARMA mają zastosowanie do reklamy produktów leczniczych wydawanych wyłącznie z przepisu lekarza.
- Kodeks Farmaceutycznej Etyki Marketingowej Leków Wydawanych Wyłącznie z Przepisu Lekarza przyjęty 28 lutego 2006 r. przez następujące organizacje zrzeszające przemysł generyczny: Izba Gospodarcza FARMACJA POLSKA, Polska Izba Przemysłu

[1] (wersja polska dostępna pod adresem: http://infarma.pl/fileadmin/doc_upload/Kodeks_Dobrych_Praktyk_Marketingowych_7_02_2012.pdf)

Applicable Laws

Advertising of medicinal products is regulated by the following legal acts:

- Pharmaceutical Law of 6 September 2001 (Journal of Laws of 2008, no. 45, item 271, as amended) ("Pharmaceutical Law")
- Regulation of the Minister of Health of 28 November 2008 on advertising of medicinal products (Journal of Laws no. 210, item 1327).

In addition to these laws, there are also acts of a general nature which are applicable to pharmaceutical advertising. These include, for example, the Act of 16 April 1993 on Combating Unfair Competition (Journal of Laws of 2003, no. 153, item 1503, as amended), the Civil Code and the Penal Code.

Advertising of medicinal products is also covered by codes of conduct adopted by industry or professional associations. They are not binding laws and they cannot be enforced by the state, but provide for sanctions which can be applied by the associations on its members. The following codes are relevant:

- The Code of Good Marketing Practices of the Pharmaceutical Industry, Interactions with Healthcare Professionals and Patient Organizations adopted by the Employer's Union of Innovative Pharmaceutical Companies ("INFARMA").[1] As INFARMA is a member of the European Federation of Pharmaceutical Industries and Associations ("EEPIA"), the Code of INFARMA is based on the Code of Practice on the promotion of prescription-only medicines to, and interactions with, healthcare professionals adopted by EFPIA. The code is applicable only to prescription products.
- Prescription Medicines Pharmaceutical Marketing Ethics Code adopted on 28 February 2006 by the following associations in the generic industry: the Economic Chamber ("FARMACJA POLSKA"), the Polish Pharmaceutical Industry and Medical Devices Chamber ("POLFARMED"), and the Polish Pharmaceutical Industry Employers' Association. We do not refer further to this code as it is not binding for innovative companies operating in Poland who are members of EFPIA and INFARMA.
- Physicians' Ethics Code
- Republic of Poland Pharmacists' Ethics Code

[1] (English version available at: http://infarma.pl/index.php?id=17&L=2.)

Farmaceutycznego, Wyborów Medycznych POLFARMED i Polski Związek Pracodawców Przemysłu Farmaceutycznego. Kodeks ten nie jest omawiany w dalszych częściach niniejszego opracowania, gdyż nie dotyczy on innowacyjnych firm farmaceutycznych działających w Polsce, zrzeszonych w EFPIA i INFARMA.,
- Kodeks Etyki Lekarskiej
- Kodeks Etyki Aptekarza Rzeczypospolitej Polskiej

Reklama a informacja

Prawo farmaceutyczne definiuje reklamę produktów leczniczych podobnie jak Dyrektywa 2001/83/WE. Jest to działalność polegająca na informowaniu lub zachęcaniu do stosowania produktu leczniczego mająca na celu zwiększenie liczby przepisywanych recept, dostarczania, sprzedaży lub konsumpcji produktów leczniczych. Obejmuje ona w szczególności:

- reklamę produktu leczniczego kierowaną do publicznej wiadomości;
- reklamę produktu leczniczego kierowaną do osób uprawnionych do wystawiania recept lub osób prowadzących obrót produktami leczniczymi;
- odwiedzanie osób uprawnionych do wystawiania recept lub osób prowadzących obrót produktami leczniczymi przez przedstawicieli handlowych i medycznych;
- dostarczanie próbek produktów leczniczych;
- sponsorowanie spotkań promocyjnych dla osób upoważnionych do wystawiania recept lub osób lecznicze prowadzących obrót produktami leczniczymi; oraz
- sponsorowanie konferencji, zjazdów i kongresów naukowych dla osób upoważnionych do wystawiania recept lub osób prowadzących obrót produktami leczniczymi.

Pojęcie „reklamy" należy przy tym odróżnić od informacji dotyczących produktów leczniczych. Informacje takie powinny mieć charakter neutralny i nie powinny zawierać elementów zachęty lub innych elementów o charakterze subiektywnym.

Zgodnie z Prawem farmaceutycznym, za reklamę produktów leczniczych nie uważa się:

- Informacji umieszczonych na opakowaniach oraz załączonych do opakowań produktów leczniczych, zgodnych z pozwoleniem na dopuszczenie do obrotu

Advertising vs. Information

Pharmaceutical Law defines advertising of a medicinal product in a similar way to Directive 2001/83/EC. It is any activity consisting of provision of information about or encouraging administering of medicinal products, aimed at increasing the number of prescriptions, supply, sale or consumption of medicinal products. It includes, in particular:

- advertising addressed to the general public;
- advertising addressed to persons authorized to prescribe or persons engaged in the trade of medicinal products;
- visits to persons authorized to prescribe and persons engaged in the trade of medicinal products by medical and sales representatives;
- supplying samples of medicinal products;
- sponsoring promotional meetings for persons authorized to prescribe and persons engaged in the trade of medicinal products; and
- sponsoring of conferences, meetings, or scientific congresses for persons authorized to prescribe and persons engaged in the trade of medicinal products.

However, the concept of "advertising" must be distinguished from information concerning medicinal products. Such information must be neutral and should not contain elements which are persuasive or subjective.

According to the Pharmaceutical Law, the following activities are not deemed to be advertising:

- information placed on packaging or attached to packaging of medicinal products, provided that it is in accordance with marketing authorization
- correspondence accompanied by informative material of non-promotional character necessary to give answers to questions regarding a particular medicinal product, including the product admitted to market without marketing authorization
- announcements of an informative character not addressed to the public regarding, in particular, change of packaging, warnings about adverse reactions, provided that the contents do not refer to the properties of pharmaceutical products (this provision results in interpretational doubts as to the admissible scope of information to patients)

- Korespondencji, której towarzyszą materiały informacyjne o charakterze niepromocyjnym niezbędne do udzielenia odpowiedzi na pytania dotyczące konkretnego produktu leczniczego, w tym produktu leczniczego dopuszczonego do obrotu bez konieczności uzyskania pozwolenia
- Ogłoszeń o charakterze informacyjnym niekierowanych do publicznej wiadomości dotyczących w szczególności zmiany opakowania, ostrzeżeń o działaniach niepożądanych, pod warunkiem że nie zawierają treści odnoszących się do właściwości produktów leczniczych (taki zapis powoduje trudności interpretacyjne dotyczące zakresu dozwolonej informacji kierowanej do pacjentów)
- Katalogów handlowych i list cenowych, zawierających wyłącznie nazwę własną, nazwę powszechnie stosowaną, dawkę, postać i cenę produktu leczniczego, w tym produktu dopuszczonego do obrotu bez konieczności uzyskania pozwolenia, a w przypadku leku objętego refundacją - cenę urzędową detaliczną, pod warunkiem, że nie zawierają treści odnoszących się do właściwości produktów leczniczych, w tym do wskazań terapeutycznych
- Informacji dotyczących zdrowia lub chorób ludzi i zwierząt, pod warunkiem że nie odnoszą się nawet pośrednio do produktów leczniczych.

Warto podkreślić, że różnica pomiędzy reklamą a informacją może być czasem trudna do jednoznacznego wyznaczenia. Odnosi się to przede wszystkim do aktywności takich jak kampanie w zakresie promocji zdrowia, programy profilaktyki zdrowotnej itp. W związku z tym, że nie istnieją oficjalne, opracowane przez organy władzy dokumenty, które zawierałyby wskazówki dotyczące tego zagadnienia, każdy przypadek wymaga odrębnej oceny.

Zasady ogólne dotyczące reklamy

Reklama produktów leczniczych, niezależnie od tego czy jest adresowana do profesjonalistów czy do publicznej wiadomości, może dotyczyć jedynie produktów dopuszczonych do obrotu na terytorium Rzeczypospolitej Polskiej oraz nie może zawierać informacji niezgodnych z zatwierdzoną ChPL.

Ponadto reklama produktu leczniczego: nie może wprowadzać w błąd, powinna prezentować produkt leczniczy obiektywnie oraz informować o jego racjonalnym stosowaniu; nie może polegać na oferowaniu lub obiecywaniu jakichkolwiek korzyści w sposób pośredni lub bezpośredni w zamian za

- commercial catalogues and price lists containing only the name, the common name, dose, pharmaceutical form and the price of a medicinal product, including the product admitted to market without marketing authorization, and with regard to reimbursable product the official retail price, provided that the contents do not refer to the properties of pharmaceutical products, including therapeutical indications
- information regarding human or animal health or diseases, provided that it does not relate, even indirectly, to medicinal products

Please note that sometimes the distinction between advertising and information can be difficult to determine. This applies in particular to activities such as health promotion campaigns and health management programs. There are no official papers issued by authorities that provide guidance as to this issue, so each case has to be evaluated individually.

General Advertising Rules

The advertising of medicinal products, whether addressed to healthcare professionals or to the general public, can only relate to products authorized for marketing in Poland and cannot include elements which do not conform with the Summary of Product Characteristics ("SmPC").

Moreover, the advertising of a medicinal product:

- cannot be misleading, shall objectively present the medicinal product and inform about its rational usage;
- may not base on offering or promising, directly or indirectly, any profits whatsoever in exchange of the purchase of medicinal products or the provision of any evidence of purchase; and
- may not be aimed or contain elements aimed at children.

In light of the existing provisions, reminder of an advertisement can only contain the name, the common name and a trade mark, which do not contain references to medical indications, pharmaceutical form, dosage, advertising slogans or other advertising content. The term "advertising content" is vague and results in interpretational doubts.

nabycie produktu leczniczego lub dostarczanie dowodów, że doszło do jego nabycia; nie może być kierowana do dzieci ani zawierać żadnego elementu, który jest do nich kierowany.

Jeżeli chodzi o tzw. reklamę przypominającą, to zgodnie z przepisami reklama produktu leczniczego będąca przypomnieniem pełnej reklamy, poza jego nazwą własną i nazwą powszechnie stosowaną, może zawierać tylko znak towarowy nie zawierający odniesień do wskazań leczniczych, postaci farmaceutycznej, dawki, haseł reklamowych lub innych treści reklamowych. Wyrażenie „inne treści reklamowe" jest nieostre i powoduje wątpliwości interpretacyjne.

Reklama kierowana do profesjonalistów

Zagadnienia ogólne

Prawo farmaceutyczne wymienia dwie grupy zawodowe uważane za profesjonalistów:

- Osoby uprawnione do wystawiania recept (zasadniczo lekarze)
- Osoby prowadzące obrót produktami leczniczymi (zasadniczo hurtownicy i aptekarze).

Reklama produktów leczniczych skierowana do profesjonalistów powinna zawierać:

- informacje zgodne z ChPL i informację o przyznanej kategorii dostępności, a w przypadku produktów refundowanych – również informację o cenie urzędowej detalicznej i maksymalnej kwocie dopłaty ponoszonej przez pacjenta.
- nazwę produktu leczniczego i nazwę powszechnie stosowaną;
- skład jakościowy i ilościowy w odniesieniu do substancji czynnych oraz tych substancji pomocniczych, które mają istotne znaczenie dla właściwego stosowania produktu leczniczego;
- postać farmaceutyczną;
- wskazanie lub wskazania terapeutyczne do stosowania (przy czym dopuszcza się przekazywanie w reklamie tylko wybranych wskazań terapeutycznych do stosowania, pod warunkiem że pozostałe przekazywane informacje będą odnosić się wyłącznie do tych wskazań);
- dawkowanie i sposób podawania;
- przeciwwskazania;
- specjalne ostrzeżenia i środki ostrożności dotyczące stosowania;

Advertisements Addressed to Healthcare Professionals

General

The Pharmaceutical Law lists two professional groups who are considered healthcare professionals:

- Persons authorized to issue prescriptions for medicinal products (in principle, doctors); and
- Persons engaged in the trade of medicinal products (in principle, wholesalers and pharmacists).

An advertisement for a medicinal product addressed to healthcare professionals should include:

- information consistent with the SmPC and information concerning the category of the product, and with regard to a reimbursable product, also the information about the official retail price and the maximum additional patient co-payment;
- the name of the medicinal product and the common name;
- the qualitative and quantitative components of active substances and also of additives that are of material importance for the proper application of the medicinal product;
- the pharmaceutical form;
- therapeutical indication or indications for use (it is allowed to include only some therapeutical indications in advertising as long as the other information refers exclusively to these indications);
- dosage and form of administration;
- information on contraindications;
- special warnings and precautionary measures to be applied when using the product;
- information on side-effects;
- the name of the marketing authorization holder ("MAH"); and
- the number of the marketing authorization and the name of the body that granted the authorization.

The abovementioned data shall be provided in compliance with SmPC and in the absence of SmPC – with the documentation containing such data – approved in the proceedings for granting marketing authorization.

Advertising addressed to healthcare professionals shall be presented in such a way that it does not reach persons to whom it is not addressed.

- działania niepożądane;
- wskazanie podmiotu odpowiedzialnego; oraz
- numer pozwolenia na dopuszczenie do obrotu i nazwę organu, który je wydał.

Wyżej wymienione dane muszą być przekazywane w brzmieniu zgodnym z ChPL, a w przypadku jej braku - z dokumentacją zatwierdzoną w procesie dopuszczenia do obrotu produktu leczniczego zawierającą przedmiotowe informacje.

Reklamę kierowaną do profesjonalistów należy przedstawiać w taki sposób, aby nie docierała ona do osób, dla których nie jest przeznaczona.

Przepisy wymagają, aby dokumentacja przekazywana osobom upoważnionym do wystawiania recept oraz prowadzącym obrót produktami leczniczymi zawierała informacje rzetelne, aktualne, sprawdzalne i na tyle kompletne, aby umożliwić odbiorcy dokonanie własnej oceny wartości terapeutycznej produktu oraz informacje o dacie jej sporządzenia lub ostatniej aktualizacji. Cytaty, tabele i inne ilustracje pochodzące z piśmiennictwa naukowego lub innych prac naukowych powinny być wiernie odtworzone oraz zawierać wskazanie źródła.

Gościnność oferowana podczas spotkań

Art. 58 ust. 1 Prawa farmaceutycznego zabrania kierowania do profesjonalistów reklamy produktu leczniczego polegającej na wręczaniu, oferowaniu i obiecywaniu korzyści materialnych, prezentów i różnych ułatwień, nagród, wycieczek oraz organizowaniu i finansowaniu spotkań promocyjnych produktów leczniczych, podczas których przejawy gościnności wykraczają poza główny cel tego spotkania.

Należy podkreślić, że chociaż Prawo farmaceutyczne nie przewiduje w sposób wyraźny możliwości pokrywania wydatków związanych z udziałem profesjonalisty w spotkaniu naukowym (takich jak opłaty wpisowe, koszty hoteli itp.), to w związku z przepisami zezwalającymi na sponsorowanie spotkań promocyjnych (art. 52 ust. 2 pkt 5 Prawa farmaceutycznego), pokrywanie takich kosztów należy uważać za dozwolone. Znajduje to potwierdzenie również w postanowieniach Kodeksu INFARMA, który w sposób wyraźny zezwala na pokrywanie takich kosztów w określonych granicach.

The regulations require that documentation addressed to persons authorized to prescribe or persons engaged in the trade of medicinal products contain information that are accurate, up-to-date, verifiable and sufficiently complete to enable the recipient to form his or her opinion of the therapeutic value of the medicinal product concerned. It shall also contain information referring to the date of preparing the documentation and the last update. Quotations as well as tables and other illustrative matter taken from medical journals or other scientific works shall be faithfully reproduced and contain precise indication of their source.

Hospitality for Healthcare Professionals

Article 58.1 of the Pharmaceutical Law provides that advertising addressed to healthcare professionals which involves awarding, offering or promising material profits, gifts and other facilities, prizes or trips, as well as organizing and funding of meetings promoting medicinal products is forbidden when the hospitality offered "goes beyond" the main purpose of the meeting.

Although Pharmaceutical Law does not provide expressly for the possibility of covering expenses (such as registration fees and hotel accommodation), related to the participation of a healthcare professional in an academic event (such as registration fees and hotel accommodation), based on provisions allowing sponsorship of meetings (Article 52.2.5), payment for such expenses should be seen as permissible. This is also confirmed by the provisions of the Code of INFARMA, which expressly allows such expenses to be covered within certain set limits.

The Code of INFARMA contains detailed restrictions with regard to acceptable limits of hospitality, as follows:

- Meetings organized or sponsored by or on behalf of a marketing authorization holder should be organized at locations appropriate for the main purpose of these meetings; venues which are considered eccentric or known for entertainment shall be avoided.
- Meetings organized or sponsored, directly or indirectly, should not be held abroad unless this is justified by substantive or organizational aspects, especially if the majority of the invited guests come from outside of the event's home country.
- Hospitality offered should not be excessive; it should be limited to covering of costs of travel, accommodation, boarding and registration fees associated with participation in the conference; the reimbursement of costs should apply to the participants in the meetings only, and not

Kodeks INFARMA zawiera szczegółowe ograniczenia dotyczące dopuszczalnych granic przejawów gościnności:

- Spotkania organizowane lub sponsorowane przez lub w imieniu podmiotu odpowiedzialnego powinny odbywać się w miejscach odpowiednich dla głównego celu tych spotkań; należy unikać miejsc, które uznawane są za ekstrawaganckie lub słynne ze względu na oferowane rozrywki.
- Nie należy organizować lub sponsorować bezpośrednio lub pośrednio spotkań poza granicami kraju, chyba, że jest to uzasadnione względami merytorycznymi, organizacyjnymi, w szczególności, gdy większość zaproszonych osób pochodzi spoza kraju, w którym spotkanie jest organizowane.
- Przejawy gościnności oferowane uczestnikom spotkań nie powinny być nadmierne i muszą pozostawać w ścisłym związku z podstawowym celem spotkania, tj. powinny być ograniczone do pokrycia kosztów: podróży zakwaterowania, wyżywienia oraz opłat rejestracyjnych związanych z udziałem w spotkaniu. Koszty te powinny dotyczyć wyłącznie uczestników spotkania, a nie osób im towarzyszących, w tym członków ich rodzin. Przejawy gościnności podczas spotkań nie mogą obejmować sponsorowania lub organizacji części rozrywkowej spotkania, np. imprez sportowych czy rekreacyjnych
- Kryteria wyboru osób, które zostaną zaproszone na kongres czy sympozjum, powinny być obiektywne i oparte na przesłankach merytorycznych

Próbki

Próbki produktów leczniczych mogą być dostarczane wyłącznie osobom uprawnionym do wystawiania recept (a więc nie osobom prowadzącym obrót produktami leczniczymi) przy zachowaniu następujących wymogów:

- Osoba upoważniona do wystawiania recept wystąpiła w formie pisemnej do przedstawiciela handlowego lub medycznego o dostarczenie próbki produktu leczniczego.
- Osoba dostarczająca próbkę prowadzi ewidencję dostarczanych próbek.
- Próbka dotyczy produktu dopuszczonego do obrotu na ternie Polski.

to persons accompanying them, including family members; hospitality offered cannot include sponsoring or organization of entertainment, including sporting or leisure events.

- The marketing authorization holder or entities/persons acting on his behalf should use objective criteria based on substantive prerequisites when selecting persons to be invited to a meeting.

Samples of Products

Samples of medicinal products may be provided only to persons authorized to issue prescriptions (therefore not to persons trading in medicinal products) and the following restrictions must be respected:

- A person authorized to issue prescriptions must request a sample in writing.
- The entity supplying a sample must monitor and keep records of the supplied samples.
- The sample must be of a product authorized for marketing in Poland.
- The sample cannot be larger than the smallest packaging unit authorized for sale in Poland (in this respect, the Pharmaceutical Law is inconsistent with the regulations of the Directive 2001/83/EC, which refers not to the smallest registered, but to the smallest presentation on the market).
- The SmPC must be attached to the sample.
- Samples must be marked: "free sample – not for sale."
- Not more than five packages of a given product can be delivered to a given person per calendar year.
- It is not permissable to distribute samples containing psychotropic or intoxicating substances.

Please note that samples of medicinal products are not marketable. Distribution of samples is also to be differentiated from donation of medicinal products, which is an issue discussed below.

Gifts

In general, gifts to medical practitioners are regarded as advertising of medicinal products. The Pharmaceutical Law allows such gifts only if:

- they are offered to persons authorized to prescribe medicinal products or persons trading in medicinal products;

- Każda dostarczana próbka nie jest większa niż jedno najmniejsze opakowanie produktu leczniczego dopuszczone do obrotu na terytorium Rzeczypospolitej Polskiej (w tym zakresie Prawo farmaceutyczne jest niezgodne z przepisami Dyrektywy 2001/83/WE, która odnosi się nie do najmniejszego zarejestrowanego, lecz najmniejszego opakowania produktu na rynku);
- Każda dostarczana próbka jest opatrzona napisem „próbka bezpłatna - nie do sprzedaży".
- Do każdej dostarczanej próbki dołączona jest ChPL.
- Ilość dostarczanych próbek tej samej osobie, tego samego produktu leczniczego, nie przekracza pięciu opakowań w ciągu roku.
  oraz
- Dostarczanie próbek nie może dotyczyć produktów leczniczych zawierających środki odurzające lub substancje psychotropowe.

Należy podkreślić, że próbki produktów leczniczych są wyłączone z obrotu. Ponadto dystrybucję próbek należy odróżnić od darowizn produktów leczniczych, która to kwestia zostanie omówiona poniżej.

Upominki

Co do zasady upominki przeznaczone dla lekarzy są uznawane za reklamę produktów leczniczych. Prawo farmaceutyczne zezwala na przekazywanie takich upominków jedynie pod warunkiem, że: są wręczane osobom uprawnionym do wystawiania recept oraz osobom prowadzącym obrót produktami leczniczymi; ich wartość nie przekracza 100 złotych, czyli około 25 euro (zgodnie ze stanowiskiem organów władzy kwota ta powinna być rozumiana jako wartość brutto w handlu detalicznym); są opatrzone znakiem reklamującym daną firmę lub produkt leczniczy; oraz mają związek z praktyką medyczną lub farmaceutyczną.

Zasady dotyczące upominków stosuje się do wszelkich korzyści materialnych oferowanych profesjonalistom przez firmy farmaceutyczne, takich jak czasopisma naukowe lub szkolenia zawodowe (przy czym należy odróżnić szkolenia od sponsorowania udziału w konferencjach i kongresach naukowych).

Należy odróżnić wręczanie profesjonalistom upominków od darowizn. Przekazywanie darowizn pieniężnych lub innych korzyści materialnych osobom uprawnionym do wystawiania recept lub osobom prowadzącym obrót produktami leczniczymi jest niedozwolone.

- their maximum value is PLN100, which is about EUR25 (public authorities represent the view that this amount should be understood as the gross value at retail level);
- they have been marked with the company logo or the name of the medicinal product; and
- they are connected with medical or pharmaceutical practice.

The rules on gifts apply to any material benefits offered by pharmaceutical companies to healthcare professionals, such as scientific journals or professional training (whereas such professional training must be differentiated from sponsorship of participation in scientific events).

Gifts offered to healthcare professionals must be distinguished from donations. Donations of money or other material benefits to persons authorized to prescribe medicinal products or persons trading in medicinal products are not permitted.

Donations

In principle, donations of money or equipment or financing of services should be made only to public institutions (such as public hospitals). They may not be given to particular persons in an institution, but only to the institution as a whole. They cannot be given to private entities such as partnerships of physicians or businesses operated by physicians (or other healthcare professionals), because in such a case the donation could be treated as a disguised illegal gift to a physician. In some exceptional cases, donations to private hospitals which perform to a large extent public functions (i.e., they provide services to patients which are financed from public funds), may be admissible.

Donations of pharmaceutical products are subject to special restrictions regarding both:

- the pharmaceutical companies as donators the company must hold a wholesale license, because donations are regarded as a form of trading in pharmaceutical products; and
- the beneficiaries – they must be one of the types of entities listed in the Regulation of the Minister of Health of 12 December 2002, on entities authorized to purchase medicinal products from a wholesaler (Journal of Laws of 2002 No 216, item 1831). In practice, the recipients of donations of medicinal products will be mostly healthcare institutions.

Darowizny

Co do zasady darowizny pieniężne, darowizny sprzętu czy polegające na finansowaniu usług powinny być przeznaczone wyłącznie dla instytucji publicznych (jak np. szpitale publiczne). Darowizny nie mogą być przekazywane poszczególnym osobom działającym w ramach danej instytucji, lecz wyłącznie instytucji jako takiej. Nie mogą być również przekazywane podmiotom prywatnym, takim jak spółki zawiązane przez lekarzy lub gabinety prowadzone przez lekarzy (lub inne osoby świadczące usługi opieki zdrowotnej), gdyż w takim przypadku darowizna mogłaby zostać uznana za ukryty, niezgodny z prawem upominek dla lekarza. W niektórych wyjątkowych przypadkach dopuszczalne mogą być darowizny na rzecz szpitali prywatnych, które w znacznym zakresie wykonują funkcje publiczne (tj. świadczą usługi na rzecz pacjentów finansowane ze środków publicznych).

Darowizny w postaci produktów leczniczych podlegają szczególnym ograniczeniom zarówno w odniesieniu do:

- firm farmaceutycznych - które jako darczyńcy muszą posiadać zezwolenie na prowadzenie hurtowni, gdyż darowizny uznawane są za formę obrotu produktami leczniczymi, jak i
- beneficjentów – którzy muszą stanowić jeden z podmiotów określonych w Rozporządzeniu Ministra Zdrowia z dnia 12.12.2002 r. w sprawie podmiotów uprawnionych do zakupu produktów leczniczych w hurtowni farmaceutycznej (Dz. U. nr 216, poz. 1831). W praktyce podmiotami otrzymującymi darowizny w postaci produktów leczniczych są przede wszystkim zakłady opieki zdrowotnej.

Badania kliniczne, badania obserwacyjne, oraz inne projekty naukowe

- Firmy farmaceutyczne mogą angażować lekarzy do prowadzenia badań klinicznych, badań obserwacyjnych i innych projektów naukowych oraz wypłacać im wynagrodzenie za poświęcony czas i wkład pracy. Relacje te oparte są na umowach cywilnoprawnych, na podstawie których usługa świadczona przez lekarza jest oferowana w zamian za korzyść materialną ze strony firmy farmaceutycznej (pieniądze, szkolenia, sprzęt itp.).

Clinical Trials, Observational Studies and Other Research Projects

Pharmaceutical companies are allowed to engage doctors for clinical trials, observational studies and other research projects, and to pay remuneration for their time and efforts. Such relationships are civil law arrangements under which the service of a doctor is offered in exchange for a material benefit from a pharmaceutical company (e.g., money, training and equipment).

Any such arrangements must be distinguished from advertisement of medicinal products. Advertising is always a "one-directional" activity performed by a pharmaceutical company with respect to a healthcare professional where the healthcare professional does not provide any reciprocal service in exchange.

A civil law arrangement between a pharmaceutical company and a doctor assumes that both parties provide reciprocal services to each other. In particular, the service of a doctor must be real and valuable to the company, and the remuneration for this service must be adequate, i.e., correspond to the average market value.

While the Pharmaceutical Law contains detailed rules on clinical trials (further defined in the Regulation of the Minister of Health of 2 May 2012, on Good Clinical Practice, Journal of Laws of 2012, item 489), the regulation of non-interventional studies is limited. Article 37al of the Pharmaceutical Law provides only that:

- a medicinal product must be applied in conformity with the marketing authorization;
- qualification for treatment cannot occur on the basis of a protocol but on the basis of medical practice, and decisions about application of a drug are fully independent from decisions regarding enrolment in the study; and
- no additional diagnostic or monitoring procedures are applied to patients and the data collected is evaluated using epidemiologic methods.

The Code of Ethics adopted by INFARMA contains detailed rules on non-interventional studies in order to prevent misuse of these studies for disguised promotion of pharmaceutical products. These rules provide, among other things, that:

- studies should be of a specific scientific purpose;

Umowy takie należy odróżnić od reklamy produktów leczniczych. Reklama jest zawsze działaniem „jednokierunkowym" podejmowanym przez firmę farmaceutyczną wobec lekarza (lub innej osoby), zaś lekarz (lub inna osoba) nie świadczy w zamian żadnej usługi. Umowa cywilnoprawna pomiędzy firmą farmaceutyczną a lekarzem zakłada, że obie strony świadczą sobie usługi wzajemne. W szczególności usługa świadczona przez lekarza musi być usługą rzeczywistą i wartościową dla firmy farmaceutycznej, a kwota wynagrodzenia oferowanego za tę usługę musi być odpowiednia, tj. odpowiadać przeciętnym warunkom rynkowym.

O ile Prawo farmaceutyczne zawiera szczegółowe przepisy dotyczące badań klinicznych (rozwinięte dalej w Rozporządzeniu Ministra Zdrowia z dnia 02.05.2012 r. w sprawie Dobrej Praktyki Klinicznej, Dz. U. z 2012 r., poz. 489), o tyle badania nieinterwencyjne zostały uregulowane w ograniczonym stopniu. Art. 37al Prawa farmaceutycznego przewiduje jedynie, że w ramach badania nieinterwencyjnego:

- produkty lecznicze są stosowane w sposób określony w pozwoleniu na dopuszczenie do obrotu;
- przydzielenie chorego do grupy, w której stosowana jest określona metoda leczenia, nie następuje na podstawie protokołu badania, ale zależy od aktualnej praktyki, a decyzja o podaniu leku jest jednoznacznie oddzielona od decyzji o włączeniu pacjenta do badania;
- u pacjentów nie wykonuje się żadnych dodatkowych procedur diagnostycznych ani monitorowania, a do analizy zebranych danych stosuje się metody epidemiologiczne.

Kodeks przyjęty przez INFARMA zawiera szczegółowe postanowienia dotyczące badań nieinterwencyjnych, mające na celu zapobieżenie niewłaściwemu wykorzystywaniu tych badań dla prowadzenia ukrytej reklamy produktów leczniczych. Przewidują one m.in., że:

- badania powinny mieć określony cel naukowy;
- badania powinny być prowadzone zgodnie z protokołem badania ściśle określającym liczbę pacjentów i czas obserwacji. Rozszerzenie w tych samych ośrodkach tego samego badania lub rozpoczęcie nowego badania z tym samym celem naukowym jest niedopuszczalne, o ile nie wynika to z decyzji odpowiednich organów lub powszechnie obowiązujących przepisów prawa; zaleca się przedkładanie protokołu badania stosownej komisji etycznej w celu zapoznania się z nim;

- studies should be conducted on a predefined number of patients and with a specified observation time, as described in the study protocol; the extension of the same study, or a new study, with the same scientific objective in mind, is prohibited unless this is a result of a decision issued by relevant authorities or generally binding legal regulations; submitting the study protocol to the relevant ethic commission is recommended;
- the study cannot be used to compare medicinal products;
- investigators may receive remuneration for conducting the study in accordance with the study agreement which corresponds to the time and workload and should reflect the practices adopted on the Polish market;
- the start of a non-interventional study must be announced to the public through placement on the website of INFARMA (or any other appropriate association); and
- results should be prepared in the form of a final report within 12 months of the end of the observation of the last patient, and published or presented at a medical symposium within 24 months of the end of the observation of the last patient.

Advertising Addressed to the General Public

Advertising addressed to the general public must state:

- the name of the product;
- the common name of the active substance, and with regard to a product containing more than three active substances, the description "complex product";
- the dose of the active substance or its concentration, excluding complex products;
- pharmaceutical form;
- therapeutic indications;
- contraindications; and
- the MAH.

Advertisements for non-prescription medicines must fulfill a number of other requirements, including advertisement proportions (content vs. warnings), or wording of warnings (such as, "Before use, please familiarize yourself with a leaflet attached to the package or contact a physician or a pharmacist, because each drug used inappropriately threatens your life or health").

- badanie nie może służyć porównywaniu produktów leczniczych;
- badacz może otrzymać wynagrodzenie za prowadzenie badania, zgodne z umową o przeprowadzenie badania. Wysokość wynagrodzenia powinna być adekwatna do czasu i nakładu pracy związanego z prowadzeniem badania oraz odzwierciedlać przyjęte zwyczaje panujące na polskim rynku;
- rozpoczęcie badania musi zostać podane do publicznej wiadomości poprzez umieszczenie na stronie internetowej INFARMA (lub innego odpowiedniego stowarzyszenia); oraz
- wyniki powinny być przygotowane w formie raportu końcowego nie później niż w terminie 12 miesięcy od zakończenia obserwacji ostatniego pacjenta oraz opublikowane lub przedstawione na sympozjum medycznym w ciągu 24 miesięcy od zakończenia obserwacji ostatniego pacjenta.

Reklama kierowana do publiczności

Reklama kierowana do publicznej wiadomości powinna określać: nazwę produktu leczniczego; nazwę powszechnie stosowaną substancji czynnej, a w przypadku produktu leczniczego zawierającego więcej niż 3 substancje czynne, określenie: „produkt złożony"; dawkę substancji czynnej lub stężenie substancji czynnej, z wyłączeniem produktu złożonego; postać farmaceutyczną; wskazanie terapeutyczne do stosowania; przeciwwskazania; oraz wskazanie podmiotu odpowiedzialnego.

Reklama leków sprzedawanych bez recepty powinna spełniać kilka innych wymogów, w tym dotyczących proporcji reklamy (treści do ostrzeżeń) lub treści ostrzeżeń („Przed użyciem zapoznaj się z treścią ulotki dołączonej do opakowania bądź skonsultuj się z lekarzem lub farmaceutą, gdyż każdy lek niewłaściwie stosowany zagraża Twojemu życiu lub zdrowiu").

Prawo farmaceutyczne wprowadza ponadto następujące ograniczenia w zakresie reklamy kierowanej do publiczności:

- Nie może ona dotyczyć produktów wydawanych wyłącznie nie na podstawie recepty, lub których nazwa jest identyczna z nazwą produktu wydawanego wyłącznie na podstawie recepty, zawierających środki odurzające i substancje psychotropowe, umieszczonych na wykazach leków refundowanych oraz o nazwie identycznej z umieszczonymi na tych wykazach.

Moreover, the Pharmaceutical Law provides for the following restrictions on advertising to the public:

- It cannot relate to prescription only medicines or OTC medicines which have names identical to prescription medicines, medicines containing intoxicating or psychotropic substances, medicines included in the reimbursement lists, or medicines which have names identical to those included in the reimbursement lists.
- It may not be presented by scientists, persons publicly known (this reference causes interpretational doubts), and persons having medical or pharmaceutical education or suggesting that they have such an education.
- It may not refer to recommendations of scientists, persons publicly known, and persons having medical or pharmaceutical training/qualifications or suggesting to have such training/qualifications.
- It may not suggest that:
    - it is possible to avoid a doctor's advice or surgery;
    - even a healthy person will improve his/her health if he/she uses the drug and that non-application of the drug may worsen a medical condition;
    - a medicinal product is a foodstuff, cosmetic or other consumer product; and
    - the effectiveness or safety of a product is a result of the natural character of that product.
- It may not assure the effectiveness of the drug, that there are no side effects, or that the effect of the drug is better or the same as another treatment.
- It may not lead to improper self-diagnosis.
- It may not refer to the therapeutic indications in a form which is inappropriate, appalling or misleading.
- It may not give an incorrect, alarming or misleading picture of a disease or effect of the drug.

Advertising in Healthcare Institutions and Pharmacies

- According to Article 13 point 2 of the Law of 15 April 2011, on healthcare activity (Journal of Laws no. 112, item 654, as amended), in the place of provision of healthcare services, economic activity other than healthcare activity (for example, advertising) can be conducted, provided that it is not disruptive to patients or to the treatment.

- Nie może polegać na prezentowaniu produktu leczniczego przez naukowców, osoby znane publicznie (to określenie rodzi problemy interpretacyjne) bądź osoby posiadające wykształcenie medyczne lub farmaceutyczne, lub sugerujące posiadanie takiego wykształcenia.
- Nie może odwoływać się do zaleceń naukowców, osób znanych publicznie, osób posiadających wykształcenie medyczne lub farmaceutyczne, lub sugerujących posiadanie takiego wykształcenia;
- Nie może zawierać treści, które sugerują, że:
    - możliwe jest uniknięcie porady lekarskiej lub zabiegu chirurgicznego, zwłaszcza przez postawienie diagnozy lub zalecanie leczenia na drodze korespondencyjnej;
    - nawet osoba zdrowa przyjmująca lek poprawi swój stan zdrowia;
    - nieprzyjmowanie leku może pogorszyć stan zdrowia danej osoby;
    - produkt leczniczy jest środkiem spożywczym, kosmetycznym lub innym artykułem konsumpcyjnym; oraz
    - skuteczność lub bezpieczeństwo stosowania produktu leczniczego wynika z jego naturalnego pochodzenia.
- Nie może zapewniać, że przyjmowanie leku gwarantuje właściwy skutek, nie towarzyszą mu żadne działania niepożądane lub że skutek jest lepszy lub taki sam, jak w przypadku innej metody leczenia albo leczenia innym produktem leczniczym.
- Nie może prowadzić do błędnej autodiagnozy przez przytaczanie szczegółowych opisów przypadków i objawów choroby.
- Nie może odnosić się w formie nieodpowiedniej, zatrważającej lub wprowadzającej w błąd, do wskazań terapeutycznych.
- Nie może zawierać niewłaściwych, niepokojących lub mylących określeń przedstawionych graficznie zmian chorobowych, obrażeń ludzkiego ciała lub działania produktu leczniczego na ludzkie ciało lub jego części.

Reklama w zakładach opieki zdrowotnej i aptekach

Zgodnie z art. 13 pkt 2 Ustawy z dnia 15.04.2011 r. o działalności leczniczej, Dz. U. nr 112, poz. 654 z późn. zm.), w miejscu udzielania świadczeń zdrowotnych może być wykonywana działalność gospodarcza inna niż działalność lecznicza (a więc m.in. działalność reklamowa), pod warunkiem jednak, że nie jest ona uciążliwa dla pacjenta lub przebiegu leczenia.

Despite some controversies concerning the ban on pharmacies advertising, which entered into force on 1 January 2012, the advertising of medicinal products in pharmacies is allowed, only if it does not constitute simultaneously the advertising of a particular pharmacy.

Detailed rules on advertising medicinal products in healthcare institutions and pharmacies are provided by the Regulation on advertising of medicinal products. The Regulation provides that the advertising of medicinal products in healthcare institutions and pharmacies may not:

- disrupt normal activities conducted there; and
- use sound and audiovisual forms.

Additionally, the advertising of medicinal products addressed to the general public in healthcare institutions must be placed only in waiting rooms, and advertising in pharmacies must be placed in separate sections and cannot limit the space designated for patients.

Pre-Approval

There is no requirement or possibility to acquire in advance an approval of a regulatory authority or industry/professional body for the planned advertisement.

Pharmaceutical companies are not required to notify a regulatory body about the planned advertising and its details. The same applies to addressees of advertisements, e.g., a healthcare professionals participating in a congress sponsored by a pharmaceutical company; persons participating in such events do not have to report this fact. Internal staff regulations of an individual doctor may, however, provide otherwise.

If consultation on the planned advertisement is needed, industry organizations usually provide assistance to their members, but this assistance does not guarantee elimination of risk of negative evaluation of an advertisement by public authorities.

The Chief Pharmaceutical Inspector (CPI), the public authority who controls pharmaceutical advertising in Poland, informally declares the will to discuss proposed advertising in order to ensure its compliance with the law. There is, however, no legal mechanism to request such advice, receive it within certain time, or refer to it in order to officially justify action taken.

Mimo pewnych kontrowersji związanych z wejściem w życie z dniem 1 stycznia 2012 r. zakazu reklamy aptek i ich działalności, dozwolona jest również reklama produktów leczniczych w aptekach, jeżeli nie stanowi ona jednocześnie reklamy danej apteki.

Szczegółowe zasady prowadzenia reklamy produktów leczniczych w zakładach opieki zdrowotnej i aptekach określa Rozporządzenie w sprawie reklamy produktów leczniczych. Zgodnie z jego przepisami reklama produktu leczniczego w aptekach i zakładach opieki zdrowotnej: nie może utrudniać prowadzonej tam działalności; oraz polegać na stosowaniu form dźwiękowych i audiowizualnych.

Ponadto reklama produktów leczniczych skierowana do publicznej wiadomości w zakładach opieki zdrowotnej może być rozmieszczana jedynie w poczekalniach dla pacjentów, zaś reklama w aptekach musi odbywać się w wydzielonych miejscach i nie może ograniczać powierzchni przeznaczonej dla osób korzystających z usług apteki.

Uprzednie zatwierdzenie reklamy

Nie ma wymogu ani konieczności uzyskania uprzedniego zatwierdzenia planowanej reklamy przez organ regulacyjny lub branżowy.

Firmy farmaceutyczne nie są zobowiązane do zawiadamiania organów regulacyjnych o planowanej reklamie i przekazywania szczegółowych informacji na jej temat. Odnosi się to również do adresatów reklam, np. lekarza uczestniczącego w kongresie sponsorowanym przez firmę farmaceutyczną; osoby uczestniczące w tego rodzaju imprezach nie są zobowiązane zgłaszać tego faktu. Kwestia ta może być jednak odmiennie uregulowana w uregulowaniach wewnętrznych, obowiązujących w miejscu pracy danego lekarza.

Jeżeli konieczne jest przeprowadzenie konsultacji w sprawie planowanej reklamy, organizacje branżowe zwykle służą swym członkom pomocą w tym zakresie, jednak pomoc ta nie gwarantuje eliminacji ryzyka negatywnej oceny reklamy przez organy władzy.

Główny Inspektor Farmaceutyczny (GIF), czyli organ sprawujący nadzór nad reklamą produktów leczniczych w Polsce, nieoficjalnie deklaruje gotowość omówienia proponowanej reklamy w celu zapewnienia jej zgodności z przepisami prawa. Nie istnieje jednak żadna procedura prawna pozwalająca zwrócić się z wnioskiem o taką konsultację, uzyskać ją w określonym czasie lub powołać się na nią w celu oficjalnego uzasadnienia podjętych działań.

Sanctions

Administrative Sanctions

Most commonly, administrative sanctions will be applied to a Marketing Authorization Holder by the CPI. This is due to the general rule that the entity responsible for the advertising of a pharmaceutical product is the MAH for this product. Should the advertisement fail to comply with Pharmaceutical law regulations, the following sanctions may be applied:

- Prohibition of further publishing of the given advertisement
- An order to publish the decision of the CPI and/or to issue a corrective statement in places (media) in which the banned advertisement has been published (broadcast)
- An order to remove the ascertained breaches (e.g., withdrawal of publications including the prohibited advertisement)

The first and last orders mentioned above have an immediate effect. In practice, the CPI mostly applies the sanction prohibiting further publishing of an advertisement.

Frequently, competitors notify the CPI about observed breaches of advertising rules. CPI has full discretion as to whether to consider such notifications, but in practice they are often the first source of information for the CPI, and therefore may lead to a faster reaction of the CPI if it is determined that a breach has taken place.

It is possible to file a motion for reconsideration of the decision with the CPI. The motion should be filed within 14 days from the receipt of the decision. Should the first instance decision of the CPI be upheld, a claim can be filed with the Voivodship Administrative Court. At the last stage, the claim can be filed with the Supreme Administrative Court.

The Pharmaceutical Law provides for instruments enabling the CPI to conduct administrative control over advertising. A Marketing Authorization Holder is obliged to keep a copy of an advertisement for two years from the end of the calendar year in which the advertisement was distributed. Upon request of the CPI, a Marketing Authorization Holder is obliged to present:

- a copy of each advertisement aimed at the public, including information on the date and means of distribution of the advertisement; and
- information concerning each advertisement aimed at professionals.

Sankcje

Sankcje administracyjne

GIF nakłada sankcje administracyjne zazwyczaj na podmiot odpowiedzialny. Wynika to z ogólnej zasady, która stanowi, że odpowiedzialność za reklamę produktu leczniczego ponosi podmiot odpowiedzialny dla tego produktu. W przypadku niezgodności reklamy z przepisami Prawa farmaceutycznego GIF może nakazać:

- Zaprzestanie ukazywania się lub prowadzenia reklamy
- Publikację wydanej decyzji w miejscach, w których ukazała się reklama sprzeczna z obowiązującymi przepisami, oraz publikację sprostowania błędnej reklamy
- Usunięcie stwierdzonych naruszeń (np. wycofanie publikacji zawierających błędną reklamę)

Nakazy wymienione w pkt 1 i 3 powyżej mają rygor natychmiastowej wykonalności. W praktyce GIF nakłada zazwyczaj sankcję w postaci nakazu zaprzestania ukazywania się lub prowadzenia danej reklamy.

Konkurenci często zawiadamiają GIF o zauważonych naruszeniach przepisów dotyczących reklamy. GIF może decydować wedle własnego uznania, czy uwzględniać tego rodzaju zawiadomienia, jednak w praktyce często stanowią one dla organu pierwsze źródło informacji i z tego względu mogą doprowadzić do szybszej reakcji ze strony GIF w przypadku ustalenia wystąpienia naruszenia.

Od decyzji GIF można złożyć,w terminie 14 od dnia jej otrzymania, wniosek o ponowne rozpatrzenie sprawy do tego samego organu. W przypadku podtrzymania decyzji GIF wydanej w pierwszej instancji, możliwe jest złożenie skargi do wojewódzkiego sądu administracyjnego. Ostatecznie możliwe jest złożenie skargi do Naczelnego Sądu Administracyjnego.

Prawo farmaceutyczne przewiduje instrumenty umożliwiające GIF sprawowanie nadzoru administracyjnego nad reklamą. Podmiot odpowiedzialny zobowiązany jest przechowywać wzory reklam przez okres 2 lat od zakończenia roku kalendarzowego, w którym reklama była rozpowszechniana. Na żądanie GIF podmiot odpowiedzialny jest obowiązany przedstawić: wzór każdej reklamy skierowanej do publicznej wiadomości, wraz z informacją o sposobie i dacie jej rozpowszechnienia; oraz informację o każdej reklamie skierowanej do profesjonalistów.

Criminal Sanctions

Both the Pharmaceutical Law and the Penal Code provide for criminal offenses relevant to the advertising of pharmaceutical products. In principle, Polish law does not establish the criminal liability of a legal person. Therefore, penal sanctions may not be imposed on a pharmaceutical company as such, but on a natural person who is found liable of unlawful advertising. Such sanction may only be imposed by a public court as a result of criminal proceedings.

The Pharmaceutical Law provides for criminal liability related to the following advertising practices (Articles 128-130):

- Advertising of medicinal products by an unauthorized entity
- Advertising of medicinal products not approved for marketing in Poland
- Advertising contrary to the approved SmPC
- Public advertising of prescription products or non-prescription products that have a name identical to prescription medicinal products
- Public advertising of medicinal products containing intoxicating and psychotropic substances
- Public advertising of reimbursable products or products that have a name identical to medicinal products included in the reimbursement lists
- Incomplete records of the supplied samples
- Delivery of samples to unauthorized persons
- Non-compliance with the requirement to store specimens and information about advertisements
- Non-compliance with a decision ordering the cessation of publication or conduct of advertising of a medicinal product; publication of the decision in the place where the advertisement was published and publication of the corrective statement; or removal of identified breaches
- Providing or promising to persons authorized to prescribe medicinal products or persons trading in medicinal products any benefits with value exceeding PLN100 (which is about EUR25), in particularly gifts, prizes, or travel benefits or organizing or financing for such persons promotional meetings where the hospitality exceeds the main purpose of the meeting
- Ascribing the characteristics of a medicinal product to a non-medicinal product

Sankcje karne

Zarówno Prawo farmaceutyczne jak i Kodeks karny określają czyny zabronione dotyczące reklamy produktów leczniczych. Co do zasady prawo polskie nie przewiduje odpowiedzialności karnej osób prawnych i z tego względu sankcje karne nie mogą być nakładane na firmę farmaceutyczną jako taką, lecz na osobę fizyczną, która zostanie uznana za winną prowadzenia sprzecznej z prawem reklamy. Sankcje takie mogą zostać nałożone wyłącznie przez sąd powszechny w wyniku postępowania karnego.

Prawo farmaceutyczne przewiduje następujące rodzaje czynów zabronionych związanych z reklamą produktów leczniczych (art. 128-130):

- Prowadzenie reklamy produktów leczniczych bez należytego uprawnienia
- Reklama produktów leczniczych niedopuszczonych do obrotu na terytorium Rzeczypospolitej Polskiej
- Reklama niezgodna z zatwierdzoną ChPL
- Kierowanie do publiczności reklamy produktów leczniczych wydawanych wyłącznie na podstawie recepty lub produktów leczniczych wydawanych bez recepty o nazwie identycznej z nazwą leku na receptę
- Kierowanie do publiczności reklamy produktów leczniczych zawierających środki odurzające i substancje psychotropowe
- Kierowanie do publiczności reklamy produktów leczniczych objętych refundacją lub o nazwie identycznej z nazwą leku umieszczonego na wykazie leków refundowanych
- Brak prowadzenia ewidencji próbek
- Dostarczanie próbek osobom nieuprawnionym
- Nieprzechowywanie wzorów reklam
- Niewykonywanie niezwłocznie decyzji nakazujących (i) zaprzestanie ukazywania się lub prowadzenia reklamy produktu leczniczego, (ii) publikację decyzji w miejscu, gdzie ukazała się reklama oraz publikację sprostowania, lub (iii) usunięcie stwierdzonych naruszeń
- Wręczanie lub obiecywanie osobom uprawnionym do wystawiania recept, osobom prowadzącym obrót produktami leczniczymi korzyści materialnych przekraczających wartość 100 złotych (czyli około 25 euro), w szczególności prezentów, nagród, wycieczek, a także organizowanie lub finansowanie dla takich osób spotkań promocyjnych, podczas których przejawy gościnności przekraczają główny cel spotkania

The offenses listed above are punishable by a fine which may vary from PLN100 to PLN720,000.

To our knowledge, penal fines have not yet been imposed against individuals acting in the name of pharmaceutical companies. However, we are aware of notifications of breaches of criminal provisions made by the CPI to the prosecution bodies.

In addition to the abovementioned criminal offenses which refer specifically to the advertising of medicinal products, there are also general criminal offenses provided for in the Penal Code which may be applicable to advertisement of medicinal products and relationships between pharmaceutical companies and healthcare professionals and institutions. These criminal offenses regard in particular passive and active corruption in the public sector (Articles 228-231) and in the private sector (Articles 296-296a).

Certain criminal offenses involving corruption under the Penal Code may lead to liability for a company. This liability does not apply to criminal offenses relating to advertising of medicinal products provided for by the Pharmaceutical Law, with the exception of prohibition of ascribing the characteristics of a medicinal product to a non-medicinal product. Detailed rules of such liability are set forth in the Law of 28 October 2002, on Liability of Collective Entities for Prohibited Acts Subject to a Penalty (Journal of Laws No 197, item 1661, as amended). If a natural person is proven guilty of a particular criminal offense in criminal proceedings, then a collective entity such as a pharmaceutical company may also be held liable, if:

- the individual was acting in the name or for the benefit of this entity within the right or the obligation to represent this entity, decide on its behalf or make an inspection, as well as with the excess of such rights or obligations;
- the entity obtained profit from actions of the individual; and
- the entity is responsible for failure to exercise due diligence and selection of the individual or control over the actions of the individual.

If the court finds a collective entity liable, this will result in:

- a fine of PLN1,000 - PLN5,000,000, however, a maximum 3 percent of the gross income of the entity in the year in which the criminal offense was committed; and
- confiscation of the obtained benefit.

- Przypisywanie właściwości produktu leczniczego produktowi niebędącemu lekiem

Wymienione powyżej czyny zabronione są zagrożone karą grzywny, której wysokość może wahać się od 100 do 720.000 złotych.

Nie są nam znane przypadki nałożenia kary grzywny na osoby fizyczne działające w imieniu firm farmaceutycznych. Jednak wiadomo nam o zawiadomieniach przez GIF organów ścigania w sprawie naruszenia przepisów karnych.

Oprócz wymienionych powyżej czynów zabronionych dotyczących reklamy produktów leczniczych istnieją również czyny zabronione wskazane w Kodeksie karnym, które mogą dotyczyć reklamy produktów leczniczych oraz relacji pomiędzy firmami farmaceutycznymi a osobami świadczącymi usługi ochrony zdrowia oraz placówkami ochrony zdrowia. Te czyny zabronione dotyczą w szczególności biernego i czynnego łapownictwa w sektorze publicznym (art. 228-231) i prywatnym (art. 296-296a).

Za niektóre czyny zabronione dotyczące łapownictwa określone w Kodeksie karnym odpowiedzialność może ponosić spółka. Odpowiedzialność ta nie dotyczy czynów zabronionych w zakresie reklamy produktów leczniczych wymienionych w Prawie farmaceutycznym, za wyjątkiem zakazu przypisywania właściwości produktu leczniczego produktowi niebędącemu lekiem. Szczegółowe przepisy dotyczące takiej odpowiedzialności zostały zawarte w Ustawie z dnia 28.10. 2002 r. o odpowiedzialności podmiotów zbiorowych za czyny zabronione pod groźbą kary (Dz. U. Nr 197, poz. 1661, ze zm.). Jeżeli fakt popełnienia przez osobę fizyczną czynu zabronionego został potwierdzony orzeczeniem wydanym w postępowaniu karnym, wówczas podmiot zbiorowy (np. firma farmaceutyczna) może również zostać pociągnięty do odpowiedzialności w przypadku, gdy:

- dana osoba fizyczna działała w imieniu lub w interesie podmiotu zbiorowego w ramach uprawnienia lub obowiązku do jego reprezentowania, podejmowania w jego imieniu decyzji lub wykonywania kontroli wewnętrznej albo przy przekroczeniu tego uprawnienia lub niedopełnieniu tego obowiązku;
- zachowanie to przyniosło lub mogło przynieść podmiotowi zbiorowemu korzyść, chociażby niemajątkową; oraz
- do popełnienia czynu zabronionego doszło w następstwie co najmniej braku należytej staranności w wyborze osoby fizycznej, lub co najmniej braku należytego nadzoru nad tą osobą.

In addition, the court may apply, for a period of one to five years, the following sanctions:

- Prohibition of promotion or advertising of an activity, product or service
- Prohibition of use of public funds
- Prohibition of making use of support of international organizations of which Poland is a member
- Prohibition of entry for public tenders
- Public announcement of the verdict

Sanctions on the Basis of the Code of INFARMA

Under the code adopted by INFARMA, a disciplinary court has been created and given certain supervisory powers. Should the advertisement fail to comply with the code, the disciplinary court may impose the following sanctions:

- Prohibition of practices which do not comply with the code, particular the immediate withdrawal from all media the advertising violating the code
- Admonition or reprimand
- Order an entity to issue a single or repeated statement of the specific content in the indicated media
- Notification of the CPI about the verdict of the disciplinary court
- Notification of the EFPIA or IFPMA about the verdict
- Notification of the entity or entities affiliated in terms of capital with the party which violated the code about the verdict
- Order single or repeated publication of the verdict or its excerpt in the indicated media

The abovementioned sanctions can be imposed simultaneously.

No right of appeal against a verdict of the disciplinary court is provided for.

Instruments Available to Competitors

- In the case of breach of advertising rules, competitors are not allowed to take direct actions via regulatory bodies against an entity which has breached these rules. They may only, as mentioned above, notify the CPI about observed breaches, which may (but does not have to) result in official action being taken by the CPI.

Jeżeli sąd uzna podmiot zbiorowy za winny, orzeka: karę pieniężną w wysokości od 1.000 do 5.000.000 złotych, nie wyższą jednak niż 3 % przychodu osiągniętego w roku obrotowym, w którym popełniono czyn zabroniony; oraz przepadek uzyskanej korzyści majątkowej.

Dodatkowo sąd może orzec, na okres na okres od 1 roku do lat 5, następujące zakazy:

- Zakaz promocji lub reklamy prowadzonej działalności, produktów lub usług
- Zakaz korzystania ze wsparcia finansowego środkami publicznymi
- Zakaz korzystania z pomocy organizacji międzynarodowych, których Rzeczpospolita Polska jest członkiem
- Zakaz ubiegania się o zamówienia publiczne
- Podanie wyroku do publicznej wiadomości

Sankcje na podstawie Kodeksu INFARMA

Na podstawie Kodeksu INFARMA został powołany sąd dyscyplinarny, który posiada uprawnienia do prowadzenia nadzoru. W przypadku reklam, które nie spełniają wymogów Kodeksu, sąd dyscyplinarny może nałożyć następujące sankcje:

- Zakaz prowadzenia działań niezgodnych z Kodeksem, w szczególności natychmiastowe wycofanie ze wszystkich środków masowego przekazu materiału reklamowego naruszającego postanowienia Kodeksu
- Zawiadomienie GIF o zapadłym orzeczeniu sądu dyscyplinarnego
- Karę upomnienia lub nagany
- Nakaz złożenia jedno- lub wielokrotnego oświadczenia określonej treści we wskazanym środku publicznego przekazu
- Zawiadomienie GIF o zapadłym orzeczeniu sądu dyscyplinarnego
- Zawiadomienie EFPIA lub IFPMA o zapadłym orzeczeniu
- Zawiadomienie podmiotu lub podmiotów powiązanych kapitałowo ze stroną, która naruszyła Kodeks, o zapadłym orzeczeniu
- Zobowiązanie do jedno krotnego lub wielokrotnego opublikowania zapadłego orzeczenia lub jego części we wskazanych środkach masowego przekazu.

Powyższe sankcje mogą być orzekane łącznie.

Od orzeczenia sądu dyscyplinarnego nie przysługuje odwołanie.

However, if a competitor's own interests are violated, it has certain instruments to claim compensation under civil law, particularly on the basis of unfair competition rules.

The rules of unfair competition are governed by the Act on Combating Unfair Competition. The following types of advertisement which endanger or violate the interests of other entrepreneurs are deemed to be acts of unfair competition:

- An advertisement which does not comply with the law or so called "good customs" (therefore, any advertisement which does not comply with the Pharmaceutical Law may be an act of unfair competition if it violates entrepreneurs'/consumers' interests)
- An advertisement misleading to a customer which may affect his/her decision regarding the purchase of goods or services
- An advertisement which makes use of personal feelings of customers by inciting fear of taking advantage of prejudices or the credulousness of children
- Hidden advertising which appears to be neutral information but encourages to the purchase of goods or services
- An advertisement which substantially interferes with somebody's privacy

The Act on Combating Unfair Competition also provides for detailed rules on comparative advertisement. A comparative advertisement is an act of unfair competition if it does not comply with "good customs." According to Article 16.3, an advertisement is deemed to comply with "good customs" if it fulfills the following requirements:

- It is not misleading.
- It compares products and services meeting the same needs or designed for the same purpose in an honest and verifiable way using objective criteria.
- It compares one or a few important, characteristic, verifiable and typical features of goods or services, such as price.
- It does not lead to confusion on the market between the advertiser and his competitor, their goods or services, trademarks or brands.
- It does not discredit the competitor, its goods or services, activity, trademarks or brands.

Narzędzia dostępne konkurentom

W przypadku naruszenia zasad reklamy konkurenci nie mogą bezpośrednio podejmować działań za pośrednictwem organów regulacyjnych przeciwko podmiotowi, który dopuścił się naruszenia tych zasad. Mogą oni jedynie, jak wskazano powyżej, poinformować GIF o zaobserwowanych naruszeniach, co może (lecz nie musi) skutkować podjęciem przez GIF formalnych działań.

Jednak w przypadku naruszenia własnych interesów, konkurent dysponuje pewnymi instrumentami umożliwiającymi dochodzenie odszkodowania na podstawie przepisów prawa cywilnego, a w szczególności na podstawie przepisów o nieuczciwej konkurencji.

Przepisy o nieuczciwej konkurencji zawarte są w Ustawie o zwalczaniu nieuczciwej konkurencji. Następujące rodzaje reklam, które zagrażają lub naruszają interes innych przedsiębiorców, są uznawane za czyny nieuczciwej konkurencji:

- Reklama sprzeczna z prawem lub dobrymi obyczajami (tak więc reklama, która nie spełnia wymogów Prawa farmaceutycznego może zostać uznana za czyn nieuczciwej konkurencji, jeżeli narusza ona interesy przedsiębiorców / konsumentów)
- Reklama wprowadzająca klienta w błąd i mogąca przez to wpłynąć na jego decyzję co do nabycia towaru lub usługi
- Reklama odwołująca się do uczuć klientów przez wywoływanie lęku, wykorzystywanie przesądów lub łatwowierności dzieci
- Wypowiedź, która sprawia wrażenie neutralnej informacji, ale mimo to sprawia wrażenie zachęcającej do nabywania towarów lub usług
- Reklama, która stanowi istotną ingerencję w sferę prywatności

Ustawa o zwalczaniu nieuczciwej konkurencji zawiera również szczegółowe zasady w zakresie reklamy porównawczej. Reklama porównawcza stanowi czyn nieuczciwej konkurencji, jeżeli jest sprzeczna z dobrymi obyczajami. Zgodnie z art. 16 ust. 3, reklama porównawcza nie jest sprzeczna z dobrymi obyczajami, jeżeli łącznie spełnia następujące przesłanki:

- Nie jest reklamą wprowadzającą w błąd.
- W sposób rzetelny i dający się zweryfikować na podstawie obiektywnych kryteriów porównuje towary lub usługi zaspokajające te same potrzeby lub przeznaczone do tego samego celu.

- It does not use in an unfair manner the reputation of a trademark, designation of an entity or any other distinguishing mark of the competitor.
- It does not present the goods as an imitation of goods bearing a protected trademark or other distinction mark.

In addition, detailed rules on comparative advertisement of medicinal products are included in the Code of Ethics of INFARMA, which provides that:

- an advertisement should indicate the name, the form and the dosage of the compared medicinal products;
- the description of the comparison, restrictions associated with the comparison and the data used in the comparison must be presented in a manner which will not be misleading for the addressee of the advertisement;
- the comparison may only concern medicinal products with similar properties or identical indications;
- the comparison may only concern particular characteristics of compared medicinal products and must be supported by studies;
- the comparison should concern one or several crucial characteristics and testable properties, such as the price of the compared medicinal products;
- the comparison should be objective, honest and verifiable; an opportunity to check the information presented in the comparison should be provided by indicating the source of that information, along with the date of publication or most recent update;
- the advertisement cannot discredit competitive medicinal products or the marketing authorization holder;
- the comparison of selected properties of the medicinal products should not be misleading as regards the properties being compared and properties not being compared, and cannot cause mistakes in distinction between medicinal products, trademarks, entrepreneur's identification or other distinctive marks; and
- the advertisement cannot present a medicinal product as the imitation of products bearing protected trademark.

According to Article 17a of the Act on Combating Unfair Competition, another category of advertisement which can be regarded as an act of unfair competition is sale of goods or services to consumers connected with providing some or all purchasers with a free bonus, which is different from

- W sposób obiektywny porównuje jedną lub kilka istotnych, charakterystycznych, sprawdzalnych i typowych cech tych towarów i usług, do których może należeć także cena.
- Nie powoduje na rynku pomyłek w rozróżnieniu między reklamującym a jego konkurentem, ani między ich towarami albo usługami, znakami towarowymi, lub oznaczeniami.
- Nie dyskredytuje konkurenta ani jego towarów, usług, działalności, znaków towarowych, lub innych oznaczeń.
- Nie wykorzystuje w nieuczciwy sposób renomy znaku towarowego, oznaczenia przedsiębiorstwa lub innego oznaczenia odróżniającego konkurenta nie przedstawia towaru jako imitacji czy naśladownictwa towaru opatrzonego chronionym znakiem towarowym albo innym oznaczeniem odróżniającym.

Szczegółowe zasady w zakresie reklamy porównawczej produktów leczniczych zawiera Kodeksu INFARMA, który stanowi, że:

- reklama powinna podawać nazwę, postać farmaceutyczną oraz dawkę porównywanych produktów leczniczych;
- opis porównania, ograniczenia związane z porównaniem oraz dane użyte w porównaniu muszą być przedstawione w sposób wykluczający wprowadzenie w błąd adresata reklamy;
- porównanie może dotyczyć wyłącznie produktów leczniczych o podobnych właściwościach lub produktów leczniczych o takich samych wskazaniach;
- porównanie powinno odnosić się do określonych, popartych wynikami badań właściwości porównywanych produktów leczniczych;
- porównanie powinno dotyczyć jednej lub kilku istotnych, charakterystycznych i możliwych do sprawdzenia cech, w tym m.in. ceny porównywanych produktów leczniczych;
- porównanie powinno być obiektywne, rzetelne i dające się zweryfikować; należy zagwarantować możliwość sprawdzenia informacji zamieszczonych w porównaniu poprzez podanie źródła prezentowanych informacji wraz z datą publikacji lub ostatniej aktualizacji;
- reklama nie może dyskredytować konkurencyjnego produktu leczniczego ani podmiotu odpowiedzialnego;
- porównanie wybranych cech produktów leczniczych nie powinno wprowadzać w błąd, co do właściwości porównywanych produktów oraz ich cech nieobjętych porównaniem, a także nie może powodować pomyłek w rozróżnieniu między produktami leczniczymi, znakami

the sold goods or service, unless the value of this bonus is insignificant. Interpretational doubts appear as to the "sameness" or "similarity" of the goods or services in question and to the "insignificance" of the value of the bonus.

An affected entrepreneur may seek protection in civil proceedings in a public court. The following can be sought in the court proceedings:

- Cessation of the prohibited activity
- Removal of the effects of the prohibited activity
- Making of one or several statements with the appropriate wording and in the appropriate form
- Remedying inflicted damage
- Surrendering unjust benefits
- In the case of an act of unfair competition for which the entity in breach in responsible – payment of a certain amount to a public benefit cause related to support of Polish culture

With the exception of claims for damages or claims for the surrender of unjust benefits, the other claims may also be raised by a regional or national organization whose purpose is to protect the interests of entrepreneurs.

Trade Practices

The rules regarding trade practices are ambiguous. On one hand, according to Article 53.2 of the Pharmaceutical Law, the advertising of medicinal products cannot consist of offering or promising directly or indirectly benefits in exchange for purchase of a medicinal product, or delivery of evidence that it has been purchased. On the other hand, Article 94.4 of Directive 2001/83/EC expressly excludes "normal" trade practices such as price discounts from the scope of advertising restrictions, which has not, however, been implemented into Polish law.

In practice, Article 53.2 of the Pharmaceutical Law is applied to promotions aimed at patients. The main rationale behind this provision is prevention of inducement to purchase a medicinal product by offering an additional bonus.

In other words, therapeutic decisions should not be influenced by the prospect of economic gain. On the contrary, trade practices between manufacturers, wholesalers and retailers, relating to sales volume and other economic factors, are normal business characteristics and should be excluded from this restriction. In fact, such trade practices are widely applied by traders in medicinal products.

towarowymi, oznaczeniami przedsiębiorstwa lub innymi oznaczeniami odróżniającymi; oraz
- reklama nie może przedstawiać produktu leczniczego jako imitacji czy naśladownictwa produktu opatrzonego chronionym znakiem towarowym.

Zgodnie z art. 17a Ustawy o zwalczaniu nieuczciwej konkurencji, inną kategorią reklamy, która może być uznana za czyn nieuczciwej konkurencji, jest sprzedaż konsumentom towarów lub usług połączona z przyznaniem wszystkim albo niektórym nabywcom towarów lub usług nieodpłatnej premii, w postaci towarów lub usług odmiennych od stanowiących przedmiot sprzedaży, chyba że wartość towaru jest niewielka. Wątpliwości interpretacyjne pojawiają się w związku z „tożsamością" czy też „podobieństwem" przedmiotowych towarów lub usług oraz z „niewielką" wartością premii.

Przedsiębiorca może dochodzić ochrony w ramach postępowania cywilnego w sądzie powszechnym. W postępowaniu sądowym można dochodzić:

- Zaniechania niedozwolonych działań
- Usunięcia skutków niedozwolonych działań
- Złożenia jednokrotnego lub wielokrotnego oświadczenia odpowiedniej treści i w odpowiedniej formie
- Naprawienia wyrządzonej szkody, na zasadach ogólnych
- Wydania bezpodstawnie uzyskanych korzyści
- Zasądzenia odpowiedniej sumy pieniężnej na określony cel społeczny związany ze wspieraniem kultury polskiej lub ochroną dziedzictwa narodowego - jeżeli czyn nieuczciwej konkurencji był zawiniony.

Z wyjątkiem roszczeń odszkodowawczych lub o wydanie bezpodstawnie uzyskanych korzyści, z roszczeniami mogą również występować regionalne lub krajowe organizacje, których celem jest ochrona interesów przedsiębiorców.

Praktyki handlowe

Zasady w zakresie praktyk handlowych są niejednoznaczne. Z jednej strony, zgodnie z art. 53 ust. 2 Prawa farmaceutycznego, reklama nie może polegać na oferowaniu lub obiecywaniu jakichkolwiek korzyści w sposób pośredni lub bezpośredni w zamian za nabycie produktu leczniczego lub dostarczanie dowodów, że doszło do jego nabycia. Z drugiej strony, art. 94.4 Dyrektywy

Medical Devices

There are no specific rules relating to advertising of medical devices. Rules on labeling, which in some cases may be applied to advertising, are contained in the Act on Medical Devices of 20 May 2010 (Journal of Laws No 107, item 679, as amended) and in its implementing regulations. General rules regarding unfair competition must also be taken into account. In particular, advertising of medical devices cannot be misleading and ascribe properties of medicinal products to the devices.

Recommendations

In order to ensure compliance with the law of marketing activities concerning medicinal products in Poland, it should be noted that:

- the concept of advertising of a medicinal product has been defined very widely, therefore it encompasses many different kinds of promotional activities relating to medicinal products;
- in order to avoid legal risk, if in of doubt as to whether a given action represents information or advertising, the stricter legal regime should be applied;
- the Polish regulations on advertising constitute the implementation of EU provisions of the law and, therefore, the rules for conducting advertising of medicinal products in Poland are in principle compliant with those applied in other European countries;
- a guide to current practice and assessment of individual activities by the Polish regulatory bodies may be the decisions of the Chief Pharmaceutical Inspector published together with the reasons therefor on the website of that authority; and
- particular caution should be exercised in the case of promotional activities relating to reimbursed products due to unclear regulations in this regard, introduced recently by the Act on Reimbursement of Medicinal Products, Foodstuffs for Special Nutritional Purposes and Medical Devices of 12.05.2011.

2001/83/WE wyraźnie wyłącza „normalne" praktyki handlowe, takie jak rabaty cenowe, z zakresu ograniczeń w zakresie reklamy. Postanowienia tego artykułu nie zostały jednak implementowane do prawa polskiego.

W praktyce art. 53 ust. 2 Prawa farmaceutycznego ma zastosowanie do promocji adresowanych do pacjentów. Głównym powodem wprowadzenia tego postanowienia jest zapobieżenie zachęcaniu do nabycia produktów leczniczych poprzez oferowanie dodatkowej premii. Innymi słowy, na decyzje w zakresie leczenia nie powinna mieć wpływu perspektywa uzyskania korzyści ekonomicznych. Z kolei inaczej, praktyki handlowe pomiędzy wytwórcami, hurtownikami i sprzedawcami detalicznymi dotyczące wielkości sprzedaży oraz innych czynników natury ekonomicznej, są normalnymi praktykami handlowymi i, jako takie, powinny być wyłączone z zakresu ograniczenia. W rzeczywistości takie praktyki handlowe są stosowane na szeroką skalę przez podmioty prowadzące obrót produktami leczniczymi.

Wyroby medyczne

Brak jest szczegółowych zasad dotyczących reklamy wyrobów medycznych. Zasady w zakresie oznakowania, które w niektórych przypadkach mogą znaleźć zastosowanie do reklamy określa Ustawa z dnia 20.05.2010 r. o wyrobach medycznych (Dz. U. Nr 107, poz. 679, ze zm.) wraz z rozporządzeniami wykonawczymi. Obowiązują również ogólne zasady w zakresie nieuczciwej konkurencji. W szczególności niedopuszczalna jest reklama wyrobów medycznych wprowadzająca w błąd oraz przypisywanie w reklamach wyrobom medycznym cech produktów leczniczych.

Rekomendacje

W celu zapewnienia zgodności z prawem działań marketingowych dotyczących produktów leczniczych w Polsce przede wszystkim należy mieć na uwadze, że:

- pojęcie reklamy produktu leczniczego zostało zdefiniowane bardzo szeroko, w związku z czym mieści ono w sobie wiele różnego rodzaju działań promocyjnych dotyczących produktów leczniczych,
- w celu uniknięcia ryzyka prawnego, w przypadku wątpliwości, czy dane działanie stanowi informację czy reklamę, należy stosować surowszy reżim prawny,

- polskie regulacje w zakresie reklamy stanowią implementację przepisów unijnych, w związku z czym zasady prowadzenia reklamy produktów leczniczych w Polsce są co do zasady tożsame z rozwiązaniami innych państw europejskich,
- pewną wytyczną w zakresie aktualnej praktyki i oceny poszczególnych działań przez polskie organy nadzoru mogą stanowić decyzje Głównego Inspektora Farmaceutycznego publikowane wraz z uzasadnieniem na stronie internetowej tego organu,
- szczególną ostrożność należy zachować w przypadku działań promocyjnych odnoszących się do produktów refundowanych ze względu na niejasne regulacje w tym zakresie wprowadzone w ostatnim czasie przez ustawę z dnia 12.05.2011 r. o refundacji leków, środków spożywczych specjalnego przeznaczenia żywieniowego oraz wyrobów medycznych.

Россия

Алексей Трусов, Сергей Ломакин

Введение

В связи с реформой российской системы здравоохранения российское законодательство, регулирующее лекарственные средства и медицинские изделия, претерпевает существенные изменения. Данный факт также влияет на регулирование продвижения и рекламы лекарственных средств и медицинских изделий.

Нам бы хотелось начать с разъяснения терминологии, используемой в сфере продвижения медицинской продукции в России, которая, в связи с постоянными изменениями в законодательстве, является довольно запутанной. Во-первых, термин «медицинская продукция», включающий в себя термины «лекарственные средства» и «медицинские изделия», не используется российским законодательством. Тем не менее, данный термин, в целях удобства, будет использован в настоящей публикации. Более того, Основы (как определено ниже) кардинальным образом поменяли терминологию в сфере медицинских изделий. Они заменили термин «изделие медицинского назначения», который включал как подкатегории собственно «изделия медицинского назначения» и «медицинскую технику», на единый термин «медицинское изделие» без его внутреннего деления для целей выделения медицинской техники. Данное изменение в терминологии сильно влияет на регулирование рекламы, которое основано на старом наборе терминов. При рассмотрении правил рекламы ниже по этой причине будет использован прежний набор терминов.

В дополнение к вышесказанному, российское регулирование не использует единый термин «работники здравоохранения», а полагается на термины «медицинские работники и руководители медицинских организаций» (совместно - «медицинские работники») и «фармацевтические работники и руководители аптечных организаций» (совместно - «фармацевтические работники»). При рассмотрении вопросов ниже термин «работник здравоохранения» будет использован для целей обозначения медицинских и фармацевтических работников.

Russia

Alexey Trusov, Sergei Lomakin

Introduction

Russian legislation regulating medicines and medical devices is undergoing substantial changes as part of the reform of the Russian healthcare system. This process also affects promotion and advertising of medicines and medical devices.

We would like to start out by explaining the terminology used in the area of promotion of medical products in Russia, which due to constant legislative changes, is rather confusing. First of all, Russian legislation does not use the term "medical products" to incorporate the terms "medicines" and "medical devices." This term will nonetheless be used in this publication for convenience purposes. Furthermore, the Fundamentals (as defined below) dramatically changed terminology in the medical devices area. They replaced the previously used term "products with medical purposes," which included "products with medical purposes" and "medical equipment" as subcategories, with the unified term "medical devices" with no internal division to single out medical equipment. This terminology change currently heavily affects the regulation of advertising, which still relies on the prior set of terms. As a result, discussion of the advertising rules below will use the prior set of terms as well.

In addition, Russian regulations in the relevant parts do not use the unified term "healthcare professionals," but rather rely on the terms medical professionals and heads of medical institutions ("Medical Professionals"); and pharmaceutical professionals and heads of pharmacies (together "Pharmaceutical Professionals"). In the discussion below, the term "Healthcare Professionals" will be used to designate medical and pharmaceutical professionals.

The Regulatory Framework

The following are the main legislative acts which currently govern the advertising and promotion of medical products:

- Federal Law No. 61-FZ on the Circulation of Medicines dated 12 April 2010 as further amended ("Law on Circulation of Medicines")

Законодательная база

Следующие акты являются основными законодательными актами, регулирующими рекламу и продвижение медицинской продукции:

- Федеральный закон от 12 апреля 2010 года № 61-ФЗ «Об обращении лекарственных средств» с изменениями и дополнениями (далее – «Закон об обращении лекарственных средств»);
- Федеральный закон от 21 ноября 2011 года № 323-ФЗ «Об основах охраны здоровья граждан в Российской Федерации» (далее – «Основы»);
- Федеральный закон от 13 марта 2006 года № 38-ФЗ «О рекламе» (далее – «Закон о рекламе»).

Лекарственные средства на настоящий момент регулируются Законом об обращении лекарственных средств. Система здравоохранения в целом, а равно медицинские изделия регулируются совершенно новыми Основами. Данный документ направлен на то, чтобы стать основой всей регуляторной системы здравоохранения в России, который должен также включать в себя регулирование медицинской продукции. Этот документ, однако, не содержит положений, регулирующих лекарственные средства (этот блок регулирования полностью содержится в Законе об обращении лекарственных средств), а две его статьи, регулирующие медицинские изделия, на сегодняшний день служат единственным источником регулирования медицинских изделий на законодательном уровне.

Несмотря на вышесказанное, продвижение лекарственных средств и медицинских изделий в России регулируется схоже, хотя нормы, касающиеся продвижения, и расположены в различных законодательных актах. При этом важно отметить, что правила рекламы лекарственных средств и медицинских изделий сгруппированы в Законе о рекламе. Основы в свою очередь устанавливают правила, регулирующие порядок взаимодействия между фармацевтическими компаниями и компаниями, занимающимися медицинскими изделиями, и медицинскими и фармацевтическими работниками.

- Federal Law No. 323-FZ on Fundamentals of the Protection of the Citizens' Health in the Russian Federation dated 21 November 2011 ("Fundamentals")
- Federal Law No. 38-FZ on Advertising dated 13 March 2006 as further amended ("Law on Advertising")

Medicines are currently regulated by the recently adopted Law on Circulation of Medicines. The healthcare system in general and medical devices are regulated by the very new Fundamentals. The latter document is intended to be the basis of all healthcare regulation in Russia, which should cover, *inter alia*, medical products. This document, however, does not address regulation of medicines (fully covered by the Law on Circulation of Medicines), and its two articles governing medical devices at present serve as the only regulations of medical devices at the legislative level.

Notwithstanding the above, regulation of promotion in Russia is rather uniform both for medicines and medical devices, even though it is also located in different legislative acts. Most importantly, the rules on advertising of medicines and medical devices are grouped in the Law on Advertising. The Fundamentals establish specific rules governing interactions between pharmaceutical and medical device companies and medical and pharmaceutical professionals.

Permitted and Prohibited Practices

Until very recently, the only area related to promotion of medical products that was specifically regulated by Russian law was simple advertising. However, with the enactment of the Fundamentals, Russian law for the first time has introduced specific regulations governing the interactions between pharmaceutical and medical device companies and Healthcare Professionals. These rules, however, are not always clear. The Russian market is currently in a transition period where the pharmaceutical and medical device industries are trying to adapt their practices to the new requirements with no official guidance on how the relevant rules should be applied.

Gifts, Seminars, Hospitality and Entertainment

The Fundamentals establish a direct prohibition on Healthcare Professionals receiving any kind of gifts or monetary payments from pharmaceutical and medical device companies and their representatives. A gift under Russian regulations is understood rather widely as a gratuitous transfer or provision of

Разрешенные и запрещенные виды деятельности

До недавнего времени единственной областью, относящейся к продвижению фармацевтической продукции, которая специальным образом регулировалась российским правом, являлась реклама. Однако с принятием Основ в российском законодательстве впервые появились конкретные правила, регулирующие вопросы взаимодействия между фармацевтическими компаниями и компаниями, занимающимися медицинскими изделиями, и работниками здравоохранения. Эти правила, однако, не всегда достаточно ясны. Российский рынок на настоящий момент находится в переходном периоде, когда фармацевтические компании и компании, занимающиеся медицинскими изделиями, пытаются адаптировать свою деятельность к новым требованиям в отсутствие официальных разъяснений по вопросам применения соответствующих правил,.

Подарки, семинары, представительские приемы, развлечения

Основы устанавливают прямой запрет на получение работниками здравоохранения любых подарков и денежных средств от фармацевтических компаний, компаний, занимающихся медицинскими изделиями, и их представителей. Подарок в российском регулировании понимается достаточно широко как безвозмездная передача, предоставление какого-либо имущества бесплатно или без иного встречного предоставления. Поэтому формально даже передача медицинскому работнику ручки с логотипом продукта может быть признана подарком и, следовательно, будет подпадать под установленное ограничение.

Более того, в результате ограничения, указанного выше, работники здравоохранения не могут посещать какие-либо конференции или иные подобные мероприятия, если они спонсируются фармацевтическими организациями или компаниями, занимающимися медицинскими изделиями. Это обусловлено тем, что любое безвозмездное спонсирование (например, оплата регистрационного взноса, транспорта, проживания) по российскому праву будет считаться подарком.

Работникам здравоохранения не запрещается участвовать в мероприятиях, не носящих развлекательного характера, организуемых фармацевтическими компаниями и компаниями, занимающимися медицинскими изделиями. Однако они (или их представители) не могут

something of material value free of charge or without any other consideration in return. Therefore, technically, even the provision of a pen with a product logo to a Medical Professional may qualify as a gift and hence be subject to the said restriction.

Furthermore, as a result of the above prohibition, Healthcare Professionals may not attend any conferences or other similar events sponsored by pharmaceutical or medical device companies. This is because any gratuitous sponsorship (e.g., payment of a fee for attendance, transportation, lodging expenses) will qualify as a gift under Russian law.

Healthcare Professionals are not restricted from participation in non-entertainment events organized by pharmaceutical and medical device companies. However, their expenses related to such participation should not be covered by the companies or their representatives. Purely formally, hospitality during events that Healthcare Professionals attend to by themselves may also be viewed as a gift under Russian law. In our view, however, modest hospitality (water, tea and coffee) is unlikely to be prosecuted in practice.

The Fundamentals contain a direct prohibition on Healthcare Professionals attending any entertainment events organized by pharmaceutical or medical device companies.

It is important to note, however, that the Fundamentals contain an important exception from the above restriction on making monetary payments with respect to Medical Professionals. Medical Professionals may receive remuneration under agreements in the course of conducting clinical trials of medicinal preparations or clinical studies of medical devices, or for teaching and/or scientific activities. Please refer to the section on contracts with healthcare professionals and medical institutions below for a more detailed analysis in this regard.

The status of state or municipal servants, which in practice is rare among Healthcare Professionals (except for military and law enforcement healthcare professionals, who are often military or law enforcement officers) should also be taken into account, as the rules applicable to those categories of individuals also contain restrictions on gifts, hospitality and entertainment. However, given the strictness of the rules set forth in the Fundamentals, this special status in our view may only further impede the ability to contract with the relevant Healthcare Professionals.

компенсировать расходы работников здравоохранения, относящиеся к такому участию. С формальной точки зрения, представительские расходы, произведенные в пользу работников здравоохранение во время мероприятий, посещаемых ими за свой счет, может также рассматриваться в качестве подарка по российскому праву. На наш взгляд, однако, скромные представительские расходы (вода, чай и кофе) на практике вряд ли будет преследоваться по закону.

Основы содержат прямой запрет на посещение работниками здравоохранения развлекательных мероприятий, организуемых фармацевтическими компаниями или компаниями, занимающимися медицинскими изделиями.

Необходимо заметить, однако, что Основы содержат важное исключение из запрета получать денежные средства, обозначенного выше, применимое только к медицинским работникам. Медицинские работники могут получать денежные средства в качестве вознаграждения по договорам при проведении клинических исследований лекарственных препаратов или клинических испытаний медицинских изделий, а также в связи с осуществлением педагогической и (или) научной деятельности. Для более подробного рассмотрения данного вопроса, пожалуйста, обратитесь к разделу о договорах с работниками здравоохранения и медицинскими учреждениями ниже.

Статус государственного или муниципального служащего, который на практике достаточно редко встречается среди работников здравоохранения (за исключением работников здравоохранения в военной и правоохранительной сферах, где они часто являются военнослужащими и лицами, состоящими на правоохранительной службе), также должен быть принят во внимание, так как правила, применимые к данным категориям лиц, содержат ограничения на дарение, представительские расходы и развлечения. Однако с учетом строгости правил, установленных Основами, данный специальный статус, на наш взгляд, может лишь затруднить возможность заключать договоры с соответствующими работниками здравоохранения.

Пожалуйста, обратите внимание, что вышеуказанные ограничения применимы исключительно к случаям взаимодействия с отдельными работниками здравоохранения и не касаются медицинских или фармацевтических организаций.

Please note that the above restrictions are only applicable to interactions with individual Healthcare Professionals and not with medical or pharmaceutical organizations.

Promotional Activities

The Fundamentals also contain further restrictions limiting certain promotional activities involving Healthcare Professionals. The Fundamentals prohibit Healthcare Professionals from:

- concluding agreements with companies or representatives of companies on prescribing or recommending certain medicines or medical devices to patients (except in the context of clinical trials of medicinal preparations or clinical studies of medical devices);
- prescribing medicines or medical devices on blank forms containing promotional information, as well as on prescription forms that already contain the name of medicines or medical devices; and
- meeting with representatives of pharmaceutical companies, manufacturers and sellers of medical products, except for cases related to performance of clinical trials of medicinal preparations or clinical studies of medical devices, or participation in meetings of medical workers or other events related to their professional development, or providing pharmacovigilance or materiovigilance information in accordance with the procedure established by the management of a medical organization (this restriction is not applicable to Pharmaceutical Professionals).

The last restriction strictly limits visits of pharmaceutical and medical device companies (medical representatives) to Medical Professionals. Such visits should be in compliance with the rules established by the management of the relevant medical institution and must be done for the purposes clearly established in the Fundamentals. The only exception to this rule is visits related to the performance of clinical trials of medicinal preparations or clinical studies of medical devices. Until the medical institution establishes the relevant rules for visits to Medical Professionals, no such visits are permitted. Once the relevant rules are established, the visits to Medical Professionals must fall under the scope permitted by such rules.

The only other type of promotional activity that is specifically regulated by Russian law is “advertising,” defined in Article 3 of the Law on Advertising

Деятельность по стимулированию сбыта продукции

Основы также содержат дополнительные запреты, ограничивающие деятельность по стимулированию сбыта продукции с участием работников здравоохранения. Основы запрещают работникам здравоохранения следующее:

- заключать с компанией или представителем компании соглашения о назначении или рекомендации пациентам лекарственных препаратов, медицинских изделий (за исключением договоров о проведении клинических исследований лекарственных препаратов, клинических испытаний медицинских изделий);
- выписывать лекарственные препараты, медицинские изделия на бланках, содержащих информацию рекламного характера, а также на рецептурных бланках, на которых заранее напечатано наименование лекарственного препарата, медицинского изделия; и
- осуществлять прием представителей фармацевтических компаний, производителей или продавцов медицинских изделий, за исключением случаев, связанных с проведением клинических исследований лекарственных препаратов, клинических испытаний медицинских изделий, участия в порядке, установленном администрацией медицинской организации, в собраниях медицинских работников и иных мероприятиях, связанных с повышением их профессионального уровня или предоставлением информации по фармакологическому надзору и информации, связанной с мониторингом безопасности медицинских изделий (неприменимо к фармацевтическим работникам).

Последний запрет существенно ограничивает возможность посещения медицинских работников фармацевтическими компаниями и компаниями, занимающимися медицинскими изделиями (их медицинскими представителями). Такие визиты должны проводиться в порядке, установленном администрацией медицинского учреждения, и должны соответствовать целям, установленным Основами. Единственным исключением из данного правила являются визиты в связи с проведением клинических исследований лекарственных препаратов или клинических испытаний медицинских изделий. В отношении же иных визитов. до момента установления администрацией

as "as information spread by any means, in any form and by any media which is addressed to an indefinite circle of persons and aimed at drawing attention to the object advertised, at creating or maintaining interest in it and at promoting it in the market."

The Law on Advertising specifically requires that prescription medicines, medicines that contain narcotic or psychotropic substances approved for medical use, treatment methods, products with medical purpose and equipment that requires special training for use can only be advertised in specialized printed publications intended for medical and pharmaceutical professionals, and at medical or pharmaceutical events. This law also allows only registered and certified medicines and medical devices to be advertised.

Furthermore, the Law on Advertising requires that the advertisement of medicines, medical services and medical equipment must be accompanied by a warning regarding contraindications against their use and application, the necessity to read the instructions on their use, or the necessity to consult a specialist. Such warning should last for at least three seconds in advertisements in radio programs; at least five seconds in television, film and video advertisements (not less than 7 percent of the frame area should be allocated to this warning); and not less than 5 percent of area/volume in advertisements disseminated by other methods. This requirement, however, does not apply to advertisements disseminated at medical or pharmaceutical events and contained in specialized printed publications for medical and pharmaceutical professionals, nor to other advertisements where the recipients are solely medical and pharmaceutical professionals.

The Law on Advertising further sets other restrictions that apply to the advertising of medicines. Thus, the advertising of medicines should not:

- be addressed to minors;
- contain references to specific cases of recovery from disease or improvement of health as a result of the advertised object being used (except in advertising exclusively for medical and pharmaceutical professionals);
- contain expressions of gratitude from individuals in connection with the use of the advertised object (except in advertising exclusively for medical and pharmaceutical professionals);
- create an impression of the advantages of the advertised object by reference to the fact that the trials required for its state registration have been conducted;

медицинского учреждения порядка посещения медицинских работников, такие визиты запрещены. С момента установления соответствующих правил посещения медицинских работников должны осуществляться в пределах, устанавливаемых такими правилами.

Российское законодательство специально регулирует лишь еще один вид деятельности по стимулированию продаж - «рекламу», определенную статьей 3 Закона о рекламе как «информация, распространенная любым способом, в любой форме и с использованием любых средств, адресованная неопределенному кругу лиц и направленная на привлечение внимания к объекту рекламирования, формирование или поддержание интереса к нему и его продвижение на рынке».

Закон о рекламе прямо устанавливает, что реклама лекарственных средств, отпускаемых по рецептам врача, а также лекарственных средств, содержащих разрешенные к применению в медицинских целях наркотические средства или психотропные вещества, методов лечения, а также медицинских изделий и медицинской техники, для использования которых требуется специальная подготовка, допускается только в предназначенных для медицинских и фармацевтических работников специализированных печатных изданиях и в местах проведения медицинских или фармацевтических мероприятий. Закон о рекламе разрешает рекламу только зарегистрированных лекарственных средств и медицинских изделий, с подтвержденным соответствием установленным требованиям по их качеству.

Кроме того, Закон о рекламе содержит требование, что реклама лекарственных средств, медицинских услуг и медицинской техники должна сопровождаться предупреждением о наличии противопоказаний к их применению и использованию, необходимости ознакомления с инструкцией по применению или получения консультации специалистов. В рекламе, распространяемой в радиопрограммах, продолжительность такого предупреждения должна составлять не менее чем три секунды, в рекламе, распространяемой в телепрограммах и при кино- и видеообслуживании, - не менее чем пять секунд (при этом такому предупреждению должно быть отведено не менее чем 7 процентов площади кадра), а в рекламе, распространяемой другими способами, - не менее чем 5 процентов рекламной площади пространства. Это требование, однако, не применяется к рекламе, распространяемой в местах проведения медицинских или

- contain statements or assumptions that consumers have certain diseases or impairments of health;
- facilitate the impression that a healthy person needs to use the advertised object (this prohibition does not apply to medicines used for prevention of diseases);
- create an impression that one does not need to consult a physician, or guarantee the positive effect of the advertised object;
- represent the advertised object as being a biologically active additive or a dietary supplement or other product that is not a medicine; and or
- contain statements that the safety and/or effectiveness of the advertised object are guaranteed by its natural origin.

The restrictions in items 2 through 5 above are also applicable to the advertising of medical services, and the restrictions in items 1 through 7 above apply equally to the advertising of medical equipment.

The Law on Advertising also contains an important general prohibition against using images of medical and pharmaceutical professionals in any advertisements, except for advertisements of medical services or personal care products, and or in advertising exclusively for medical and pharmaceutical professionals.

The Law on Advertising contains general restrictions on advertising that are equally applicable to advertising medical products. One general requirement is that advertising should be fair and true.

Samples

With the adoption of the Fundamentals, distribution of samples to Healthcare Professionals is now expressly prohibited by Russian law. Healthcare Professionals are not allowed to receive samples of medicinal preparations or medical devices for the purposes of giving them to patients. The only applicable exception relates to clinical trials of medicinal preparations and clinical studies of medical devices.

Furthermore, provision of samples of medicinal preparations by wholesalers of medicinal preparations directly to Healthcare Professionals (except for privately practicing licensed Healthcare Professionals) will still violate rules of circulation of medicinal preparations and therefore, will qualify as a violation of licensing terms and conditions by the involved wholesalers of medicinal preparations.

фармацевтических мероприятий, а также в предназначенных для медицинских и фармацевтических работников специализированных печатных изданиях, и на иную рекламу, потребителями которой являются исключительно медицинские и фармацевтические работники. Закон о рекламе устанавливает ряд иных ограничений на рекламу лекарственных средств. Так, реклама лекарственных средств не должна:

1. обращаться к несовершеннолетним;
2. содержать ссылки на конкретные случаи излечения от заболеваний, улучшения состояния здоровья человека в результате применения объекта рекламирования (кроме рекламы, потребителями которой являются исключительно медицинские и фармацевтические работники);
3. содержать выражение благодарности физическими лицами в связи с использованием объекта рекламирования (кроме рекламы, потребителями которой являются исключительно медицинские и фармацевтические работники);
4. создавать представление о преимуществах объекта рекламирования путем ссылки на факт проведения исследований, обязательных для государственной регистрации объекта рекламирования;
5. содержать утверждения или предположения о наличии у потребителей рекламы тех или иных заболеваний либо расстройств здоровья;
6. способствовать созданию у здорового человека впечатления о необходимости применения объекта рекламирования (данный запрет не распространяется на рекламу лекарственных средств, применяемых для профилактики заболеваний);
7. создавать впечатление ненужности обращения к врачу или гарантировать положительное действие объекта рекламирования;
8. представлять объект рекламирования в качестве биологически активной добавки или пищевой добавки или иного не являющегося лекарственным средством товара; и
9. содержать утверждения о том, что безопасность и (или) эффективность объекта рекламирования гарантированы его естественным происхождением.

Ограничения, приведенные в пунктах 2 – 5 выше, распространяются также на рекламу медицинских услуг, а ограничения, приведенные в пунктах 1 – 7 выше, распространяются также и на рекламу медицинской техники.

Again, this prohibition does not apply to interactions with medical or pharmaceutical organizations. Pharmaceutical and medical device companies may make gifts or donations (generally beneficial purpose-specific gifts) to these organizations, provided those are non-commercial organizations, which may receive such gifts or donations. When this activity is performed, all other rules governing circulation of medicinal products need to be carefully observed.

Consequences of Breach

Civil Law Liability

There are two main types of civil law liability that may be imposed by Russian courts on individuals and companies carrying out promotional and similar activities in violation of the abovementioned legislative provisions:

- Invalidation of the relevant transaction
- Compensation for losses, which include actual losses and/or lost profits

According to a general principle of Russian civil law, stipulated in the Russian Civil Code, a transaction that does not correspond to the requirements of the law is considered to be invalid. Based on this principle, the receipt of benefits by a Medical Professional in breach of the legislative restrictions would constitute an invalid transaction. As a consequence of a breach, an interested party may, through a court, demand "mutual restitution," that is, the return to each of the parties of what they received as a result of the invalid transaction. In the case of such a gift, the doctor would be obliged by a court decision, to return the gift or its value to the individual who provided it.

Similarly, the receipt of restricted benefits by a Healthcare Professional would also constitute an invalid transaction because it would constitute a breach of the Fundamentals.

If promotional activity is carried out in violation of the Law on Advertising or other applicable laws, an obligation to compensate may be imposed to the extent that this activity has caused losses to individuals or legal entities. The Civil Code provides for compensation of such losses provided that a direct connection is established by the court between the unlawful activity and the losses caused by the activity. In cases involving promotional activity, especially advertising, the individuals or legal entities that would commonly seek to recover such compensation for losses before the Russian courts would be customers or competitors of the infringer.

Закон о рекламе содержит важный общий запрет на использование образов медицинских и фармацевтических работников в любой рекламе, за исключением такого использования в рекламе медицинских услуг, средств личной гигиены и в рекламе, предназначенной исключительно для медицинских и фармацевтических работников.

Закон о рекламе также содержит общие ограничения, применимые к рекламе, которые в равной степени распространяются на рекламу медицинской продукции. Общее требование закона состоит в том, что реклама должна быть добросовестной и достоверной.

Образцы

С принятием Основ был введен прямой запрет на деятельность по распространению образцов работникам здравоохранения. Работникам здравоохранения запрещено получать образцы лекарственных препаратов или медицинских изделий для целей передачи их пациентам. Исключение сделано в отношении случаев, связанных с проведением клинических исследований лекарственных препаратов и клинических испытаний медицинских изделий.

Более того, передача образцов лекарственных препаратов оптовыми продавцами напрямую работникам здравоохранения (за исключением частнопрактикующих, имеющих лицензию, работников здравоохранения) будет по-прежнему являться нарушением правил обращения лекарственных препаратов и поэтому будет признано нарушением вовлеченным лицом, занимающимся оптовой торговлей лекарственными препаратами, лицензионных требований и условий.

Данный запрет, опять же, не относится к случаям взаимодействия с медицинскими или фармацевтическими организациями. Фармацевтические компании и компании, занимающиеся

медицинскими изделиями, могут делать подарки или пожертвования (имеют общеполезную цель) данным организациям, при условии, что такие организации являются некоммерческими, и имеют право получать подарки или пожертвования. При осуществлении данной деятельности должны внимательным образом соблюдаться все иные правила, регулирующие обращение медицинской продукции.

Administrative Liability

Administrative liability may be imposed on individuals and legal entities carrying out promotional activity prohibited by the Law on Advertising. In most cases, administrative liability is imposed in the form of fines of various amounts to be paid to the state budget. In the case of advertising activity, a court or an authorized governmental agency, such as the Russian Federal Antimonopoly Service, may also demand the publication of corrective advertising, the removal/destruction of unlawful advertising, and other measures.

In addition to the above, it is planned to support the restrictions imposed by the Fundamentals through the establishment of specific administrative penalties for their violation applicable to both the pharmaceutical and medical device companies and the Healthcare Professionals involved.

This has not yet been done, even though the draft amendments to the Code of Administrative Violations are already being prepared.

Lastly, in relation to the analysis of the potential anti-corruption aspect of promotional activities below please note that Russian legislation establishes administrative liability for legal entities involved in corrupt activities (Russian criminal law does not include the concept of corporate criminal liability).

Criminal Liability

There is a theoretical possibility that the receipt of benefits by a Healthcare Professional could give rise to criminal liability under Articles 204, 291 and 291.1 of the Criminal Code of the Russian Federation ("Criminal Code"). These articles deal with different types of bribery, i.e., the transfer of money or other assets or the rendering of services to an individual with the intent of obtaining certain benefits or with the intent of inducing the recipient to take certain actions in the interests of the giver, or acting as a mediator by assisting the recipient and/or giver of the bribe in the achievement of their unlawful aim. Article 204 also imposes liability on the recipient of the commercial bribe and Article 290 deals with the liability of a public official for the receipt of a bribe. A detailed analysis follows on the liability arising for the giver of a commercial bribe under Article 204 and the giver of a bribe under Article 291 of the Criminal Code.

Последствия нарушения

Гражданская ответственность

Существуют два основных вида гражданской ответственности физических и юридических лиц, занимающихся продвижением продукции на рынок и иной аналогичной деятельностью в нарушение вышеупомянутых законодательных положений, которые могут применяться российскими судами:

1. Признание соответствующей сделки ничтожной; и
2. Возмещение убытков, включая фактический ущерб и (или) упущенную выгоду.

В соответствии с общим принципом российского гражданского права, предусмотренного ст. 168 ГК РФ, любая сделка, не соответствующая требованиям закона, считается ничтожной. Исходя из этого принципа, получение материальных выгод медицинским работником в нарушение указанных законодательных ограничений представляет собой ничтожную сделку. Как следствие нарушения положений законодательства, заинтересованная сторона может потребовать через суд «двустороннюю реституцию», т.е. возвращение каждой из сторон того, что они получили в результате совершения ничтожной сделки. В случае с подарками врач на основании решения суда будет обязан вернуть подаренную вещь или ее стоимость подарившему ее лицу.

Аналогичным образом получение запрещенных материальных выгод медицинским работником будет представлять собой ничтожную сделку, так как будет являться нарушением статьи 74 Основ.

Если деятельность по продвижению товаров на рынок осуществляется в нарушение положений Закона о рекламе или иного применимого законодательства, на осуществляющее такую деятельность лицо может

быть наложено обязательство по возмещению ущерба, если в результате этой деятельности физические или юридические лица понесли убытки. Статья 15 Гражданского кодекса РФ предусматривает возмещение таких убытков при условии, что судом будет установлена прямая связь между осуществлением незаконной деятельности и убытками, понесенными в результате осуществления этой деятельности. В случаях, связанных с деятельностью по продвижению товаров на рынок и стимулированию их сбыта, в особенности, с рекламной деятельностью, физические или юридические лица, обращающиеся в

For criminal liability to arise under Articles 204 and 291 of the Criminal Code, the recipient of the benefits would have to be either a person holding a managerial position in the medical institution concerned (Article 204) or a public official (Article 291), although in the case of a public official, liability could arise if he or she was the indirect recipient (e.g., the money was paid to a third person for onward transmission to the public official). Consequently, any benefits provided to professionals who are not public officials and who hold no managerial position in the institution concerned cannot give rise to liability under these articles.

A gratuitous benefit can only be deemed a bribe if the necessary intent on the part of the giver (as described above) can be proved. While of course it could always be argued that a pharmaceutical company would not provide the benefits if it is not in its commercial interests to do so, it would be extremely difficult to use a general intention - for example, to familiarize a Medical Professional with products - as a sufficient basis for criminal liability.

As of now, there is no concept of corporate criminal liability under the Russian law, and so criminal liability may attach to individuals only. Criminal liability that could be imposed on individuals under the abovementioned articles of the Criminal Code are as follows:

- Article 204 (Commercial Bribery)

Liability for this violation can involve a fine varying from 10 to 50 times the amount of the commercial bribe, with a deprivation of the right to hold specific offices or engaging in specified activities for a term of up to two years, or a restraint of liberty for a term of up to two years, or compulsory labor for a term of up to three years, or imprisonment for the same term.

If the crime was committed by a group of persons in conspiracy or by an organized group or the commercial bribe was given for conducting knowingly illegal actions or omissions, it is punishable with a fine varying from 40 to 70 times the amount of the commercial bribe with disqualification from holding specific office or engaging in specified activities for a term of up to three years, or with compulsory labor for a term of up to four years, or with an arrest for a term of hree to six months, or with imprisonment for a term of up to six years.

российские суды с требованием о взыскании компенсации за понесенные убытки, обычно являются заказчиками или конкурентами правонарушителя.

Административная ответственность

Меры административной ответственности могут применяться к физическим и юридическим лицам, осуществляющим деятельность по продвижению товаров на рынок, запрещенную Законом о рекламе. В большинстве случаев привлечение к административной ответственности осуществляется путем наложения штрафов различной величины, которые подлежат уплате в государственный бюджет. Когда речь идет об осуществлении рекламной деятельности, суд или иной уполномоченный государственный орган, такой как Федеральная антимонопольная служба (ФАС), может также потребовать опубликования опровергающих материалов, устранения/уничтожения незаконной рекламы или применения иных мер ответственности.

В дополнение к вышесказанному, планируется подкрепить ограничения, установленные Основами, посредством установления мер административной ответственности за их нарушение, применимых в равной степени к вовлеченным компаниям и работникам здравоохранения. До настоящего момента этого не сделано, однако известно, что проект соответствующих поправок в Кодекс об административных правонарушениях.

Наконец, в отношении приведенного ниже анализа антикоррупционного аспекта деятельности по продвижению необходимо заметить, что российское законодательство устанавливает административную ответственность применительно к юридическим лицам, вовлеченным в коррупционную деятельность (российский уголовный закон не содержит концепции уголовной ответственности юридического лица).

Уголовная ответственность

Существует теоретическая вероятность того, что получение материальных выгод работником здравоохранения может преследоваться в уголовном порядке в соответствии с положениями статей 204, 291 и 291.1 Уголовного кодекса Российской Федерации (далее – «УК РФ»). В этих статьях рассматриваются различные формы подкупа, т.е. передача денег, иного имущества, а равно оказание услуг лицу с целью получения от него определенных выгод либо с целью

Under certain circumstances (e.g., active assistance in a criminal investigation or voluntary disclosure of information to the relevant body empowered to initiate criminal proceedings with respect to the crime of commercial bribery) a bribe-giver is relieved from criminal liability.

- Article 291 (Bribery)

Liability for this violation can involve a fine varying from 15 to 30 times the amount of the bribe, or compulsory labor for a term of up to three years, or imprisonment for up to two years accompanied by a fine 10 times as much as the sum of the bribe.

If the bribe was substantial (i.e., in excess of RUB25,000, which as of June 2012 is approximately USD764), the crime shall be punishable with a fine varying from 20 to 40 times the amount of the bribe or with imprisonment for up to three years accompanied by a fine 15 times the amount of the bribe.

If the bribe was given for knowingly conducting illegal actions or omissions, the crime shall be punishable with a fine varying from 30 to 60 times the amount of the bribe or with imprisonment for a term of up to eight years accompanied by a fine of 30 times the amount of the bribe.

If the crime was committed by a group of persons in conspiracy, by an organized group, or the bribe qualified as large (i.e., in excess of RUB150,000, which as of June 2012 is approximately USD4,587), it is punishable with a fine varying from 60 to 80 times the amount of the bribe with disqualification from holding specific offices or engaging in specified activities for a term of up to three years or with imprisonment for a term of five to 10 years accompanied by a fine of 60 times the amount of the bribe.

If the bribe was classed as being extremely large (i.e., in excess of RUB1,000,000, which as of June 2012 is approximately USD30,580), it shall be punishable with a fine varying from 70 to 90 times the amount of the bribe or with imprisonment for a term from seven to 12 years accompanied by a fine of 70 times the amount of the bribe.

We reiterate that under certain circumstances (e.g., active assistance in a criminal investigation or voluntary disclosure of information to the relevant body empowered to initiate criminal proceedings with respect to the crime of bribery), a bribe-giver is relieved from criminal liability.

Article 291.1 of the Criminal Code also now establishes liability for mediation in bribery.

побуждения такого лица к совершению действий в интересах дающего, а также способствование взяткодателю и (или) взяткополучателю в достижении незаконного результата. Необходимо отметить, что статья 204 также устанавливает ответственность за получение подкупа, а статья 290 предусматривает ответственность должностного лица за получение взятки. Детально рассмотрена будет, однако, только ответственность, возникающая в отношении лица, совершившего коммерческий подкуп в нарушение статьи 204 УК РФ и лица, давшего взятку в нарушение статьи 291 УК РФ.

Уголовная ответственность согласно положениям статей 204 и 291 УК РФ возникает только в том случае, если получатель материальных выгод является лицом, занимающим управленческую должность в соответствующем медицинском учреждении (статья 204), либо должностным лицом (статья 291), хотя во втором случае ответственность может возникнуть даже если должностное лицо является косвенным получателем (т.е. деньги вручаются третьему лицу для последующей их передачи должностному лицу). Следовательно, предоставление материальных выгод работникам, которые не являются должностными лицами и не занимают руководящих должностей в соответствующем учреждении, не может служить основанием для возникновения уголовной ответственности в соответствии с положениями указанных статей.

Безвозмездные выгоды могут быть квалифицированы как взятка только в том случае, если будет доказано наличие соответствующих намерений со стороны дающего (как указано выше). Конечно, можно всегда попытаться доказать, что фармацевтическая компания не стала бы предоставлять кому-то какие-то материальные выгоды, если бы это не было в ее коммерческих интересах; но даже несмотря на это, будет очень трудно квалифицировать общую цель – например, ознакомление медицинского работника с продукцией - как достаточное основание для возникновения уголовной ответственности.

В российском праве на данный момент не существует концепции корпоративной уголовной ответственности, поэтому к уголовной ответственности могут привлекаться только физические лица. Согласно положениям указанных статей УК РФ, уголовная ответственность в отношении физических лиц предусматривается в следующих случаях:

Professional Codes of Conduct

In 1994 a group of multi-national research-based pharmaceutical manufacturers doing business in Russia formed the Association of International Pharmaceutical Manufacturers ("AIPM"). AIPM member companies currently represent approximately 80 percent of world production and sales of pharmaceuticals. AIPM has adopted its own Code of Marketing Practices ("Code"), with which all AIPM member companies agree to comply.

The AIPM Code was revised during the second half of 2006 and subsequently in 2009 when the current version was adopted. Due to the recent changes in the pharmaceuticals and healthcare regulations, and in order to comply with these changes, the AIPM is now working on a new version of the Code. It is understood that the amendments are of such an extent that this is essentially a new document, governing good practices in general and not just marketing practices.

The international medical devices industry also has a local association - the International Medical Device Manufacturers Association ("IMEDA"). IMEDA adopted its Ethical Code for Medical Devices Manufacturers ("IMEDA Code") in 2008. The members of IMEDA have voluntarily undertaken to follow the IMEDA Code, which does not apply to medical device companies that are not IMEDA members. Currently, the IMEDA Code is also undergoing revision in order to reflect the recent changes in the legislation governing the healthcare sector.

Contracts with Healthcare Professionals and Medical Institutions

The procedure for entering into agreements with Healthcare Professionals and institutions, and the rules relating to such agreements, are subject to the general rules established by the Russian contract law and the restrictions imposed by the Fundamentals.

Both Medical and Pharmaceutical Professionals are prohibited from receiving money from pharmaceutical and medical device companies and their representatives. As mentioned above, relating to Medical Professionals, the Fundamentals contain an important exception from this general prohibition. Medical Professionals may receive remuneration under agreements in the course of conducting clinical trials of medicinal preparations or clinical

Статья 204 (Коммерческий подкуп)

Предусмотренные данной статьей деяния наказываются штрафом в размере от 10-кратной до 50-кратной суммы коммерческого подкупа с лишением права занимать определенные должности или заниматься определенной деятельностью на срок до двух лет, либо ограничением свободы на срок до двух лет, либо принудительными работами на срок до трех лет, либо лишением свободы на тот же срок.

Те же деяния, совершенные группой лиц по предварительному сговору, организованной группой или за заведомо незаконные действия (бездействие), наказываются штрафом в размере от сорокакратной до семидесятикратной суммы коммерческого подкупа с лишением права занимать определенные должности или заниматься определенной деятельностью на срок до трех лет, либо принудительными работами на срок до четырех лет, либо арестом на срок от трех до шести месяцев, либо лишением свободы на срок до шести лет.

Лицо, давшее взятку, при определенных обстоятельствах освобождается от уголовной ответственности (например, если оно активно способствовало расследованию преступления или добровольно сообщило о даче взятки органу, имеющему право возбудить уголовное дело).

Статья 291 (Дача взятки)

Предусмотренные данной статьей деяния наказываются штрафом в размере от пятнадцатикратной до тридцатикратной суммы взятки, либо принудительными работами на срок до трех лет, либо лишением свободы на срок до двух лет со штрафом в размере десятикратной суммы взятки.

Дача взятки в значительном размере (т.е. свыше 25 тысяч рублей, что по состоянию на июнь 2012 года составляет примерно 764 доллара США) наказывается штрафом в размере от двадцатикратной до сорокакратной суммы взятки либо лишением свободы на срок до трех лет со штрафом в размере пятнадцатикратной суммы взятки.

Дача взятки за совершение заведомо незаконных действий (бездействие) наказывается штрафом в размере от тридцатикратной до шестидесятикратной суммы взятки либо лишением свободы на срок до восьми лет со штрафом в размере тридцатикратной суммы взятки.

studies of medical devices, or in relation with their performance of teaching and/or scientific activities.

As a result, Medical Professionals who are duly engaged by pharmaceutical and medical device companies within clinical trials or for teaching and/or scientific activities may not only be paid a fair market compensation for their activities but may be entitled under the relevant agreement to reasonable compensation of their travel and living expenses incurred in connection with the performed activities.

The Fundamentals do not establish any specific definitions of either teaching or scientific activity; therefore, some guidance may be obtained from regulations governing education and science, respectively.

The meaning of the term "teaching activity" used by the Fundamentals is not defined even in the Russian legislation governing education. Therefore, a common sense approach to its understanding should be taken and an activity whereby knowledge is transferred from one person to another or others (e.g., by lectures, practical exercises) should qualify as such. In the context of Medical Professionals, this usually means transfer of a professional's medical knowledge and practical experience.

The situation with scientific activity is not much clearer, even though Federal Law No. 127-FZ "On Science and Scientific-Technical Policy" dated 23 August 1996 (as amended), defines scientific (scientific-research) activity as activity aimed at deriving and use of new knowledge, and includes the following:

- Fundamental scientific research - experimental or theoretical activity aimed at deriving new skills on general morphology, the understanding and development of humanity, society and the environment
- Applied scientific research - research mainly aimed at implementation of new knowledge for the achievement of practical objectives and solution of specific tasks

Thus, the basic definition of scientific (scientific-research) activity is extremely wide and relies on new knowledge. At the same time, our recommendation in this respect is again to use common sense judgment as to what qualifies as scientific. As an example, performance of a feasibility study for a clinical trial, performance of a pharmacoeconomic study of a medicinal preparation, participation in observational studies of a medicinal preparation,

Деяния, совершенные группой лиц по предварительному сговору, организованной группой или в крупном размере (т.е. свыше 150 тысяч рублей, что по состоянию на июнь 2012 года составляет примерно 4 587 долларов США), наказываются штрафом в размере от шестидесятикратной до восьмидесятикратной суммы взятки с лишением права занимать определенные должности или заниматься определенной деятельностью на срок до трех лет либо лишением свободы на срок от пяти до десяти лет со штрафом в размере шестидесятикратной суммы взятки.

Дача взятки в особо крупном размере (т.е. свыше 1 миллиона рублей, что по состоянию на июнь 2012 года составляет примерно 30 580 долларов США) наказывается штрафом в размере от семидесятикратной до девяностократной суммы взятки либо лишением свободы на срок от семи до двенадцати лет со штрафом в размере семидесятикратной суммы взятки.

Необходимо отметить, что лицо, давшее взятку, при определенных обстоятельствах освобождается от уголовной ответственности (например, если оно активно способствовало расследованию преступления или добровольно сообщило о даче взятки органу, имеющему право возбудить уголовное дело).

Статья 291.1 УК РФ также устанавливает ответственность за посредничество во взяточничестве.

Профессиональные кодексы поведения

В 1994 году группа транснациональных научно-производственных фармацевтических компаний, осуществляющих деятельность в России, создала Ассоциацию международных фармацевтических производителей (AIPM). В настоящее время на долю компаний-членов AIPM приходится 80 процентов мирового производства и реализации лекарственных препаратов. AIPM приняла свой собственный Кодекс маркетинговой практики (далее по тексту – «Кодекс»), положения которого все компании-члены AIPM обязались соблюдать.

Кодекс был пересмотрен во второй половине 2006 года, а затем и в 2009 году, когда была принята его действующая редакция. В связи с недавними изменениями в регулировании здравоохранения и фармацевтики и необходимостью соблюдения нового законодательства, AIPM активно занимается разработкой новой версии Кодекса.

and round table discussions with peers to discuss treatment problems resulting in a set of methodological recommendations should qualify as scientific activities.

No exceptions of this sort are established in relation to Pharmaceutical Professionals, and hence in accordance with the general prohibition set out in the Fundamentals, they may not receive money under any type of agreement with pharmaceutical and medical device companies.

Again, the restrictions imposed on Medical and Pharmaceutical Professionals do not extend to medical and pharmaceutical institutions.

We note that the contracting with Medical Professionals allowed by the Fundamentals is likely to be further restricted if the Medical Professionals involved simultaneously have the status of a state or municipal servant.

Under Federal Law No. 58-FZ on the System of State Service in the Russian Federation dated 27 May 2003 as amended (the "Law on State Service"), the Russian system of state service comprise state civil service (*gosudarstvennaya grazhdanskaya sluzhba*), military service (*voennaya sluzhba*), and law enforcement service (*pravookhranitelnaya sluzhba*). Military service and law enforcement service exist only at the level of federal state service, whereas state civil service may be both federal and regional.

A person is considered to be a state servant if he or she meets the following criteria:

- occupies a position in the federal or regional registers of state servants maintained by federal or regional state authorities, respectively;
- and receives his or her salary from the state budget (federal or regional).

The state civil service is specifically regulated by Federal Law No. 79-FZ on Civil State Service in the Russian Federation dated 27 July 2004 as amended ("Civil Service Law").

Under the Civil Service Law, state civil servants may not do any of the following:

- Conduct any entrepreneurial activity.
- Receive any remuneration in the form of monetary compensation, gifts, loans, services, payment for entertainment, vacations, transportation expenses or other such remuneration related to the fulfillment of their duties as state civil servants from legal entities or individuals.

Предполагается, что изменения будут настолько существенными, что могут быть приравненными к новому документу, устанавливающему надлежащие практикики в целом, а не исключительно практики маркетинга.

Продвижение медицинских изделий в России регулируется Этическим Кодексом компаний-производителей медицинских изделий, утвержденным Ассоциацией Международных производителей медицинской аппаратуры IMEDA (далее – «Кодекс IMEDA») в 2008 году. Члены IMEDA добровольно согласились следовать Кодексу IMEDA, который не применяется к компаниям-производителям медицинских изделий, не являющимся членами IMEDA. Кодекс IMEDA разделен на шесть частей, регулирующих, главным образом, различные виды взаимодействия членов IMEDA с медицинскими работниками и устанавливающих процедуру реагирования на несоблюдение Кодекса IMEDA. В настоящее время Кодекс IMEDA также находится в стадии пересмотра для отражения всех изменений в законодательстве, регулирующем отрасль здравоохранения.

Заключение договоров с работниками здравоохранения и медицинскими учреждениями

Порядок заключения договоров с работниками здравоохранения и медицинскими учреждениями, а также относящиеся к таким договорам правила регулируются общими положениями российского договорного права, а равно положениями Основ.

Медицинским и фармацевтическим работникам запрещено получать денежные средства от фармацевтических компаний и компаний, занимающихся медицинскими изделиями, и их представителей. Как указано выше, в отношении медицинских работников Основы содержат важное исключение из данного общего запрета. Медицинские работники могут получать вознаграждение по договорам при проведении клинических исследований лекарственных препаратов или клинических испытаний медицинских изделий, а равно по договорам, связанным с осуществлением медицинскими работниками педагогической или научной деятельности.

В результате медицинские работники, надлежащим образом привлеченные фармацевтическими компаниями и компаниями, занимающимися медицинскими изделиями, при проведении клинических исследований или осуществления педагогической и (или)

- Leave the state territory of the Russian Federation in connection with the fulfillment of their duties at the expense of legal entities or individuals, save for trips in connection with their duties made pursuant to the legislation of the Russian Federation or on a mutual basis by an agreement between Russian state bodies or the state bodies of the subjects of the Russian Federation or municipal bodies of the Russian Federation and foreign state or municipal bodies (or international or foreign organizations)
- Use state property or facilities other than in connection with the fulfillment of their duties as state civil servants or transfer such property to third parties
- Disclose or use for purposes not connected with state civil service any confidential or other privileged information which became known to the state civil servant in connection with fulfillment of his or her professional duties
- Use the official powers of the state civil servant for the benefit of a political party, any other social or religious organization or other organization and publicly express an opinion regarding such organizations in the capacity of a state civil servant, unless this constitutes a part of his/her official duties.
- Create a conflict of interest, i.e., a situation when the vested personal interest of a state civil servant influences or may influence the impersonal fulfillment of his or her official duties and may lead to the conflict of the personal interests of a state civil servant with the lawful public interests of the citizens, companies or society of the Russian Federation and the Russian Federation and its subjects

Under Federal Law No. 25-FZ on Municipal Service in the Russian Federation dated 2 March 2007 as amended ("Municipal Service Law"), a municipal servant is a Russian citizen who is at least 18 years old and permanently discharges the duties of a municipal office, other than electoral, for a monetary compensation from the municipal budget.

Pursuant to the Municipal Service Law, a municipal office is a position within the municipal body or electoral commission of the municipal body provided for in the municipality's charter and vested with particular duties to exercise and procure the exercise of authority of the municipal body, electoral commission of the municipal body or persons holding municipal office. Municipal offices are established by municipal normative acts in accordance with the register of municipal service positions within the subject of the Russian Federation approved by a law of the subject of the Russian Federation.

научной деятельности, могут не только иметь право на справедливую рыночную оплату своей деятельности, но также, по соответствующему договору, получать разумное возмещение своих затрат на проезд и проживание, понесенных в связи с оказанными услугами.

Необходимо отметить, что Основы не содержат конкретных определений педагогической или научной деятельности, поэтому некоторые разъяснения можно найти в положениях, регулирующих образование и науку, соответственно.

Значение термина «педагогическая деятельность», используемого Основами, не раскрыто даже в российском законодательстве, регулирующем образование. Поэтому, на наш взгляд, под педагогической деятельностью, полагаясь на здравый смысл, необходимо понимать деятельность, посредством которой знание передается от одного лица к другому лицу или другим лицам (например, через лекции, практические задания). В контексте медицинских работников это обычно значит передачу профессионального медицинского знания и практического опыта.

Вопрос о научной деятельности не кажется более простым даже несмотря на то, что Федеральный закон «О науке и научно-технической политике» №127-ФЗ от 23 августа 1996 года (с изменениями и дополнениями), определяет научную (научно-исследовательскую) деятельность как деятельность, направленную на получение и применение новых знаний, и включает следующее:

- фундаментальные научные исследования - экспериментальная или теоретическая деятельность, направленная на получение новых знаний об основных закономерностях строения, функционирования и развития человека, общества, окружающей среды; и
- прикладные научные исследования - исследования, направленные преимущественно на применение новых знаний для достижения практических целей и решения конкретных задач.

Таким образом, основное определение научной (научно-исследовательской) деятельности является очень широким и опирается на новизну знания. В то же время мы рекомендуем, при оценке вопроса, что является научной деятельностью, снова полагаться на здравый смысл. Например, проведение исследования на предмет

Under the Municipal Service Law, municipal servants may not do any of the following:

- Conduct entrepreneurial activity.
- Use municipal property or facilities other than in connection with fulfillment of the professional duties of a municipal servant.
- Receive from individuals or legal entities remuneration in the form of monetary compensation, gifts, loans, services, payment for entertainment, vacations, transportation expenses or other if such remuneration is related to the fulfillment of their duties as municipal servants.
- Go on business trips at the expense of individuals and legal entities, other than business trips made on a reciprocal basis and on the basis of an agreement of municipalities or electoral municipal commissions with other municipal authorities or electoral municipal commissions as well as with municipal authorities of foreign countries or international and foreign non-commercial organizations.

Federal Law No. 76-FZ on Military Service dated 27 May 1998 as amended ("Military Service Law") contains a list of activities prohibited for those military servants. The relevant part of this list is almost identical to the list of prohibited activities for municipal servants. Although at the moment there is no separate law governing the status of law enforcement officers, an approach similar to that for those serving in the military is recommended.

Restrictions placed on state and municipal servants effectively prohibit pharmaceutical companies from entering into, and making payments under, almost any type of contract with them aimed at promotion of medical products.

Additionally, Russian law distinguishes, as a category which is separate from state and municipal servants, officials whose offices are established by the Russian Constitution, constitutions and charters of the subjects of the Russian Federation, federal and regional laws for direct exercise of federal and regional powers ("Supreme Officers"), e.g., the Russian President and the Ministers of the Russian Government. These offices are not regulated by the Law on State Service, but rather by separate laws and/or regulations. For example, the office of the Minister of Health is governed by Federal Constitutional Law No. 2-FKZ on the Government of the Russian Federation dated 17 December 1997 as amended. Similar restrictions apply to Supreme Offices as to state and municipal servants.

целесообразности осуществления клинического исследования, проведение фармакоэкономического исследования лекарственного препарата, участие в наблюдательном исследовании лекарственного препарата, дискуссия в формате круглого стола с учеными для обсуждения проблем лечения с выработкой методологических рекомендаций должны являться научной деятельностью.

Для фармацевтических работников не установлено исключений такого плана, поэтому, в соответствии с общим запретом, установленным в Основах, они не могут получать какие-либо платежи.

Данный запрет, опять же, не относится к случаям взаимодействия с медицинскими или фармацевтическими организациями.

Необходимо отметить, что возможность заключения договоров, разрешенных Основами, с медицинскими работниками будет несколько ограничена в том случае, если привлеченный медицинский работник является государственным или муниципальным служащим.

В соответствии с пунктом 1 статьи 2 Федерального закона от 27 мая 2003 года № 58-ФЗ «О системе государственной службы в Российской Федерации» с изменениями и дополнениями (далее – «Закон о системе государственной службы») система государственной службы России состоит из государственной гражданской службы, военной службы и правоохранительной службы. Военная служба и правоохранительная служба существуют лишь на уровне федеральной государственной службы, в то время, как государственная гражданская служба может быть как федеральной, так и региональной.

Физическое лицо считается государственным служащим, если он или она удовлетворяет следующим критериям: (1) занимает должность, внесенную в федеральный или региональный реестр государственных служащих, ведущийся федеральной или региональной государственной властью, соответственно, и (2) получает вознаграждение за счет государственного бюджета (федерального или регионального).

Государственная гражданская служба специальным образом регулируется Федеральным законом от 27 июля 2004 года № 79-ФЗ «О государственной гражданской службе в Российской Федерации» (далее – «Закон о гражданской службе»).

Recommendations

In order to ensure compliance with Russian legislation governing promotion of medical products, we recommend to:

- implement transparent internal policies on interactions with healthcare professionals, promotion and compliance matters;
- appoint leaders responsible for monitoring compliance with the applicable rules;
- refrain from giving any gifts, monetary payments or charitable donations, regardless of their value and purpose, to individual healthcare professionals;
- analyze carefully every agreement which is intended to be concluded with a medical professional from the perspective of its compliance with the restrictions set out in the Fundamentals and applicable legislation governing the status of state and municipal servants and Supreme Officers; and
- organize training programs for employees in order to develop professional awareness and ensure law-abiding conduct while interacting with healthcare professionals.

Пункт 1 статьи 17 Закона о гражданской службе запрещает государственным гражданским служащим, среди прочего, все нижеследующее:

(i) осуществлять предпринимательскую деятельность;
(ii) получать в связи с исполнением должностных обязанностей вознаграждения от физических и юридических лиц (подарки, денежное вознаграждение, ссуды, услуги, оплату развлечений, отдыха, транспортных расходов и иные вознаграждения);
(iii) выезжать в связи с исполнением должностных обязанностей за пределы территории Российской Федерации за счет средств физических и юридических лиц, за исключением служебных командировок, осуществляемых в соответствии с законодательством Российской Федерации, по договоренности государственных органов Российской Федерации, государственных органов субъектов Российской Федерации или муниципальных органов с государственными или муниципальными органами иностранных государств, международными или иностранными организациями;
(iv) использовать в целях, не связанных с исполнением должностных обязанностей, средства материально-технического и иного обеспечения, другое государственное имущество, а также передавать их другим лицам;
(v) разглашать или использовать в целях, не связанных с гражданской службой, сведения, отнесенные в соответствии с федеральным законом к сведениям конфиденциального характера, или служебную информацию, ставшие ему известными в связи с исполнением должностных обязанностей;
(vi) использовать должностные полномочия в интересах политических партий, других общественных объединений, религиозных объединений и иных организаций, а также публично выражать отношение к указанным объединениям и организациям в качестве гражданского служащего, если это не входит в его должностные обязанности;
(vii) создавать конфликт интересов, т.е. ситуацию, когда личная заинтересованность гражданского служащего влияет или может повлиять на объективное исполнение им/ей должностных обязанностей и при которой возникает или может возникнуть противоречие между личной заинтересованностью гражданского служащего и законными интересами граждан, организаций, общества, субъекта Российской Федерации или Российской Федерации.

В соответствии с пунктом 1 статьи 10 Федерального закона от 2 марта 2007 года № 25-ФЗ «О муниципальной службе в Российской Федерации» с изменениями и дополнениями (далее – «Закон о муниципальной службе»), муниципальным служащим является гражданин Российской Федерации, достигший возраста 18 лет, исполняющий обязанности по должности муниципальной службы, кроме выборных, за денежное содержание, выплачиваемое за счет средств местного бюджета. Пункт 1 статьи 6 Закона о муниципальной службе указывает, что муниципальная должность – это должность в органе местного самоуправления, аппарате избирательной комиссии муниципального образования, которые образуются в соответствии с уставом муниципального образования, с установленным кругом обязанностей по обеспечению исполнения полномочий органа местного самоуправления, избирательной комиссии муниципального образования или лица, замещающего муниципальную должность. Должности муниципальной службы устанавливаются муниципальными правовыми актами в соответствии с реестром должностей муниципальной службы в субъекте Российской Федерации, утверждаемым законом субъекта Российской Федерации.

Пункт 1 статьи 14 Закона о муниципальной службе запрещает муниципальным служащим, среди прочего, все нижеследующее:

(viii) заниматься предпринимательской деятельностью;
(ix) использовать в целях, не связанных с исполнением должностных обязанностей, средства материально-технического, финансового и иного обеспечения, другое муниципальное имущество;
(x) получать в связи с должностным положением или в связи с исполнением должностных обязанностей вознаграждения от физических и юридических лиц (подарки, денежное вознаграждение, ссуды, услуги, оплату развлечений, отдыха, транспортных расходов и иные вознаграждения);
(xi) выезжать в командировки за счет средств физических и юридических лиц, за исключением командировок, осуществляемых на взаимной основе по договоренности органа местного самоуправления, избирательной комиссии муниципального образования с органами местного самоуправления, избирательными комиссиями других муниципальных образований, а также с органами государственной власти и органами местного самоуправления иностранных государств, международными и иностранными некоммерческими организациями.

Пункт 7 статьи 10 Закона о военнослужащих также содержит список видов деятельности, запрещенных военнослужащим. Этот список в его соответствующей части практически идентичен списку видов деятельности, запрещенных муниципальным служащим. Несмотря на то что на настоящий момент не существует отдельного закона, определяющего статус правоохранительных служащих, рекомендуется использовать подход к их деятельности, сходный с подходом к деятельности военнослужащих.

Ограничения, установленные в отношении государственных и муниципальных служащих делают практически невозможным заключение фармацевтическими компаниями каких бы то ни было договоров с ними, а равно осуществление выплат по таким договорам, направленным на продвижение медицинской продукции.

Кроме того, российское право выделяет в качестве категории, отдельной от государственных и муниципальных служащих, служащих, чьи должности установлены Российской Конституцией, конституциями и уставами субъектов Российской Федерации, федеральными и региональными законами для непосредственного осуществления федеральной и региональной власти («Высшие должностные лица»), к примеру, Президент России и Министры Правительства России. Эти должности регулируются не Законом о системе государственной службы, но отдельными законами и/или нормативными актами. К примеру, должность Министра здравоохранения урегулирована Федеральным конституционным законом от 17 декабря 1997 года № 2-ФКЗ «О Правительстве Российской Федерации» с изменениями и дополнениями. К Высшим должностным лицам применяются ограничения, схожие с ограничениями, установленными в отношении государственных и муниципальных служащих.

Рекомендации

Для целей обеспечения соблюдения российского законодательства, регулирующего продвижение медицинской продукции, мы рекомендуем:

- Внедрить прозрачные внутренние политики по взаимодействию с работниками здравоохранения, вопросам продвижения и комплаенс;
- Назначить лиц, ответственных за соблюдение соответствующих правил;

- Воздерживаться от передачи каких-либо подарков, вне зависимости от их стоимости и цели дарения, конкретным работникам здравоохранения;
- Внимательно анализировать каждый отдельный договор, предлагаемый к заключению с медицинским работником, с точки зрения его соответствия ограничениям, установленным в Основах и применимом законодательстве, регулирующем статус государственных и муниципальных служащих, а также Высших должностных лиц;
- Организовывать программы тренинга для работников в целях повышения их профессиональной осведомленности и обеспечения законопослушного поведения при взаимодействии с работниками здравоохранения.

España

Montserrat Llopart, Ester Navas, Cecilia Pastor, Ariadna Casanueva

Introducción

En España, la regulación relativa a la publicidad está basada en la trasposición al ordenamiento jurídico de la legislación europea y en la incorporación a los códigos éticos sectoriales de los códigos de buenas prácticas europeos (EFPIA y EUCOMED). Sin embargo, es de destacar que tanto la legislación española como los códigos sectoriales son más detallados en materia de incentivos a profesionales sanitarios y estudios no clasificados como ensayos clínicos y los códigos sectoriales establecen mecanismos adicionales de notificación y control en materia de la hospitalidad, de contratos con profesionales sanitarios y de estudios de investigación de mercado.

Normativa aplicable

La Ley 29/2006 de 26 de julio, de garantías y uso racional de los medicamentos y productos sanitarios ("Ley 29/2006") establece el marco general de regulación de la promoción y publicidad de medicamentos y productos sanitarios en España.

La norma básica relativa a la publicidad de medicamentos es el Real Decreto 1416/1994, de 25 de junio, por el que se regula a nivel nacional la publicidad de los medicamentos de uso humano. Mediante la Circular núm. 6/98, la Dirección General de Farmacia y Productos Sanitarios, actualmente Agencia Española de Medicamentos y Productos Sanitarios, realizó una serie de aclaraciones al contenido de dicho Real Decreto 1416/1994.

El Real Decreto 1416/1994 incluye una definición muy amplia del concepto de publicidad de medicamentos, en el que se incluyen de manera general todo tipo de actividades de promoción y prospección comercial.

Por otra parte, las Comunidades Autónomas han ido adquiriendo competencias relativas a la sanidad, y entre ellas el control de determinados aspectos de la publicidad y promoción de los medicamentos de uso humano. En consecuencia, en función del ámbito de difusión de la publicidad o actividad promocional y/o del domicilio del laboratorio responsable de la

Spain

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Introduction

In Spain, regulations regarding the advertising of medical products for human use are based on the implementation of EU legislation into Spanish law as well as the European Federation of Pharmaceutical Industries and Associations code ("EFPIA Code") and Eucomed Code into the codes of ethics approved by the Spanish industry associations. However, it must be highlighted that both the Spanish law and the industry code of ethics are more detailed with regard to incentives to healthcare professionals and studies not classified as clinical trials, and that the industry codes of ethics establish additional control mechanisms regarding hospitality, contracts with healthcare professionals and market research studies.

Regulatory Framework

Law 29/2006, of 26 July 2006 on Guarantees and the Rational Use of Medicines and Medical Devices ("Law 29/2006") establishes the general framework to regulate the promotion and advestising of medicinal products and medical devices in Spain.

The basic legislation concerning advertising of medicines for human use is Royal Decree 1416/1994, of 25 June 1994, which regulates the advertising of medicines for human use. Through Circular 6/98, the General Directorate of Pharmacy and Medical Devices, today Medicines and Medical Devices Agency, clarified various points contained in Royal Decree 1416/1994.

Royal Decree 1416/1994 includes a broad definition of the concept of advertising of medicines, which includes generally all types of promotion and market research.

The autonomous communities have progressively been acquiring responsibilities in the health field, including certain aspects relating to the advertising and promotion of medicines for human use. Consequently, depending on the area in which the advertising or promotion takes place and/or the location of the corporate headquarters of the pharmaceutical company advertising or promoting its products, not only must Royal Decree

misma deberemos tener en cuenta, adicionalmente al Real Decreto 1416/1994 y la Ley 29/2006, la legislación complementaria e interpretativa del Real Decreto elaborada por la correspondiente Comunidad Autónoma. A título de ejemplo pasamos a enumerar la normativa propia de las Comunidades Autónomas de Cataluña y Madrid, por ser el lugar donde radican la mayor parte de los laboratorios y donde tienen su sede algunas de las publicaciones médicas de mayor difusión.

Cataluña: Guía para la publicidad de medicamentos de uso humano (3ª edición Octubre de 2009).

Madrid: Ley 19/98, de 25 de noviembre de 1998, de la Comunidad de Madrid. Orden núm. 1085/1998, de 25 de mayo de 1998, de la Consejería de Sanidad y Servicios Sociales que regula el reconocimiento de interés sanitario y/o social para actos de carácter científico. Circular de Farmacia núm. 1/2000 de la Dirección General de Sanidad de la Comunidad de Madrid relativa a normas generales de aplicación de algunos artículos del Real Decreto 1416/1994, de 25 de junio, respecto a la publicidad dirigida a las personas facultadas para prescribir o dispensar medicamentos. Circular 1/2002 de la Dirección General de Farmacia y Productos Sanitarios relativa a la ordenación de la visita médica y otras actividades de promoción de medicamentos en la red sanitaria única de utilización pública de la Comunidad de Madrid.

Por otra parte, las compañías farmacéuticas pertenecientes a Farmaindustria (Asociación Nacional Empresarial de la Industria Farmacéutica) se rigen por el Código Español de Buenas Prácticas par la Promoción de los Medicamentos y de Interrelación de la Industria Farmacéutica con los Profesionales Sanitarios ("Código de Farmaindustria")[1] basado en el Código de la EFPIA. Farmaindustria ha adoptado guías de desarrollo del Código de Farmaindustria y ha instaurado un procedimiento de consultas.

La normativa que regula la publicidad de productos sanitarios está regulada en los diferentes reales decretos que regulan este tipo de productos: Real Decreto 1591/2009 por el que se regulan los productos sanitarios, Real Decreto 1662/2000 por el que se regulan los productos sanitarios para diagnóstico in vitro, y el Real Decreto 1616/2009 por el que se regulan los productos sanitarios implantables activos.

[1] Versión vigente de fecha octubre 2010.

1416/1994 and Law 29/2006 be taken into account, but also the complementary and interpretative legislation developed in the corresponding autonomous community. By way of example, below is a list of the regulations of the autonomous communities of Catalonia and Madrid, since the majority of pharmaceutical companies and medical journals with the largest circulation are located there.

Catalonia: Guide for Advertising of Medicines for Human Use (Third Edition, October 2009).

Madrid: Law 19/98, of 25 November 1998 of the Autonomous Community of Madrid. Order No. 1085/1998, of 25 May 1998 of the Department of Public Health and Social Services, regulates the acknowledgement of public health and/or social interest of acts of a scientific nature; Pharmacy Circular No. 1/2000, of the General Directorate of Public Health of the Autonomous Community of Madrid, is regarding applicable general standards contained in certain articles of Royal Decree 1416/1994, of 25 June 1994, on advertising aimed at persons qualified to prescribe or supply medicines; and Pharmacy Circular 1/2002 of the General Directorate of Public Health, regards promotional visits to physicians and other promotional activities performed in the public healthcare centers of the Autonomous Community of Madrid.

On the other hand, the pharmaceutical companies belonging to Farmaindustria are governed by the Spanish Code of Good Practices for the Promotion of Medicines and Interaction with Healthcare Professionals ("Farmaindustria code"),[1] based on the EFPIA Code. Farmaindustria has also adopted guides for the development of the Farmaindustria Code of Good Practices and has set up a queries procedure.

The promotion of medical devices is regulated by several royal decrees: Royal Decree 1591/2009 on medical devices, Royal Decree 1662/2000 on in vitro diagnostics medical devices and Royal Decree 1616/2009 on active implantable medical devices.

Meanwhile the pharmaceutical companies belonging to Spanish Federation of Health Technology Companies ("Fenin") are governed by the Code of Good Practices ("Fenin Code"),[2] which is based on the Eucomed Code. Fenin has adopted an implementation guide for the Fenin Code.

[1] Version October 2010.
[2] Version December 2009.

Por otra parte, las compañías pertenecientes a Fenin (Federación Española de Empresas de Tecnología Sanitaria) se rige por el Código de Buenas Prácticas ("Código de Fenin")[2] basado en el Código de EUCOMED. Fenin ha adoptado una guía de aplicación del Código Fenin.

Prácticas permitidas y prohibidas

El Real Decreto 1416/1994 incluye, formando parte de las actividades publicitarias, todo tipo de actividades de promoción de medicamentos, tanto en soporte documental como no documental.

Es de destacar que no se puede iniciar la promoción de un medicamento o nueva indicación ni de un producto sanitario susceptible de financiación, hasta haber finalizado los trámites del procedimiento de financiación.

Además de la publicidad documental, encontramos dentro de las actividades de promoción la información técnica del medicamento a través de la visita médica, la distribución de muestras gratuitas, la regulación de los incentivos y del patrocinio de reuniones científicas. A continuación examinaremos cada una de las anteriores actividades.

Obsequios

La legislación española regula los incentivos a las personas facultadas para prescribir o dispensar medicamentos o productos sanitarios, prohibiendo expresamente otorgar, ofrecer o prometer a las personas facultadas para prescribir o dispensar medicamentos o productos sanitarios, y en el marco de la promoción de los mismos frente a dichas personas, incentivos, bonificaciones, descuentos, primas u obsequios, con excepción de aquellos que tengan un valor insignificante y que sean relevantes para la práctica de la medicina o la farmacia.

Es de destacar que la Ley 29/2006 ha especificado que se entenderán como incentivos prohibidos las bonificaciones y descuentos y ha exceptuado de la anterior prohibición los descuentos por pronto pago o por volumen de compras, que realicen los distribuidores a las oficinas de farmacia. En el supuesto de descuentos relativos amedicamentos financiados con cargo al Sistema Nacional de Salud, los descuentos están limitados al 10% y sujetos a

[2] Versión vigente de fecha diciembre 2009.

Permitted and Prohibited Practices

Royal Decree 1416/1994 includes advertising activities involving the promotion of medicines by written advertising and by other means.

No medical product may be advertised until it has received the relevant marketing authorization or customer engagement ("CE") marking. For medical products eligible for reimbursement, no promotion can start until the reimbursement procedure has ended.

In addition to written advertising, promotion includes technical information on medicines which is transmitted during visits to physicians, the distribution of free samples, the regulation of incentives, and the sponsorship of scientific meetings. These activities are examined further below.

Gifts

Spanish legislation regulates the incentives given to persons qualified to prescribe or supply medical products and expressly prohibits giving, offering, or promising to such persons, in the framework of promoting medical products, incentives, bonuses, discounts or gifts, except those of insignificant value, which are relevant to the practice of medicine or pharmacy.

Law 29/2006 specifically states that bonuses and discounts shall be considered prohibited incentives. The exceptions to this prohibition are discounts for early payment or volume of sales offered by distributors to pharmacies. In the case of discounts relating to medicines financed by the National Health Service, the discounts are limited to 10 percent and subject to the product not being promoted against its competitors. Discounts should be reflected in the relevant invoice.

The legislation does not include a list of the possible incentives or gifts to that may be given to healthcare professionals. Therefore, gifts traditionally given for Christmas or for other social events are also subject to the legislation if their purpose is the promotion of medical products.

Giving money is expressly prohibited under all circumstances, regardless of the amount. With respect to giving gifts, two criteria should be met: the value of the gift is insignificant; and the gift is relevant to the practice of medicine or pharmacy. Consequently, objects not intended for professional use by the receiver are excluded.

que no se incentive la compra de un producto frente al de sus competidores y queden reflejados en la correspondiente factura.

La legislación no incluye una enumeración de los tipos de incentivos u obsequios que pueden ser entregados a los profesionales sanitarios. En consecuencia, los obsequios que tradicionalmente se entregan con ocasión de las fiestas navideñas u otros eventos están sometidos al mismo régimen, si su objetivo es la promoción de medicamentos o productos sanitarios.

Se prohíben expresamente las entregas pecuniarias, en todo caso e independientemente de la cantidad. En cuanto a la entrega de obsequios, se incluyen dos criterios para su validez: que su valor sea insignificante, y ser relevantes para la práctica de la medicina o la farmacia. En consecuencia, están excluidos los objetos que no están destinados a un uso profesional por el receptor. Las autoridades no han señalado ningún importe de referencia para determinar que debe ser considerado como valor insignificante. Los Códigos sectoriales precisan que el valor máximo por regalo no debe superar: 10 Euros en el caso del Código de Farmaindustria y 30 Euros en el caso del Código de Fenin.

Asimismo, los códigos sectoriales establecen que las donaciones a instituciones sanitariassolo están permitidas si: (i) se realizan con el propósito de colaborar con la asistencia sanitaria, la investigación, la docencia/formación o la asistencia social o humanitaria; (ii) se formalizan documentalmente conservando la compañía copia de dichos documentos; y (iii) no constituyen un incentivo para la recomendación, prescripción, compra, suministro, venta o administración de medicamentos o productos sanitarios. Las donaciones que no cumplan los anteriores requisitos podrán ser consideradas como incentivos prohibidos.

Conviene recordar que los obsequios que incluyan publicidad de medicamentos, habrán de incluir las menciones exigidas legalmente para la publicidad documental, y que varían dependiendo de que se trate o no de publicidad de recuerdo. Si se trata de publicidad de recuerdo, únicamente podrán incluir la denominación del producto y el nombre y logotipo del laboratorio. Si no se trata de publicidad de recuerdo o se excede de las menciones permitidas para la publicidad de recuerdo, deberán incluir de forma legible y accesible todas las menciones obligatorias exigidas por el Real Decreto 1416/1994 para la publicidad documental.

Los laboratorios deberán incluir en el índice anual de actividades publicitarias que deben remitir a las autoridades sanitarias de su domicilio (antes de finalizar el primer trimestre del año siguiente en Cataluña y antes

The authorities have given no indication as to what constitutes an insignificant amount. The industry codes specify the value that a gift should not exceed: EUR10 in the Farmaindustria Code and EUR30 in the Fenin Code. However, objects such as medicine or pharmacy books, or materials in optical, magnetic, electronic or other similar format sponsored by the pharmaceutical company are also excluded.

In addition, the industry codes establish that donations to health institutions, are only permitted if:

- they are carried out in order to collaborate with healthcare, research, teaching/training or social or humanitarian care;
- they are formalized in writing, with the company retaining a copy of the evidencing documents; and
- they do not constitute an incentive for the recommendation, prescription, purchase, supply, sale or administration of medical products.

Any donations which do not meet the above requirements may be considered prohibited incentives.

It is important to remember that gifts including advertising events of medicines must contain the necessary language, which vary depending on whether or not it is a case of "reminder advertising". If it is reminder advertising, only the product name, and the pharmaceutical company's name and logo need to be included. If it is not reminder advertising, all the necessary content required by Royal Decree 1416/1994 for written advertising must be included in legible and accessible form.

Pharmaceutical companies must include in the annual index of advertising activities, to be submitted to the health authorities in the area where their registered office is located (in Catalonia, before the end of the first quarter of the following year, and in Madrid, before 1 March of the following year), all the advertising activities carried out, as well as a list of the incentives given to persons qualified to prescribe or supply medicines, indicating the amount and group of receivers by specialty.

The above requirements applicable to the promotion of medicines. If it is the general image of the pharmaceutical company which is being promoted (i.e., corporate advertising), without reference to specific medicines, the above limitations do not apply provided that there is no direct relation or association between the image of the pharmaceutical company and any specific

del 1 de marzo del año siguiente en Madrid), comprensivo de toda la actividad publicitaria realizada, una relación de los incentivos otorgados a personas facultadas para prescribir o dispensar medicamentos, con indicación de la cantidad y grupo de destinatarios, por especialidades.

Las anteriores limitaciones sobre menciones legales y obligación de información anual operan en el supuesto de actividades de promoción de medicamentos. Si se promociona la imagen general del laboratorio (publicidad corporativa), sin referencia a medicamentos concretos, las anteriores disposiciones no son de aplicación, sujeto a que no exista una relación directa o asociación entre la imagen que se promueve del laboratorio y medicamentos específicos. Sin embargo, la Circular núm. 6/95 de la Dirección General de Farmacia y Productos Sanitarios, actualmente Agencia Española de Medicamentos y Productos Sanitarios, indica que si se efectúa publicidad de un laboratorio en un soporte que tenga la condición de incentivo, este deberá tener un valor insignificante y estar relacionado con la práctica de la medicina o la farmacia. Este requisito excede las exigencias del Real Decreto 1416/1994, cuyo ámbito de aplicación se limita a la promoción y publicidad de medicamentos y no es de aplicación en los supuestos de promoción de la imagen general del laboratorio.

Patrocinio de reuniones científicas, congresos, cursos, premios o becas

La actividad publicitaria y promocional de medicamentos y productos sanitarios por parte de los laboratorios puede llevarse a cabo en el marco de reuniones científicas o congresos. Destacar que en el marco de congresos internacionales de importancia y nivel científicos reconocidos que se lleven a cabo en España y a los que asistan una representación significativa de profesionales de otros países, es posible la publicidad de medicamentos o indicaciones no autorizados en España pero que estén autorizados en otros países representados en el congreso. En estos casos, deberá indicarse claramente que el medicamento o la indicación no están autorizados en el estado español. Disposiciones similares se aplican en el caso de productos sanitarios que no hayan obtenido todavía el marcado CE.

El Código de Farmaindustria establece la obligación de los laboratorios de comunicar a la Unidad de Supervisión Deontológica (“USD”, órgano responsable de la vigilancia activa del cumplimiento del Código de Farmaindustria) las reuniones y eventos de carácter científico y promocional que organicen o patrocinen, con carácter previo a su celebración. Si cumplen las tres condiciones siguientes: (i) que estén organizados -directa o indirectamente- o patrocinados exclusiva o mayoritariamente por el laboratorio comunicante;(ii) que incluyan al menos una pernoctación

medicines. However, Circular No. 6/95 issued by the General Directorate of Pharmacy and Medical Devices (now Medicines and Medical Devices Agency) indicates that if pharmaceutical company advertising includes an offer or support which is an incentive, that benefit must have an insignificant value and related to the practice of medicine or pharmacy. This requirement goes beyond the provisions of Royal Decree 1416/1994, which treats exclusively the promotion and advertising of medicines and does not apply to the promotion of the general image of the pharmaceutical company.

Sponsorship of Scientific Meetings, Congresses, Courses, Prizes and Grants

Advertising and promotion of medical products by pharmaceutical companies may be carried out within the framework of scientific meetings or congresses. In the framework of international congresses of acknowledged prestige and importance held in Spain, attended in significant numbers by professionals of other countries, it is possible to promote medicines and indications not authorized in Spain but authorized in the countries represented in the congress. In these cases, the fact that the medicine or indication is not authorized in Spain must be clearly stated. Similar provisions apply regarding medical devices which have not yet obtained the CE marking.

The Farmaindustria Code establishes the obligation on the part of pharmaceutical companies to inform the Surveillance Unit of the Pharmaceutical Industry ("USD"), the body responsible for the active monitoring of compliance with the Farmaindustria Code, of any scientific and promotional meetings and events organized by them prior to their taking place. This obligation will only be applicable if the three following conditions are met: the event is organized – directly or indirectly - or sponsored exclusively or mainly by the notifying pharmaceutical company; they include at least one night accommodation (for attendees or speakers); and the participants include at least 20 healthcare professionals. Failure to inform – when it is compulsory – shall be considered a breach of the Farmaindustria Code, regardless of whether the meeting or event abides by the Farmaindustria Code or not.

It is also mandatory to inform USD of any events organized by third parties when the pharmaceutical company organizes the attendance of a group of more than 20 healthcare professionals who practice in Spain to a referred third-party event (e.g., scientific societies, professional organizations, etc.) at a national and international level. However, if USD previously validated the event, notice will not be required. Such sponsorship activities must be included in the annual index of advertising activities to be submitted to the

(asistentes o ponentes); y (iii) que cuenten con la participación de, al menos, 20 profesionales sanitarios. La falta de comunicación cuando sea obligatoria, será constitutiva de infracción del Código de Farmaindustria, con independencia de que la reunión o evento sea conforme o no al Código de Farmaindustria.

Son también de obligada comunicación a la USD los eventos organizados por terceros cuando la compañía farmacéutica organice la asistencia de un grupo de más de 20 profesionales sanitarios que ejercen su actividad en España al referido evento de tercero (sociedades científicas, organizaciones profesionales, etc.) tanto a nivel nacional como internacional. Sin embargo, si el evento ha sido validado previamente por la USD la comunicación no será obligatoria en este caso.

Las actividades de patrocinio deben incluirse en el índice anual de actividades publicitarias que todos los laboratorios deben remitir a las autoridades sanitarias, comprensivo de toda la actividad publicitaria realizada. Por otra parte, deberá quedar constancia en el laboratorio, a disposición de las autoridades competentes, de las cantidades aportadas a reuniones científicas, así como la relación de los profesionales sanitarios a loa que se ha ofrecido hospitalidad.

El concepto de patrocinio incluye la hospitalidad ofrecida, directa o indirectamente, en el marco de manifestaciones de carácter exclusivamente profesional y científico, a todo tipo de eventos (congresos, conferencias, simposios, jornadas, reuniones o cualquier otro tipo de actividad similar-reuniones de expertos, de investigadores o de formación), que sean organizados o patrocinados por una compañía farmacéutica o bajo su control, y a todos los participantes en los mismos, sean profesionales sanitarios o cualquier otra persona que, en el ejercicio de su profesión, pueda realizar o condicionar las actividades de prescribir, comprar, distribuir, dispensar o administrar un medicamento o producto sanitario. Las actividades patrocinadas deberán tener un carácter exclusivamente científico y profesional, y pueden ser organizadas por el propio laboratorio o por una entidad externa. El elemento esencial es el carácter exclusivamente científico y profesional del evento que da origen a la hospitalidad. En este sentido no está permitido organizar o colaborar en eventos que contengan elementos o actividades de entretenimiento o de carácter lúdico. El Código de Farmaindustria precisa que no se incluyen dentro de la anterior prohibición el cóctel de bienvenida, los almuerzos de trabajo y la cena de gala que aparecen habitualmente en los programas oficiales de los congresos y reuniones

health authorities. Pharmaceutical companies must also keep a record, to be made available to the competent authorities, of the amounts contributed to scientific meetings, as well as a list of the health professionals offered hospitality.

The definition of sponsorship includes hospitality offered, directly or indirectly, within the framework of exclusively professional and scientific events, as well as any kind of event (whether it be a congress, conference, symposium, seminar, meeting or any other similar activity, experts' meetings, researchers' meetings or training sessions) organized or sponsored by a pharmaceutical company or company under its control, and to all participants in the above, whether they are healthcare professionals or any other persons who, in the practice of their profession, may prescribe, purchase, distribute, dispense or administer medical products, or may have an impact on any of those activities.

Sponsored activities must be exclusively scientific and professional, and may be organized by the pharmaceutical company or by an external company. The essential element is the exclusively scientific and professional nature of the event, which gives rise to the hospitality. In this regard, it is not permitted to organize or collaborate in events containing entertainment or leisure activities. The Farmaindustria Code specifies that this prohibition does not include welcome cocktails, business lunches and gala dinners, which are customary in the official programs of scientific conferences and meetings, provided that they are reasonable and moderate and do not include additional elements (cultural, leisure and entertainment, etc.)

The term hospitality includes the actual travel and accommodation expenses and the registration fee paid by the pharmaceutical company. Hospitality must always be moderate and subordinate to the main purpose of the meeting. The receivers of such hospitality may only be health professionals.

The idea of moderation must be understood in the sense that travel and accommodation expenses be reasonable and not exaggerated, and that they be limited to the days scheduled period of the scientific meeting. The Farmaindustria Code used by the industry includes the criteria that the cost of hospitality should not exceed that which the receivers would normally be willing to pay in the same circumstances, without providing any figures. By way of example, four-star hotels are the appropriate standard for all kinds of events. It is permitted to use a five-star hotel provided that all the conditions are met: there are more than 200 healthcare professionals; it is a business

científicas, siempre que resulten razonables y moderadas y no incorporen elementos adicionales (culturales, de ocio o entretenimiento, etc.).

El concepto de hospitalidad incluye los gastos reales de desplazamiento, inscripción y estancia abonados por el laboratorio. La hospitalidad deberá ser siempre moderada en su nivel y subordinada al objetivo principal de la reunión. Los beneficiarios de la hospitalidad están limitados a los profesionales sanitarios.

El concepto de moderado en su nivel ha de entenderse en el sentido de que los gastos de desplazamiento y estancia sean mesurados y no exagerados, y que se ajusten a los días en que está prevista la reunión científica. El criterio adoptado por la industria en su Código de Farmaindustria es que su coste no exceda de aquel que los destinatarios estarían normalmente dispuestos a pagar en las mismas. A modo de ejemplo, los hoteles de 4* son el estándar adecuado para todo tipo de eventos. Es admisible el uso de un hotel de 5* únicamente cuando se cumplan la totalidad de las siguientes condiciones: (i) los profesionales sanitarios excedan de 200; (ii) hotel de negocios en casco urbano consolidado y no ostentoso; (iii) sea la sede del evento (o en el caso de eventos organizados por terceros, no hubiera disponibilidad de habitaciones en la sede del evento), y; adicionalmente (iv) previa autorización de la USD en el caso de eventos patrocinados mayoritariamente u organizados por el Laboratorio.

Sin embargo, nunca está justificado el patrocinio u organización de eventos que se lleven a cabo en los siguientes tipos de hoteles: 5* superior, 5* lujo, 5* gran lujo, resort deportivo, parque temático, hoteles bodega, y categorías similares. Asimismo, el Código de Farmaindustria limita la posibilidad de organizar o patrocinar eventos fuera de España, a menos que (i) la mayor parte de los participantes invitados procedan del extranjero; o (ii) esté localizado en el extranjero un recurso o *expertise* relevante y que es el objeto principal del evento (en este último caso deberá contar con la previa autorización de la USD). El Código Fenin incluye disposiciones similares.

El concepto de subordinado expresa la dependencia que debe existir entre el objetivo principal de la reunión y la función que ejerce el profesional al que se ofrece la hospitalidad. Asimismo, la hospitalidad deberá limitarse a los actos propios de la reunión científica, por lo que no debe extenderse a actividades de ocio. Los actos de hospitalidad que no se sometan a lo establecido legalmente se considerarán ventajas en especie, prohibidas expresamente por la legislación. La normativa española no establece límite

hotel within city limits and it is not ostentatious; it is the venue for the event (or for events organized by third parties, if there is no room availability in the seat of the event); and prior authorization is obtained from the USD for events mainly sponsored or organized by the pharmaceutical company. However, it can never be justified to sponsor or organize events taking place in the following types of hotels: five-star superior, five-star lujo, five-star gran lujo (various types of five-star luxury hotels in Spain), sports resorts, theme parks, wine-hotels and other similar categories.

In addition, the Farmaindustria Code limits the possibility of organizing or sponsoring events outside Spain, unless most of the guest participants are from other countries; or a relevant resource or certain expertise, which is the main purpose of the event, is located in another country (in this case, it must have the prior authorization of the USD). The Fenin Code includes similar provisions.

The concept of being subordinate expresses the fact that there must be a relationship between the main purpose of the meeting and the job, which the professional who is being offered hospitality performs. Likewise, hospitality must be limited to the acts directly related to the scientific meeting and must not be extended to leisure activities and entertainment. Acts of hospitality in violation of legal provisions shall be considered advantages in kind, which are expressly forbidden by law. Spanish regulations do not limit to the amount a pharmaceutical company may contribute to scientific meetings.

The Farmaindustria Code establishes that where a pharmaceutical company sponsors a meeting, congress, symposium or similar act, the sponsorship will be mentioned in all documentation relating to said event as well as in any work, speech or document published relating to the event. It also establishes that reasonable fees and expenses, including travel expenses, may be paid to those participating as speakers or moderators at said scientific meetings.

No monetary compensation may be offered merely to compensate for the time used by healthcare professionals to attend the event.

Moreover, Spanish pharmaceutical companies shall ensure compliance with the above provisions by their parent company, subsidiaries and other related companies if the promotional activities are directed at health professionals performing their services in Spain, whether invited to foreign countries or to events in Spain.

alguno sobre la cantidad que el laboratorio puede aportar a las reuniones científicas.

El Código de Farmaindustria establece que cuando las reuniones, congresos, simposios y actos similares estén patrocinados por compañías farmacéuticas, se hará constar dicho patrocinio en todos los documentos relativos a la reunión y también en cualquier trabajo, ponencia o documento que se publique en relación a los mismos. Además, también establece que es aceptable el pago de honorarios razonables y el reembolso de gastos personales, incluyendo el viaje, a los moderadores y ponentes de estas reuniones, congresos, simposios y actos similares de carácter profesional o científico. En ningún caso se podrá ofrecer dinero para compensar meramente el tiempo empleado por los profesionales sanitarios para asistir al evento.

Además, las compañías farmacéuticas establecidas en España y pertenecientes a grupos empresariales con centrales o afiliadas o, en general, con empresas vinculadas ubicadas en el extranjero, serán responsables del cumplimiento del Código de Farmaindustria por parte de estas empresas vinculadas, en lo que se refiere a actividades de promoción a profesionales sanitarios que ejercen su actividad en España, ya sean invitados al extranjero o a eventos que se desarrollen en territorio nacional.

Por tratarse de una competencia de ejecución de la legislación de productos farmacéuticos, corresponde a las Comunidades Autónomas la realización de la función inspectora en materia de premios, becas, contribuciones y subvenciones a congresos, viajes de estudio y actos similares.

La Comunidad Autónoma de Madrid ha regulado la obtención de un certificado que reconoce el interés sanitario y/o social de actos de carácter científico que se lleven a cabo en la Comunidad de Madrid. Los beneficiarios podrán señalar que disponen del certificado en el material publicitario y en la documentación relativa a la actividad reconocida. Por otra parte, la gerencia de los centros públicos deberá autorizar la asistencia a los actos de formación organizados o patrocinados por la industria.

En la Comunidad Autónoma de Cataluña, puede solicitarse al Consejo Catalán de Formación Médica Continuada la obtención de su sello de calidad para actividades científicas patrocinadas. Por otra parte la Guía incluye la obligación de comunicar previamente las actividades de patrocinio a realizar, excediendo en nuestra opinión las obligaciones impuestas por el Real Decreto 1416/1994.

Inspection of prizes, grants, and contributions and subsidies to congresses, travel grants, and similar items is an executive power granted to the Autonomous Communities by the legislation on pharmaceutical products.

The Autonomous Community of Madrid regulates the issue of certificates acknowledging the health and/or social interest of scientific acts which take place in the Autonomous Community of Madrid. The recipients may mention their certificates in the advertising and documentation regarding the activity so certified. In addition, the management of public healthcare centers shall have to authorize the assistance to scientific acts organized or sponsored by pharmaceutical companies.

In the Autonomous Community of Catalonia, a seal of quality for sponsored scientific activities may be requested from the Catalan Council of Continuing Medical Training. On the other hand, the guide includes the obligation to inform of any sponsoring activities to be carried out prior to their taking place, which, in our view, exceeds the obligations imposed by Royal Decree 1416/1994.

Visits to Physicians

Visits to physicians are one of the preferred types of interactions between pharmaceutical companies and persons qualified to prescribe or supply medicines. Royal Decree 1416/1994 defines the visit to a physician as "the type of relationship between the pharmaceutical companies and the persons qualified to prescribe or supply medicines for the purpose of informing and advertising medicines, carried out by the medical representative and based on the transmission of technical knowledge required for the objective assessment of its therapeutic utility."

Medical representatives must be duly accredited by the pharmaceutical company they represent. The pharmaceutical company must train its medical representatives adequately, as they must have sufficient scientific knowledge to provide precise, complete orientation of the medicines they are promoting.

Royal Decree 1416/1994 establishes the documentation and information that medical representatives must provide or have available in each visit relating to the products presented: the summary of product characteristics, information on the different pharmaceutical forms and dosages, the prescription and supply regime, price information, conditions of the National Health System's financing of the medicine, and, when possible, the estimated cost of treatment.

La información técnica del medicamento o visita médica

La visita médica es uno de los medios preferentes de relación entre los laboratorios farmacéuticos y los profesionales facultados para prescribir o dispensar medicamentos. El Real Decreto 1416/1994 la define como "el medio de relación entre los laboratorios y las personas facultadas para prescribir o dispensar medicamentos a efectos de la información y publicidad de los mismos, realizada por el visitador médico y basada en la transmisión de los conocimientos técnicos adecuados para la valoración objetiva de la utilidad terapéutica".

Los visitadores médicos deberán estar debidamente acreditados por el laboratorio al que representen. El laboratorio está obligado a formar adecuadamente a sus visitadores médicos, quienes deberán poseer los conocimientos científicos suficientes para proporcionar orientaciones precisas y lo más completas posible sobre los medicamentos que promocionen.

El Real Decreto 1416/1994 establece una serie de documentación e información que los visitadores médicos deberán proporcionar, o tener disponible, en cada visita en relación con los productos presentados: la ficha técnica autorizada, información sobre las diferentes formas farmacéuticas y dosis, el régimen de prescripción y dispensación, información sobre el precio, condiciones de la prestación farmacéutica del Sistema Nacional de Salud y, cuando sea posible, la estimación del coste del tratamiento.

En la actividad de visita médica los visitadores médicos pueden utilizar los distintos medios de promoción y publicidad autorizados por la legislación, como son la entrega de información de tipo documental o de muestras gratuitas, o el ofrecimiento de incentivos e invitaciones a seminarios o congresos. En todos los casos deberán ajustarse a los requisitos que para cada tipo de actividad promocional exige la legislación.

Los visitadores médicos son un eslabón importante del sistema de farmacovigilancia. La legislación establece que deberán notificar al servicio científico del laboratorio todas las informaciones que reciban de los profesionales visitados relativas a los medicamentos que promocionen, y en especial las reacciones adversas que les sean comunicadas.

La actividad de visita médica es incompatible con el ejercicio de una actividad profesional en el ciclo de prescripción, dispensación o administración de medicamentos.

In visits to physicians, the medical representatives may use the various legally authorized methods of promotion and advertising, such as providing documentary information or free samples, or offering incentives and invitations to seminars and congresses. In each case, the medical representatives must comply with the legal requirements for each type of promotional activity.

Medical representatives are an important link in the pharmacovigilance system for medicines. The law establishes that they must report to the pharmaceutical company's scientific service any information they receive from the professionals visited regarding the medicines they promote, especially adverse reactions reported to them. The activity of the medical representative is incompatible with the exercise of any professional activity in the cycle of prescription, supply, or administering of medicines.

Legal regulations do not require a medical representative to work exclusively for one pharmaceutical company. The pharmaceutical companies for which the medical representative works are responsible for the fulfillment of the obligations imposed on visits to physicians by legal regulations.

Visits to physicians have traditionally taken place in person, with the physical presence of the medical representative. However, there is nothing to prevent a visit to a physician from taking place by video-conference or using other media in which the relationship between the medical representative and the visited professional does not include physical presence. In such cases, the requirements of providing or having available the summary of product characteristics and all other information and documentation stipulated by law must be met, just as for in-person visits.

The assumption of health competences by all Autonomous Communities, including the cost of the provision of health assistance, has caused several of them to regulate or begin the process of regulating promotional visits to physicians, with the intention of restricting such visits.

Since the review of the different regulations would exceed the scope of this chapter, we shall limit ourselves to highlighting the prevailing tendencies and the more recent experiences. The points that differ by degrees of restriction are: encouragement of collective visits in favor of individual visits, limitations on the places in which the promotional visits may take place, requirements concerning prior schedules of the visits, limitation of the days and hours that may be dedicated to visits, and limitation of the frequency of visits to physicians by any given pharmaceutical company.

La normativa no exige que los visitadores médicos presten sus servicios exclusivamente para un laboratorio farmacéutico. Los laboratorios para los que presten sus servicios serán responsables en cada caso del cumplimiento de las obligaciones que la normativa impone a la actividad de visita médica.

La visita médica se ha realizado tradicionalmente de manera presencial, con la presencia física del visitador médico. Sin embargo, nada impide que la visita médica se lleve a cabo a través de videoconferencias o de otros medios en que la relación visitador médico / profesional visitado no incluya la presencia física. En estos casos, deben cumplirse igualmente las exigencias legales de proporcionar o tener a disposición de la persona visitada la ficha técnica de los medicamentos presentados, así como el resto de información y documentación exigida.

La asunción de competencias sanitarias por parte de la totalidad de las Comunidades Autónomas, incluyendo el coste de la asistencia sanitaria, ha propiciado que muchas de ellas hayan regulado o estén en proceso de regular la visita médica, orientando dicha regulación a una restricción de la misma.

Dado que el examen detallado de las normativas autonómicas de visita médica excedería la extensión de este capítulo, nos limitaremos a indicar cuales son las tendencias de dichas regulaciones y las experiencias más recientes. Los elementos que encontramos recogidos en todas ellas, en mayor o menor grado, son los siguientes: potenciación de la visita colectiva frente a la individual, delimitación del lugar donde debe realizarse la visita, exigencia de un calendario previo con una antelación creciente, establecimiento de días y horas limitados de visita y de máximos de visita por laboratorio.

La visita a farmacéuticos se ha incrementado notablemente debido al desarrollo del mercado de medicamentos autorizados para hacer publicidad al público y medicamentos genéricos, así como al incremento de la distribución directa por parte de los laboratorios. El Código de Farmaindustria especifica que sus disposiciones también se aplicarán a las visitas de promoción en oficinas de farmacia.

Finalmente el Código de Farmaindustria establece que los laboratorios son responsables de que sus visitadores dispongan de los conocimientos científicos suficientes para presentar la información de los medicamentos de forma precisa y responsable, y también de que conozcan las obligaciones establecidas en el Código de Farmaindustria, así como de la actualización de sus conocimientos.

Visits to pharmacists have grown in Spain since the development of over-the-counter ("OTC") medicines and the generics market, as a result of the direct distribution by pharmaceutical companies. The Farmaindustria Code specifies that the above provisions also apply to promotional visits to pharmacists.

Finally, the Farmaindustria Code establishes that pharmaceutical companies must ensure that their medical representatives have sufficient scientific knowledge to be able to present the information of the medicines accurately and responsibly; that they are aware of the obligations set forth in the Farmaindustria Code; and that their knowledge is up-to-date on the developments in the field.

Samples

Spanish law considers the distribution of free samples an exceptional promotional activity and therefore limits the kinds of medicines which can be promoted in this way the receivers of such promotion, and duration of the promotional activity. Distribution of free samples is limited to persons qualified to prescribe, excluding therefore distribution to persons qualified to supply medicines. The Farmaindustria Code specifies that the free samples must be delivered directly to the health professionals qualified to prescribe, or to the persons duly authorized by the above. In addition, the Autonomous Community tends to additionally regulate the distribution of free samples in public healthcare centers.

Since it is an exceptional activity, distribution of free samples does not extend to all medicines. Those which can be so distributed are subject to limitations in time and quantity given.

Only industrially-manufactured medicines which meet the following requirements can be given out as free samples:

- Those whose formulas contain an active medicinal substance or substances which, because of their novelty in the therapeutic field, require prior knowledge on the part of prescribing physicians
- Those which, though not included in the preceding category, present a new pharmaceutical preparation or form, a unit dose or concentration, or a form of administering or are intended for a different manner of administering from those currently used, and represent as well a therapeutic advantage over them

Muestras Gratuitas

La legislación considera la entrega de muestras gratuitas como una actividad promocional excepcional, y por ello limita los tipos de medicamentos que pueden estar sujetos a este tipo de promoción, los destinatarios de dicha promoción, y la duración de este tipo de actividad promocional. La entrega de muestras gratuitas está limitada a las personas facultadas para prescribir medicamentos, excluyéndose por tanto su entrega a las personas facultadas para dispensar medicamentos. El Código de Farmaindustria establece que las muestras gratuitas deben ser entregadas directamente a los profesionales sanitarios facultados para prescribir medicamentos que las hayan solicitado o a personas autorizadas para recibirlas en su nombre. Por otra parte, se observa una tendencia a regular adicionalmente por parte de las Comunidades Autónomas la actividad promocional de entrega de muestras gratuitas en los centros públicos.

Por su carácter excepcional, no todos los medicamentos pueden ser promocionados mediante la entrega de muestras gratuitas, y aquellas que pueden ser entregadas están sujetas a limitaciones en el tiempo y en la cantidad entregada. Únicamente pueden suministrarse muestras gratuitas de medicamentos y medicamentos fabricados industrialmente que cumplan los siguientes requisitos:

- Que su fórmula esté constituida por una sustancia o sustancias activas medicinales que, por ser novedad en el campo terapéutico, precise del previo conocimiento de las personas facultadas para prescribirlos.
- Que, aun no tratándose de una sustancia medicinal de las referidas en el apartado anterior, su preparación o forma farmacéutica, dosis por unidad o concentración, forma de administración, sean nuevas o estén dirigidas a la administración por vía distinta de las utilizadas y suponga además, una ventaja terapéutica respecto de aquellas.
- Que, aun siendo conocidas farmacológica y terapéuticamente las sustancias medicinales, se hubieran descubierto acciones farmacológicas nuevas y por consiguiente tengan una nueva indicación terapéutica.

En consecuencia, los medicamentos genéricos no podrán promocionarse vía la entrega de muestras gratuitas, al faltar el elemento de novedad terapéutica.

- Those for which, while they contain known pharmacological or therapeutic medicinal substances, new pharmacological actions have been discovered and which therefore have a new therapeutic indication

Thus, generic medicines may not be promoted through distribution of free samples, as they lack the element of therapeutic novelty.

However, even those medicines which meet the above requirements may not be given out as free samples if they contain psychotropic or narcotic substances, or if they cause dependence. The Ministry of Public Health and Consumer Affairs may also expressly exclude certain medicines from this manner of promotion.

The owner of the marketing authorization must apply for a further authorization to manufacture and distribute free samples from the Medicines and Medical Devices Agency. Such application is not subject to any particular formality.

After the special authorization is obtained, free samples may be distributed - limited only to prescribing physicians - under the following conditions:

- A maximum of 10 samples of each medicine per year and per physician. The health authorities may increase the number of samples per year for those medicines whose special therapeutic interest so warrants.
- Distribution for a maximum of two years from the date of authorization.
- Each set of samples distributed must be in response to a written request, signed and dated by the receiver.
- Pharmaceutical companies which distribute free samples must maintain a system of adequate control. This includes the authorizations, as well as a register of requests and deliveries of free samples handled. Besides this, the annual advertising index must include a list of the free samples distributed.
- Samples must be identical to the smallest presentation of the medicine being marketed.
- Each sample must bear the words “Free Sample: Not for Sale” and have the coupon-seal removed or nullified.
- Each delivery of free samples must be accompanied by a copy of the technical data sheet, together with the latest price information, financing conditions offered by the National Health System, if applicable, and, when possible, the estimated cost of treatment.

Sin embargo, aún cuando reúnan los anteriores requisitos, no podrá suministrarse muestra alguna de medicamentos que contengan sustancias psicotrópicas o estupefacientes o que causen dependencia, ni tampoco de los medicamentos que expresamente determine el Ministerio de Sanidad y Consumo.

El titular de la autorización de comercialización solicitará a la Agencia Española de Medicamentos y Productos Sanitarios autorización para elaborar y suministrar muestras gratuitas, solicitud que no está sujeta a ninguna formalidad particular. Tras la obtención de la autorización, y limitado a las personas facultadas para prescribir medicamentos, la entrega de muestras gratuitas se realizará de acuerdo con las siguientes condiciones:

- Un máximo de 10 muestras de cada medicamento por año y persona facultada. Las autoridades sanitarias podrán ampliar el número de muestras por año de aquellos medicamentos que su especial interés terapéutico lo aconseje.
- Entrega durante un tiempo máximo de dos años contados desde la fecha de la autorización del medicamento.
- Cada suministro de muestras deberá responder a una petición formulada por escrito, fechada y firmada, que proceda del destinatario.
- Los laboratorios que suministren muestras deberán mantener un sistema adecuado de control. Ello incluye las autorizaciones, así como un registro de las solicitudes y suministros de muestras gratuitas tramitados. Por otra parte, el mencionado índice anual de actividades publicitarias deberá incluir una relación de las muestras gratuitas suministradas.
- Las muestras deberán ser idénticas a la presentación más pequeña del medicamento comercializado.
- Cada muestra deberá llevar la mención “Muestra gratuita. Prohibida su venta”, y suprimido o anulado el cupón-precinto del medicamento.
- Cada entrega de muestras deberá acompañarse de un ejemplar de la ficha técnica, junto con la información actualizada del precio, condiciones de la oferta del Sistema Nacional de Salud, en su caso, y, cuando sea posible, la estimación del coste del tratamiento.

In general, distribution of free samples of pharmaceuticals limited to hospital use or diagnostics is not prohibited. Any rules adopted by the relevant hospital should be observed.

In line with the above, the Farmaindustria Code stipulates that, when samples are distributed in hospitals, the requirements and procedures of the hospital in question must be respected.

Finally, it must be highlighted that changes made to the EFPIA Code in June 2011 included the limitation that healthcare professionals cannot be given more than four samples for each new medicine, provided that such medicine has been requested. This restriction has not been implemented in the Farmaindustria Code as of the publishing date of this book.

No specific regulation applies to the delivery of samples regarding medical devices. Therefore, the delivery of samples is subject to the restrictions applicable to gifts, unless they are samples with no commercial value.

Consequences of Breach

The health authorities are responsible for enforcing compliance with the legal provisions applicable to the advertising of medical products, among them, the promotional activities aimed at health professionals.

Royal Decree 1416/1994 does not establish any definition of infractions or administrative sanctions, but refers to the infractions and sanctions as given in Law 25/1990, on Medicines, and Law 14/1986, on General Public Health Act. The reference to Law 25/1990 should now be understood as a reference to Law 29/2006. The royal decrees relating to medical devices include specific infractions, in addition to those of Law 14/1986 and Law 29/2006.

Infractions are classified into three categories: minor, serious and very serious. The criteria used in determining the class of infraction takes into account health risk, profits to be earned, degree of intentionality, seriousness of the health and social alarm caused, generalization of the infraction and recidivism.

Minor infractions relating to the activities examined above are:

- failure to provide obligatory information in the annual advertising index;
- obstruction of inspections by means of any action or omission which obstructs or delays such inspections;

No está prohibida con carácter general la entrega de muestras gratuitas de especialidades farmacéuticas de uso hospitalario o de diagnóstico hospitalario. Deberán cumplirse las normas internas que haya adoptado cada hospital al respecto. En línea con lo anterior, el Código de Farmaindustria precisa que en la distribución de muestras en hospitales deberán respetarse los requisitos y procedimientos del hospital en cuestión.

Finalmente, cabe señalar que la modificación del Código de la EFPIA de fecha junio de 2011, introdujo la limitación de que a los profesionales sanitarios no se les puede entregar más de 4 muestras por cada nuevo medicamento y previa solicitud de este. Hasta la fecha de edición del presente libro, dicha restricción no ha sido implementada en el Código de Farmaindustria.

No existe regulación específica relativa a la entrega de muestras de productos sanitarios. Por ello, la entrega de muestras a profesionales sanitarios estará sujeta a las limitaciones relativas a los obsequios, salvo que sean muestras sin valor comercial.

Consecuencias de la infracción

Las autoridades sanitarias tienen la responsabilidad de velar por el cumplimiento de las disposiciones aplicables a la publicidad de medicamentos y productos sanitarios, y entre ellas las relativas a las actividades de promoción dirigidas a los profesionales sanitarios.

El Real Decreto 1416/1994, no establece una tipificación propia de faltas y sanciones administrativas, sino que se remite a las infracciones y sanciones previstas en la Ley 25/1990 del Medicamento y Ley 14/1986, General de Sanidad. La mención a la Ley 25/1990 debe entenderse ahora realizada a la Ley 29/2006. Los reales decretos relativos a productos sanitarios incluyen sanciones específicas, adicionales a las establecidas en la Ley 14/1986 y Ley 29/2006.

Las infracciones se clasifican en tres categorías, leves, graves y muy graves, atendiendo a los criterios de riesgo para la salud, cuantía del eventual beneficio obtenido, grado de intencionalidad, gravedad de la alteración sanitaria y social producida, generalización de la infracción y reincidencia.

Constituyen faltas leves en relación con las actividades examinadas en el apartado anterior: (i) no aportar los datos obligados a suministrar en el índice anual de actividades publicitarias; (ii) dificultar la labor inspectora mediante cualquier acción u omisión que perturbe o retrase la misma; (iii) realizar

- the advertising of master formulas or official preparations;
- the display of non-authorized medical devices at trade fairs and scientific meetings without disclosing the fact that they are not yet authorized, and
- failure to meet the requirements laid down by the regulations of the Autonomous Communities governing visits to physicians.

Fines for minor infractions may be up to EUR30,000.

Serious infractions of the activities described above include:

- the direct or indirect offering of any type of incentive, bonus, unauthorized discount or gift by anyone with direct or indirect interests in the production, manufacture and marketing of medical products, to healthcare professionals, for the prescription, dispensing or administering of medical products, or to patients or persons with whom they live;
- health professionals engaged in the prescription, dispensing, and administering cycle, provided that they are currently engaged in such responsibilities, acting as medical representatives, representatives, commissioned personnel, or information agents of pharmaceutical companies;
- provide or conceal data, declarations or any other information to be mandatorily submitted to the competent health authorities so that such data, declarations or information is not truthful or gives rise to untruthful conclusions, with the aim of obtaining a profit, whether financial or otherwise (this infringement has been included by Royal Decree 9/2011); and,
- the commission of three minor infractions within a period of one year.

Fines for serious infractions range from EUR30,001 to EUR90,000.

Very serious infractions will include:

- the offering of bonuses, gifts, prizes, contests, or the like as methods for the promotion or sale of medical products to the public;
- the promotion, advertising or disclosure of information to the public of products or preparations, with medicinal purposes, even though the product itself does not explicitly mention such purposes, including medicinal substances and their compounds that are not authorized as medicines;

publicidad de formulas magistrales o de preparados oficinales; (iv) la presentación en ferias y congresos científicos de productos sanitarios que no hayn obtenido el marcado CE sin indicarlo expresametne; y (v) incumplir los requisitos que, para la realización de las visitas médicas, establezca la normativa de las Comunidades Autónomas.

La sanción por infracciones leves puede llegar a alcanzar 30.000 Euros.

Constituyen faltas graves en relación con las actividades examinadas en el apartado anterior: (i) ofrecer directa o indirectamente cualquier tipo de incentivo, bonificaciones, descuentos prohibidos, primas u obsequios, efectuados por quien tenga intereses directos o indirectos en la producción, fabricación y comercialización de medicamentos o productos sanitarios, a los profesionales sanitarios, con motivo de la prescripción, dispensación y administración de los mismos, o a sus parientes y personas de su convivencia; (ii) la actuación de los profesionales sanitarios implicados en el ciclo de prescripción, dispensación y administración, siempre que estén en ejercicio, con las funciones de delegados de visita médica, representantes, comisionistas o agentes informadores de los laboratorios de especialidades farmacéuticas; (iii) aportar u ocultar las entidades o personas responsables, datos, declaraciones o cualquier información que estén obligados a suministrar a las administraciones sanitarias competentes de forma que no resulten veraces o den lugar a conclusiones inexactas, con la finalidad de obtener con ello algún beneficio, ya sea económico o de cualquier otra índole (supuesto incluido mediante Real Decreto Ley 9/2011); y (iv) cometer tres infracciones leves en el plazo de un año.

La sanción por infracciones graves varía entre 30.001 Euros y 90.000 Euros.

Constituyen faltas muy graves en relación con las actividades examinadas en el apartado anterior (i) el ofrecimiento de prima, obsequios, premios, concursos o similares como métodos vinculados a la promoción o venta al público de medicamentos o productos sanitarios; (ii) efectuar promoción, publicidad o información destinada al público de productos o preparados, con fines medicinales, aún cuando el propio producto no haga referencia explícita a dichos fines, incluidas las sustancias medicinales y sus combinaciones, que no se encuentren autorizados como medicamentos; (iii) no cumplir los requisitos y condiciones reglamentariamente exigidos en materia de publicidad y promoción comercial de los productos, materiales, sustancias, energías o métodos a los que se atribuyan efectos beneficiosos sobre la salud; (iv) cometer tres infracciones calificadas como graves en el plazo de dos años.

- failure to fulfill the requirements and conditions set forth by law regarding the advertising and commercial promotion of products, materials, substances, energies or methods which have beneficial effects on health; and
- the commission of three infractions classified as serious within a period of two years.

Fines for very serious infractions range from EUR90,001 to EUR1,000,000. This amount may be increased by up to five times the value of the products or services involved in the infraction.

The health authorities set penalties taking into account the negligence or intentionality of the violator, fraud or collusion, noncompliance with previous warnings, the company's business volume, the number of persons affected, damages caused, profits earned from committing the infraction, and permanence or transience of risks and recidivism for the commission within a period of one or more years of an infraction of the same nature when so declared by a final ruling.

Likewise, Law 29/2006 sets forth provisions governing a specific action of cessation that may be taken when the advertising of medicines for human use, medical devices or products with purported health properties violates the Law itself, its implementing provisions or the General Public Health Act, affecting the collective or individual interests of consumers and users.

The Law provides that the following persons are authorized to seek such cessation:

- The Spanish National Institute of Consumption and the relevant bodies or entities of the Autonomous Communities and local corporations competent in matters concerning the protection of consumers
- Consumer and user associations meeting the requirements set forth by the General Act for the Protection of Consumers and Users, or where applicable, in the Autonomous Community legislation governing the protection of consumers
- Institutions of other Member States of the European Union created for the protection of the collective or individual interests of consumers authorized as a result of their inclusion on the list published for such purpose in the Official Journal of the European Communities
- Those individuals having been conferred a lawful right or having a lawful interest

La sanción por infracciones muy graves varía entre 90.001 Euros y 1.000.000 Euros, pudiendo rebasar dicha cantidad hasta alcanzar el quíntuplo del valor de los productos o servicios objeto de la infracción.

Las autoridades sanitarias gradúan las infracciones en función de la negligencia e intencionalidad del sujeto infractor, fraude o connivencia, incumplimiento de las advertencias previas, cifra de negocios de la empresa, número de personas afectadas, perjuicio causado, beneficios obtenidos a causa de la infracción, permanencia y transitoriedad de los riesgos y reincidencia por comisión en el término de un año de más de una infracción de la misma naturaleza cuando así haya sido declarado por resolución firme. Asimismo, la Ley 29/2006 regula una acción de cesación específica, que puede ejercitase cuando una publicidad de medicamentos de uso humano, de productos sanitarios o de productos con supuestas propiedades sobre la salud sea contraria a la propia Ley, a sus disposiciones de desarrollo o a la Ley General de Sanidad, afectando a los intereses colectivos o difusos de los consumidores y usuarios.

Como sujetos legitimados para solicitar dicha cesación, la Ley recoge los siguientes:

- El Instituto Nacional del Consumo y los órganos o entidades correspondientes de las Comunidades Autónomas y de las corporaciones locales competentes en materia de defensa de los consumidores.
- Las asociaciones de consumidores y usuarios que reúnan los requisitos establecidos en la Ley General para la Defensa de los Consumidores y Usuarios, o, en su caso, en la legislación autonómica en materia de defensa de los consumidores.
- Las entidades de otros Estados miembros de la Unión Europea constituidas para la protección de los intereses colectivos y de los intereses difusos de los consumidores que estén habilitadas mediante su inclusión en la lista publicada a tal fin en el "Diario Oficial de las Comunidades Europeas".
- Los titulares de un derecho o de un interés legítimo.
- La cesación podrá ser solicitada desde el comienzo hasta el fin de la actividad publicitaria. Asimismo, la acción podrá ejercitarse para prohibir la realización de una conducta cuando esta haya finalizado al tiempo de ejercitar la acción, si existen indicios suficientes que hagan temer su reiteración de modo inmediato.

The cessation may be sought from the time when such advertising activity commences to its conclusion. Similarly, action may be taken to prohibit any practice when such practice has ceased at the time of such action, if there is sufficient indication to fear that such practice may be resumed immediately.

Professional Codes of Conduct

As indicated above, Farmaindustria has a Code of Good Practices in the Promotion of Medicines and Interaction with Healthcare Professionals. The currently applicable Farmaindustria Code was approved in October 2010.

The Farmaindustria Code covers all promotional practices targeted at health professionals authorized to prescribe and supply medicines, and does not cover general promotional activities targeted at the general public.

Possible sanctions for violation of the Farmaindustria Code include monetary penalties, reporting of the infraction to the competent health authority and expulsion of the offending company from Farmaindustria.

The Farmaindustria Ethics Committee, and the Self-regulation Board of the *Asociación Para la Autorregulación de la Comunicación Comercial* (Association for the Self-Regulation of Commercial Communications) supervise compliance with the Farmaindustria Code. Farmaindustria's members have agreed to try to settle their disputes within the Ethics Committee as a first step and on a confidential basis. If no agreement is reached, the Ethics Committee will refer the matter to the Board. The Board's decisions are binding. Since the creation of of the Self-Regulation Board as a decision-making body, the Board has issued a large number of decisions concerning several aspects of the Farmaindustria Code.

In addition, Farmaindustria updated all the documents which complete the Farmaindustria Code during 2010:

- The Guide for the Implementation of the Code of Good Practices for the Promotion of Medicines and Interaction with Healthcare Professionals
- A Q&A document
- The Internal Regulations for the supervisory bodies

Finally, in 2008, Farmaindustria approved the Spanish Code of Good Practices for the Promotion of Medicines and Interaction between the pharmaceutical industry and the associations of patients, which has been

Códigos Profesionales de Conducta

Tal y como hemos indicado con anterioridad, la Asociación Nacional Empresarial de la Industria Farmacéutica (Farmaindustria), asociación que reúne a la industria farmacéutica española, dispone de un Código de Buenas Prácticas para la Promoción de los Medicamentos y la Interrelación de la Industria Farmacéutica con los Profesionales Sanitarios. El vigente Código fue aprobado en Octubre de 2010.

El Código de Farmaindustria cubre todas las prácticas de promoción dirigidas a profesionales sanitarios habilitados para prescribir o suministrar medicamentos yno cubre la promoción dirigida al público en general.

Las posibles sanciones por incumplimiento del Código de Farmaindustria incluyen sanciones económicas, comunicación de la infracción a la autoridad sanitaria competente y la expulsión de la compañía infractora de la asociación Farmaindustria.

La Comisión Deontológica de Farmaindustria y el Jurado de Autocontrol controlan el cumplimiento del Código de Farmaindustria. Los miembros de Farmaindustria han acordado que en primer término intentarán resolver sus diferencias de manera confidencial en el marco de la Comisión de Deontología. Si no se llega a un acuerdo, la Comisión de Deontología referirá el asunto al Jurado. Las decisiones del Jurado son obligatorias. Desde la designación del Jurado de Autocontrol como órgano resolutorio, este ha dictado numerosas resoluciones relativas a diversos aspectos del Código de Farmaindustria.

Asimismo, en el año 2010, Farmaindustria actualizó el resto de documentos que completan el Código de Farmaindustria mediante: La Guía de Desarrollo del Código de Buenas Prácticas para la Promoción de los Medicamentos; El documento de preguntas y respuestas; El Reglamento interno de los órganos de control.

Finalmente, durante el año 2008, Farmaindustria aprobó el Código Español de Buenas Prácticas de Promoción de Medicamentos y de Interrelación de la Industria Farmacéutica con las Organizaciones de Pacientes queha sido modificado en 2011 para adaptarlo a la nueva versión del Código EFPIA aprobada en junio de 2011.

amended in 2011 to adapt it to the new version of the EFPIA Code of Patient Associations approved in June 2011.

The pharmaceutical companies producing medical devices which belong to Fenin have adopted a Code of Good Practices, which entered into force in 2005, and was updated in 2009. In addition, Fenin approved, and updated in December 2009, the regulations of implementation and the implementation guide of its code. The code is implemented by means of the Fenin's Code of Conduct Commission, which refers any cases which are not solved by conciliation to the Jury of the Association for Commercial Self-Regulation ("Autocontrol"). The code provides penalties to be imposed on infringers: economic penalties ranging from EUR1,000 to EUR100,000, notice of the infringement to be served on the competent health authority and deregistration of the infringing company from Fenin.

Civil and Criminal Liability

Civil Liability

As mentioned above, infractions with regard to medical products are subject to administrative sanctions (please see "Consequences of breach" above). In addition to the administrative sanctions, if an infraction of the regulations entails a significant market advantage for the offending pharmaceutical company, any competitor (understood to mean any person acting in the market whose economic interests have been directly damaged or threatened) may legitimately file suit for unfair competition. Based on such suit, the competitor may request, among other actions, the removal of the effects caused by the offending act and compensation for damages caused by the offending act, if willful misconduct or negligence were involved. Compensation may include publication of the sanction. If the suit for unfair competition is filed by workers or other agents in the exercise of their contractual duties and responsibilities, the suits will be filed against their principal.

Suits for unfair competition may be filed up to one year after grounds for filing are known and the party who committed the act of unfair competition is identified and, in any event, up to three years after the commission of the act.

Criminal Liability

Some of the administrative infringements examined may give rise to criminal liability. In this case, the criminal proceedings for the same offence suspend the administrative proceedings.

Las compañías farmacéuticas de productos sanitarios pertenecientes a la Federación Nacional de Empresas de Tecnología Sanitaria ("Fenin") adoptaron un Código de Buenas Prácticas que entró en vigor en el año 2005 y que fue actualizado en el año 2009. Además, Fenin ha aprobado, y actualizado en diciembre de 2009, un Reglamento de Aplicación y una Guía de Aplicación de su Código. La aplicación del Código se lleva a cabo a través de la Comisión Deontológica de Fenin, la cual refiere los casos no resueltos por conciliación al Jurado de la Asociación para la Autorregulación Comercial (Autocontrol), quien ya ha emitido varias resoluciones en aplicación del Código Fenin. El Código prevé la imposición de sanciones a los infractores: sanciones económicas (de 1.000 Euros a 100.000 Euros), la comunicación de la infracción a la autoridad sanitaria competente y la baja de la compañía infractora de Fenin).

Responsabilidad civil y penal

Responsabilidad civil

Como ya hemos adelantado las infracciones en materia de medicamentos y productos sanitarios pueden ser objeto de sanción administrativa. Además, si la infracción de la normativa examinada conlleva una ventaja significativa en el mercado para el laboratorio infractor, cualquier competidor, entendido como cualquier persona que participe en el mercado y cuyos intereses económicos resulten directamente perjudicados o amenazados, estará legitimado para el ejercicio de una acción de competencia desleal. En base a dicha acción, podrá solicitar, entre otras actuaciones, la remoción de los efectos producidos por el acto y el resarcimiento de los daños y perjuicios ocasionados por el acto, si hubiera intervenido dolo o culpa. El resarcimiento podrá incluir la publicación de la sentencia. Si el acto de competencia desleal es realizado por trabajadores u otros colaboradores en el ejercicio de sus funciones y deberes contractuales, las acciones se dirigirán contra su principal.

Las acciones de competencia desleal prescriben por el transcurso de un año desde el momento en que pudieron ejercitarse y el legitimado tuvo conocimiento de la persona que realizó el acto de competencia desleal; y, en cualquier caso, por el transcurso de tres años desde el momento de la realización del acto.

The Spanish Criminal Code lists crimes and misdemeanors and their penalties, as well as criminal liability. The Criminal Code was amended by Organic Law 5/2010 to, among others, introduce the criminal liability of legal entities. Therefore, according to the Criminal Code, legal entities will be criminally responsible for offenses committed, on its behalf and to its benefit, by its legal representatives, directors and/or directors in fact; and offenses committed in the exercise of its activities, on its behalf and to its benefit, by those subject to the authority of the legal representatives, directors and/or directors in fact of the legal entity "due to the lack of proper control given the specific facts of each case."

The Spanish Criminal Code includes various types of crimes which should be noted. Regarding the content of the promotion or advertising of medical products, the Criminal Code punishes manufacturers and marketers which, in their offers or advertising of products or services, make false allegations or claim untrue characteristics for them, causing serious, evident damage to consumers.

A civil servant may not receive gifts in connection with his or her public activity, since this could constitute a bribe. Thus, a civil servant incurs criminal liability if he or she requests or receives gifts in exchange for executing an unfair act in the exercise of his or her position or for failing to perform or delaying performance. He or She also incurs criminal liability for accepting a gift offered in consideration of his or her function or in exchange for an act which is not legally prohibited. In the same way, any person who corrupts or attempts to corrupt authorities or civil servants with gifts, offers, or promises incurs criminal liability. The Spanish Civil Code does not include a minimum amount above which liability exists. Academics have suggested application of the doctrine of the social adequacy (importance of the gift to influence the conduct of the civil servant), in order to exclude from criminal liability socially accepted behavior or behavior that is clearly insufficient to achieve the alleged objective. However, the Spanish Supreme Court has warned that the existence of a gift is sufficient to incur criminal liability, without the need to quantify the gift. Criminal liability is also incurred if the gift or donation is given to a third party intermediary acting under instructions from the civil servant or public authority.

Likewise, criminal liability is incurred when any individual influences a civil servant or public authority who is a healthcare professional by using any situation derived from his/her personal relationship with this or any other civil servant or public authority in order to obtain a resolution which may

Responsabilidad penal

Algunas de las infracciones administrativas examinadas pueden dar lugar a responsabilidad penal. La instrucción de una causa penal por los mismos hechos suspende la tramitación del expediente administrativo.

El Código Penal español recoge los delitos y faltas, y sus penas, así como la responsabilidad penal. El Código Penal fue modificado mediante Ley Orgánica 5/2010 para, entre otras, regular la responsabilidad penal de las personas jurídicas En consecuencia, el Código Penal establece que las personas jurídicas serán penalmente responsables (i) de los delitos cometidos en nombre o por cuenta de las mismas, y en su provecho, por sus representantes legales y administradores de hecho o de derecho; y (ii) de los delitos cometidos, en el ejercicio de actividades sociales y por cuenta y en provecho de las mismas, por quienes, estando sometidos a la autoridad de los representantes legales y administradores de hecho o de derecho de la persona jurídica, han podido realizar los hechos por no haberse ejercido sobre ellos el debido control atendidas las concretas circunstancias del caso.

El Código Penal recoge varios tipos delictivos que consideramos conveniente señalar. En cuanto al contenido de la promoción y publicidad que se lleve a cabo sobre medicamentos o productos sanitarios, el Código Penal castiga a los fabricantes y comerciantes que, en sus ofertas o publicidad de productos o servicios, hagan alegaciones falsas o manifiesten características inciertas sobre los mismos, de modo que puedan causar un perjuicio grave y manifiesto a los consumidores.

El profesional sanitario funcionario público no puede recibir regalos relacionados con su actividad pública, puesto que puede incurrir en un delito de cohecho. Así, el funcionario público incurre en responsabilidad penal si solicita o recibe regalos para ejecutar en el ejercicio de su cargo un acto contrario a los deberes inherentes al mismo o para no realizar o retrasar injustificadamente el que debiera practicar. También incurrirá en responsabilidad penal si admite un regalo que le sea ofrecido en consideración a su función o para la consecución de un acto no prohibido legalmente. De manera equivalente, incurre en responsabilidad penal el que con presentes, ofrecimientos o promesas corrompiere o intentase corromper a las autoridades o funcionarios públicos. El Código Penal no incluye una cantidad a partir de la cual se incurra en responsabilidad. La doctrina ha sugerido la aplicación de la teoría de la adecuación social (relevancia de la dádiva para motivar la actuación del funcionario), a fin de extraer del ámbito delictivo conductas socialmente aceptadas o manifiestamente insuficientes para alcanzar el supuesto fin pretendido. Sin embargo, el Tribunal Supremo

either directly or indirectly generate economic benefit for such individual or any other.

In the same way, any civil servant who influences another civil servant in this way incurs criminal liability, as does one who requests gifts or any other remuneration from another to carry out such acts.

Additionally, criminal liability is incurred by any civil servant or public authority who, acting by virtue of his/her position in any phase of public contracting or in the liquidation of government-issued securities or government assets, makes an arrangement with the interested parties or uses any other artifice to defraud a public institution.

Lastly, it must be noted that another of the novelties introduced by the Organic Law 5/2010 is the regulation of corruption between private individuals. Criminal liability is incurred by any person who directly or through a third party, offers or grants to a private healthcare professional any nonjustified benefit or any advantage of any other nature in order to obtain a favor from such healthcare professional in breach of his/her duties related to the purchase or sale of goods or the engagement of professional services. Criminal liability is also incurred by any private healthcare professional who directly or through any third person, receives, requests or accepts any non-justified benefit or any advantage of any other nature in order to favor the person providing such benefit or advantage over third parties, in breach of his/her duties in the purchase or sale of goods or in the engagement of professional services.

Finally, payment of outlays for legally permitted activities, such as pharmacovigilance activities for medicines and travel expenses to scientific seminars and congresses, when such activities do not meet the obligatory scientific requirements or are for illicit purposes, may involve criminal liability. Thus, on 7 November 2001 the Supreme Court upheld the conviction for bribery and two-year prison sentence for the person in charge of a pharmaceutical company and its medical representative for giving incentives to Social Security physicians so that they would prescribe certain medicines. The Court ruled that the money was paid in order to increase sales of the pharmaceutical company's products and thus was to be considered a prohibited incentive, regardless of it being paid in the guise of pharmacovigilance activities for medicines. In addition, the expert opinions had shown that said activities did not meet the normally required scientific standards.

ha advertido que es suficiente la existencia de la dádiva para incurrir en delito, sin ser necesario cuantificarla. Se incurrirá igualmente en responsabilidad penal si el regalo o dádiva se entrega a un tercero bajo instrucciones del funcionario o autoridad pública.

Asimismo, cuando el profesional sanitario es un funcionario público, incurre en responsabilidad penal por un delito de tráfico de influencias el particular que influyere en dicho profesional sanitario prevaliéndose de cualquier situación derivada de su relación personal con este o con otro funcionario público o autoridad para conseguir una resolución que le pueda generar, directa o indirectamente, un beneficio económico para sí o para un tercero. De manera equivalente, incurre en responsabilidad penal el funcionario público que influyera de la misma forma en la actuación de otro funcionario público, y el funcionario público que solicitase de terceros presentes o cualquier otra remuneración por realizar dichas conductas.

Igualmente es de destacar que la autoridad o funcionario público que, interviniendo por razón de su cargo en cualquiera de los actos de las modalidades de contratación pública o en liquidaciones de efectos o haberes públicos, se concertara con los interesados o usase de cualquier otro artificio para defraudar a cualquier ente público, incurrirá en responsabilidad penal.

Finalmente, es de destacar que, otra de novedades introducidas por la Ley Orgánica 5/2010 es la regulación del delito de corrupción entre particulares. Así, incurre en dicho delito quien por sí o por persona interpuesta promete, ofrece o concede a un profesional sanitario del sector privado un beneficio o ventaja de cualquier naturaleza no justificados para que le favorezca a él o a un tercero frente a otro, incumpliendo sus obligaciones en la adquisición o venta de mercancías o en la contratación de servicios profesionales. Incurre también en dicho delito, el profesional sanitario del sector privado que, por sí o por persona interpuesta, recibe, solicita o acepta un beneficio o ventaja de cualquier naturaleza no justificados con el fin de favorecer frente a terceros a quien le otorga o del que espera el beneficio o ventaja, incumpliendo sus obligaciones en la adquisición o venta de mercancías o en la contratación de servicios profesionales.

En último lugar, es posible también incurrir en responsabilidad penal cuando los desembolsos se realizan en el marco de actividades legalmente permitidas, como estudios de farmacovigilancia o gastos de viajes a seminarios o congresos científicos, si dichas actividades no cumplen con los requisitos científicos exigidos o carecen de objetivos lícitos. Así, en fecha 7 de noviembre de 2001, el Tribunal Supremo español ratificó la condena por

The punishment for private individuals for offers or advertising which include false or untrue allegations is imprisonment for six months to one year, or a *per diem* fine of 12 to 24 months; the punishment for legal entities is a fine for six months to two years.

The punishment for bribery of civil servant healthcare professionals is imprisonment for three to six years, a *per diem* fine for 12 to 24 months, and disqualification to act as a civil servant for seven to 12 years, if the act is an unfair act; imprisonment for two to four years, a *per diem* fine for 12 to 24 months, and disqualification to act as a civil servant for three to seven years, if the act falls within the scope of acts inherent to his position; and imprisonment for six months to one year and suspension as a civil servant for one to three years, if the gift was offered in consideration of the professional's function.

The penalty for private individuals for bribery is the same as the punishment and fines mentioned above. The punishment for private legal entities is a fine for two to five years, or from three to five times the value of the gift if higher, if the punishment for individuals is imprisonment for more than five years; a *per diem* fine for one to three years, or from twice to four times the value of the gift if higher, if the punishment for individuals is imprisonment for more than two years; or a *per diem* fine for six months to two years or from twice to three times the value of the gift if higher, otherwise.

The punishment for influencing healthcare professionals who are also civil servants is imprisonment for six months to two years, a fine from once to twice the price of the income, and disqualification to act as a civil servant for three to seven years. The punishment for private individuals who influence a civil servant or public authority is imprisonment for six months to two years, and a fine of up to twice the amount of profit sought or earned; and for legal entities, a *per diem* fine from six months to two years.

The punishment for a public authority or civil servant who commits fraud in public tenders or against government assets is imprisonment for one to three years, and barring from public office or employment for six to 10 years.

The penalty for individuals for private corruption is imprisonment for six months to four years, disqualification to act as an entrepreneur from one to six years, and a fine of up to three times the value of the gift; and for the legal entity, *per diem* fines from one to three years.

The penalties that may be imposed upon legal entities are particular to each of the crimes for which legal entities can be held criminally liable. The

cohecho a dos años de prisión al responsable de un laboratorio farmacéutico y al visitador médico implicado, por incentivar a facultativos de la Seguridad Social para que recetasen determinados medicamentos. El Tribunal Supremo consideró que las cantidades se entregaron al objeto de aumentar las ventas de las especialidades médicas del laboratorio, y por ello debían considerarse como incentivos prohibidos, con independencia de que se entregasen bajo la cobertura de actividades de farmacovigilancia. Por otra parte, los dictámenes periciales habían probado que dichos estudios no tenían el nivel científico normalmente requerido.

La pena por ofertas o publicidad con alegaciones falsas o inciertas es para la persona física de prisión de seis meses a un año o multa de doce a veinticuatro meses y para la persona jurídica de multa de seis meses a dos años.

La pena para el profesional sanitario funcionario público por el delito de cohecho es (i) de prisión de tres a seis años, multa de doce a veinticuatro meses e inhabilitación especial para empleo o cargo público por tiempo de siete a doce años, si el acto a realizar fuera un acto injusto; (ii) de prisión de dos a cuatro años, multa de doce a veinticuatro meses e inhabilitación especial para empleo o cargo público por tiempo de tres a siete años si el acto a realizar fuera un acto propio de su cargo; o (iii) de prisión de seis meses a un año y suspensión de empleo y cargo público de uno a tres años, si hubiera recibido el regalo o dádiva simplemente en consideración a su cargo.

Estas mismas penas de prisión y multa son aplicables a los particulares persona física que hubieran incurrido en delito de cohecho. Para los particulares persona jurídica la pena es de (i) multa de dos a cinco años, o del triple al quíntuple del beneficio obtenido cuando la cantidad resultante fuese más elevada, si el delito cometido por la persona física tiene prevista una pena de prisión de más de cinco años o de (ii) multa de uno a tres años, o del doble al cuádruple del beneficio obtenido cuando la cantidad resultante fuese más elevada si se ejecuta, si el delito cometido por la persona física tiene prevista una pena de más de dos años de privación de libertad, y de (iii) multa de seis meses a dos años, o del doble al triple del beneficio obtenido si la cantidad resultante fuese más elevada, en el resto de los casos.

La pena por tráfico de influencias para el funcionario público es de prisión de seis meses a dos años, multa del tanto al duplo del beneficio perseguido u obtenido e inhabilitación especial para empleo o cargo público por tiempo de tres a seis años. Para los particulares persona física que influyan en un

following are examples of sanctions set forth in the Spanish Criminal Code: fines; winding up of the entity; suspension of the legal entity's activities for a maximum period of five years; closure of the legal entity's premises and establishments for a maximum period of five years; a prohibition on the legal entity to continue engaging in the same activities in the course of which the offense was committed; this may be for a defined period of up to 15 years, or indefinitely; ineligibility of the legal entity for subsidies and other public grants, public sector contracts, and tax/social security rebates and incentives, for up to 15 years; and judicial intervention, for as long as considered necessary (up to a maximum of five years).

In addition, during the preliminary investigation of a case, the examining magistrate may order the temporary closure of a company's premises or establishments, the suspension of its operations, or any other intervention deemed appropriate, as a precautionary measure.

The Spanish Criminal Code requires that, in the application of these penalties – excluding the penalty of a fine – the following factors must be taken into account: the need for the penalty in order to prevent the continuation of the criminal activity or the effects thereof; the economic or social consequences of the penalty, particularly for the employees; and the position within the organization of any individual who failed to exercise due control.

Public Procurement and Fraud

Supply contracts signed with public administrations, generally, the result of public tenders, must meet the conditions and requirements established by the applicable legislation, as well as the general and particular administrative specifications and the applicable technical specifications. Consequently, promotion offers for public administration contracts which do not fit into the legally-established contract award procedure are inadmissible. By way of example, bids offering the delivery of products at a reduced price or without costs or the delivery of technical equipment, unless included in the administrative specifications of the tender in question, are inadmissible. Specifically, no bids should be presented outside the normal procedures of public tender.

Infraction of administrative regulations may result in the cancellation of the tender, with the consequent termination of the contract and the obligation to indemnify the party not guilty of the cancellation, as well as a temporary prohibition to contract with the public administration. Criminal liability could also be incurred if the civil servant used the bids received for his or her own profit.

funcionario público o autoridad es de prisión de seis meses a dos años, y multa del tanto al duplo del beneficio perseguido u obtenido y para los particulares persona jurídica de multa de seis meses a dos años.

La pena a la autoridad o funcionario público por fraude en la contratación pública o contra haberes públicos es de prisión de uno a tres años e inhabilitación especial para empleo o cargo público por tiempo de seis a diez años.

La pena por un delito de corrupción entre particulares para la persona física es de prisión de seis meses a cuatro años, inhabilitación especial para el ejercicio de industria o comercio por tiempo de uno a seis años y multa del tanto al triplo del valor del beneficio o ventaja, y para la persona jurídica es de multa de uno a tres años.

Las penas se imponen a las personas jurídicas por cada delito del que deriva su responsabilidad penal. A modo de ejemplo, algunas de las sanciones que impone el Código Penal español son: (i) multas; (ii) disolución de la persona jurídica; (iii) suspensión de su actividad por periodo máximo de cinco años; (iv) clausura de locales y establecimientos de la persona jurídica por un periodo máximo de cinco años; (v) prohibición de que la persona jurídica siga participando en actividades en cuyo ejercicio se haya cometido el delito, por un periodo temporal de hasta quince años o por tiempo indefinido; (vi) inhabilitación de la persona jurídica a percibir subvenciones u otras ayudas públicas, para contratar con el sector público, y para beneficiarse de beneficios e incentivos fiscales o de la Seguridad Social, por un plazo que no podrá exceder de quince años; (vii) intervención judicial durante el tiempo considerado necesario, sin que pueda exceder de cinco años.

Además, durante las diligencias previas, el juez de instrucción puede ordenar, como medida cautelar, la clausura temporal de locales o establecimientos de la persona jurídica, la suspensión de su actividad, o cualquier otra intervención que considere apropiada.

El Código Penal español establece que, en la aplicación de estas penas - con exclusión de la pena de multa - se deben tener en cuenta las siguientes circunstancias: (i) su necesidad para evitar la continuidad de la actividad delictiva o de sus efectos, (ii) sus consecuencias económicas o sociales, especialmente para los empleados, y (iii) el puesto que ocupa en la estructura de la persona jurídica la persona física que no cumplió con su deber control.

Contracts with Healthcare Professionals and Medical Institutions

There are many types of contracts with healthcare professionals and medical institutions, depending on the purpose and objectives of the contract. As indicated above, contracts for the purpose of encouraging the prescription or dispensing of medical products are prohibited, regardless of the fact that such a contract may have a legally-acceptable purpose.

In order to examine the legal requirements to be met, we will divide contracts into the following categories: clinical trial contracts; post-authorization contracts; market research studies contracts; and scientific consulting and advisory contracts with healthcare professionals and entities composed of healthcare professionals.

Clinical Trial Contracts

The requirements for clinical trial contracts are to be found in Royal Decree 223/2004, which incorporate Directive 2001/20/EC of April 4. Clinical trials must have prior authorization from the Medicines and Medical Devices Agency and from the Ethics Committee of the corresponding hospital or healthcare institution where they will be carried out. The Ethics Committee will examine the trial protocol.

The purpose of this type of contract is not the promotion of medical products, but the study of some of the elements necessary for their initial authorization or later modifications of the technical data sheets or CE marking. Due to the scientific rigor with which they are prepared and reviewed and their eminently-scientific goals, these trials should have nothing to do with the promotion of medical products. The promotion of medical products that have not obtained the relevant authorization is prohibited.

Post-Authorization Contracts

Studies carried out after authorization is granted are included among the pharmacovigilance activities for medicines. These studies are carried out on authorized medicines and must adhere to the content of the summary of technical characteristics. Their goal is to identify or quantify a specific aspect of the medicine's safety profile. Here, we will refer to observation studies rather than Phase IV clinical trials.

Royal Decree 1344/2007, of 11 October 2007 governing the pharmacovigilance of medicines for human use, defines post-authorization

Contratación con las Administraciones Públicas y Fraude

Los contratos de suministro celebrados con las Administraciones Públicas, generalmente a través de procedimientos de concurso, deben ajustarse a las condiciones y requisitos establecidos por la legislación aplicable, así como a los pliegos de cláusulas administrativas generales y particulares y pliego de prescripciones técnicas aplicables. En consecuencia, no son admisibles las ofertas de promoción relativas a contrataciones con las Administraciones Públicas que no tengan encaje en el procedimiento de adjudicación de la contratación previsto legalmente. A título de ejemplo, no son admisibles las ofertas relativas a la entrega de otros productos a precio reducido o sin coste, o la entrega de equipo técnico, salvo que se haya previsto en el pliego de cláusulas administrativas del concurso en cuestión. En particular, no deben realizarse ofertas dirigidas a la adjudicación del concurso, fuera de los cauces del procedimiento de concurso.

La infracción de la normativa administrativa puede conllevar la nulidad de la contratación, con la consiguiente liquidación del contrato y obligación de indemnizar a la parte no culpable de la nulidad, así como una prohibición temporal de contratar con las Administraciones Públicas. Podría incurrirse también en responsabilidad penal si el funcionario público derivase las ofertas recibidas en provecho propio.

Contratos con profesionales sanitarios e instituciones sanitarias

Los contratos con profesionales sanitarios y con instituciones sanitarias pueden ser de muy variada índole, en función del objeto y objetivos de dicho contrato. Como hemos señalado anteriormente, no está permitido celebrar contratos cuyo objetivo sea incentivar la prescripción o dispensación de medicamentos o productos sanitarios, con independencia de que dicho contrato formalmente tenga un objeto lícito.

Para el examen de los requisitos legales a cumplir podemos dividir los contratos en las siguientes categorías: (i) contratos de ensayos clínicos; (ii) contratos relativos a estudios post-autorización; (iii) contratos de estudios de investigación de mercado y (iv) contratos de consultoría y asesoramiento científico con profesionales sanitarios o entidades integradas por profesionales sanitarios.

studies as those studies whose purpose is to complete the information obtained during the clinical development of medicines prior to their authorization, prohibiting those studies whose aim may be to promote the prescription of medicines, and establishing that the health authorities, within the scope of their duties, must provide guidelines on the conditions under which such studies must be carried out, in order to favor those with a real scientific interest and to prevent those with purely a promotional purpose. Such guidelines must be implemented through specific regulations laid down by each Autonomous Community with authority to enforce laws on pharmaceutical products.

In order to ensure that homogenous regulations are established, relevant guidelines have been drafted to serve as guidance and reference points for the implementation of regulations by the different Autonomous Communities in his area. Such guidelines are set forth in Order SAS/ 3470/2009 of 16 December 2009.

In the case of a post-authorization observational prospective follow-up study (post-authorization observational studies in which the patients are selected for their exposure to a certain medicine and are then monitored during a sufficient period of time depending on the event in question after the date when the initial research began), the promoter and the principal researcher must specifically stipulate in the study protocol the procedures that must be followed to ensure that the study does not modify the normal prescription practices of the physician or practices for the dispensing of the drug (in the case of medicines that do not require a prescription). The medicine must be prescribed through the normal channels. If it is viewed that the medicine must be provided through different procedures, this must be properly justified in the protocol.

The guidelines establish a procedure for registration and control by the Autonomous Communities and the Spanish Medicine Agency, which is only applicable to prospective follow-up studies. Any post-authorization prospective follow-up studies avoiding such procedures is not deemed to be authorized and the participation of promoters and health professionals in non-authorized studies is treated as a misdemeanor and is subject to an administrative penalty, without prejudice to any civil, criminal or other liabilities that may arise. Likewise, when the post-authorization observational study is required as a condition in the marketing authorization of the medicinal product, or when it is required by the health authorities to clarify safety issues, or when it forms part of the risk management plan to be carried

Contratos de ensayos clínicos

Los requisitos de los contratos de ensayos clínicos se encuentran regulados por el Real Decreto 223/ 2004 que incorporó la Directiva 2001/ 20/CE, de 4 de abril de 2001. Los ensayos clínicos deben someterse a autorización previa de la Agencia Española de Medicamentos y Productos Sanitarios y del Comité Ético que corresponda al hospital o institución sanitaria donde se vayan a llevar a cabo, el cual examina el protocolo del ensayo.

El objetivo de este tipo de contratos no es la promoción del medicamento o producto sanitario, sino el estudio de alguno de los elementos necesarios para su autorización inicial de comercialización o modificaciones posteriores de su ficha técnica. Por el rigor científico con el que son preparados y revisados y por sus objetivos de carácter eminentemente científico, no deberían suscitar cuestiones relativas a la promoción de medicamentos o productos sanitarios. Recordemos que no está autorizada la promoción de medicamentos o productos sanitarios que no hayan obtenido la correspondiente autorización.

Contratos relativos a estudios de post-autorización

Los estudios post-autorización se enmarcan dentro de las actividades de farmacovigilancia de medicamentos. Estos estudios se llevan a cabo sobre medicamentos autorizados y deben ajustarse al contenido de la ficha técnica. Su objetivo es identificar o cuantificar un aspecto concreto del perfil de seguridad del medicamento. En este apartado nos referiremos a los estudios observacionales y no a aquellos que tienen la consideración de ensayos clínicos en fase IV.

El Real Decreto 1344/2007, de 11 de octubre, que regula la farmacovigilancia de medicamentos de uso humano define a los estudios de post-autorización como aquellos estudios que tienen como finalidad el completar la información obtenida durante el desarrollo clínico de los medicamentos previo a su autorización, prohibiendo que puedan tener como finalidad la promoción de la prescripción de medicamentos y estableciendo que las administraciones sanitarias, en el ámbito de sus competencias, deben regular las condiciones por las que se realizarán dichos estudios, al objeto de favorecer los que tengan verdadero interés científico e impedir los que tengan un fin puramente promocional. Este mandato debe desarrollarse a través de normativas específicas por cada una de las Comunidades Autónomas (CC.AA.) con competencias en ejecución de la legislación sobre productos farmacéuticos.

out by the marketing authorization holder, such study must be authorized by the Spanish Medicinal Products and Medical Devices Agency.

The Farmaindustria Code includes provisions on post-authorization studies, following the recommendations given by the Advisory Commission. The Farmaindustria Code includes the obligation to comply with the relevant legislation in the carrying out of such studies. It establishes that the aim of post-authorization studies must be, in substance, scientific or training-related. The Farmaindustria Code also establishes that the medical and research departments shall be responsible for the design and monitoring of post-authorization studies, and sales persons should only be involved in logistic matters.

Market Research Studies

The Farmaindustria Code also governs market research studies. Market research (including social and opinion research) consists of the systematic collection and interpretation of information on individuals or organizations, using statistical and analytical methods and techniques of the social sciences applied to obtain new perceptions or provide elements of support for decision-making.

In these studies, the identities of respondents are not revealed to the user of the information without their specific consent, nor are respondents contacted for sales actions as a direct result of having provided the information.

In addition, to ensure that market research studies do not represent an inducement to prescription or contain incentives prohibited by the Farmaindustria Code, pharmaceutical companies undertake to:

- communicate existence of the study prior to its start, in accordance with the Rules of Procedure of the Control Bodies of the Code;
- ensure the study does not modify the physicians' prescriptions habits or the pharmacists' dispensing habits;
- have a written protocol in which the study's objectives, methodology, expected results and its use are clearly established;
- ensure that payment to participating professionals must be based on market criteria and be proportionate to the time devoted, the work done, and the responsibilities assumed, and the payment adequately documented; and
- be approved prior to their conduct by the pharmaceutical company scientific service or by the compliance officer.

Con la finalidad de establecer una normativa homogénea, se han elaborado unas directrices que sirven de guía o referencia para los desarrollos normativos de las diferentes CC.AA. en esta materia. Dichas directrices han sido recogidas en la Orden SAS/3470/2009, de 16 de diciembre. Cuando se trate de un estudio post-autorización observacional de seguimiento prospectivo (estudio post-autorización de tipo observacional en el que los pacientes son seleccionados por su exposición a un determinado medicamento y son después seguidos durante un período de tiempo suficiente en relación con el acontecimiento de interés, siendo el periodo de estudio posterior al inicio de la investigación), el promotor y el investigador principal deberán expresar específicamente en el protocolo los procedimientos que se emplearán para garantizar que la realización del estudio no modificará los hábitos de prescripción del médico, o de dispensación del farmacéutico (en caso de medicamentos que no requieran prescripción). La prescripción del medicamento habrá de seguir los cauces habituales. Si se considera necesario un suministro del medicamento diferente al habitual, deberá justificarse apropiadamente en el protocolo.

Las directrices establecen un procedimiento de registro y control por parte de las CC. AA. y de la Agencia Española del Medicamento, que es aplicable únicamente a los estudios de seguimiento prospectivos. Los estudio post-autorización de seguimiento prospectivo que eludan dichos procedimientos se consideran como no autorizados y la intervención de los promotores y profesionales sanitarios en estudios no autorizados se considera como falta y está sujeta a sanción administrativa sin perjuicio de las responsabilidades civiles, penales o de otro orden que puedan concurrir. Asimismo, requerirá la autorización de la Agencia Española de Medicamentos y Productos Sanitarios, todo estudio postautorización de tipo observacional que sea una condición establecida en el momento de la autorización de un medicamento, o bien constituya una exigencia de la autoridad competente para aclarar cuestiones relativas a la seguridad del medicamento, o forme parte del plan de gestión de riesgos que debe llevar a cabo el titular.

El Código de Farmaindustria incluyó, siguiendo las recomendaciones de la Comisión Asesora, una regulación de los estudios post- autorización. El Código de Farmaindustria recuerda la obligación de cumplir con la legislación vigente en la realización de estos estudios y establece que el objetivo de los estudios post- autorización tiene que ser fundamentalmente científico o formativo. El Código de Farmaindustria también establece que los departamentos médicos y de investigación clínica deben ser responsables del diseño y seguimiento de los estudios post-autorización y que el departamento comercial solo podrá estar involucrado en aspectos logísticos.

Scientific Consulting and Advisory Contracts with Healthcare Professionals and Entities Comprised of Healthcare Professionals

The Farmaindustria Code permits using healthcare professionals as consultants and advisors, whether in groups or individually, for services such as speaking at and chairing meetings, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, and participation in market research where such participation involves remuneration and/or travel and boarding expenses. Those arrangements must meet the following requirements:

- A written contract or agreement is agreed in advance of the commencement of the services which specifies the nature of the services to be provided.
- A legitimate need for the services is present.
- The criteria for selecting consultants are directly related to the identified need and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular healthcare professionals meet those criteria.
- The number of healthcare professionals retained is not greater than the number reasonably necessary to achieve the identified need.
- The contracting company maintains records concerning, and makes appropriate use of, the services provided by consultants.
- The hiring of the healthcare professional to provide the relevant service is not an inducement to recommend, prescribe, purchase, supply, sell or administer a particular medicinal product.
- Payment to participating professionals must be based on market criteria and be proportionate to the time devoted, the work done, and the responsibilities assumed, and must be adequately documented. Note that payments shall be made in cash; payments in kind are only permitted with prior authorization of the Unit.
- If a healthcare professional attends an event in a consultant or advisory capacity, the relevant provisions regarding hospitality shall apply (Article 11 of the Farmaindustria Code).

When the contracting of this kind of service for a single project or activity involves paid participation of at least 20 healthcare professionals, the pharmaceutical company must notify such contracting before the services start. Failure to notify these services shall constitute an infringement of this Farmaindustria Code. The above is also applicable to the agreement made with healthcare institutions composed of healthcare professionals.

Estudios de investigación de mercado.

El Código de Farmaindustria regula también los estudios de investigación de mercado. La investigación de mercado (incluye la investigación social y de opinión) consiste en la recopilación e interpretación sistemáticas de información sobre personas u organizaciones, utilizando métodos estadísticos y analíticos y técnicas de las ciencias sociales, aplicadas para obtener nuevas percepciones o aportar elementos de apoyo a la toma de decisiones.

En estos estudios, la identidad de los entrevistados no se revela al usuario de la información sin el consentimiento específico de aquellos, ni los entrevistados son contactados para acciones de venta como resultado directo de haber facilitado información.

Para garantizar que los estudios de investigación mercado no suponen una inducción a la prescripción o puedan contener un incentivo prohibido por el Código de Farmaindustria los laboratorios deberán: Comunicarlos a la USD con carácter previo a su inicio de conformidad con el procedimiento establecido en el Reglamento; Velar que el estudio no modifique los hábitos de prescripción del medico o de dispensación del farmacéutico; Contar con un protocolo por escrito en el que se establezcan claramente los objetivos, la metodología, los resultados previstos y su uso; La remuneración de los profesionales participantes deberá obedecer a criterios de mercado y ser acorde con el tiempo empleado, el trabajo realizado y las responsabilidades asumidas, y deberá estar adecuadamente formalizada; y Ser aprobado de forma previa por el servicio científico del laboratorio.

Contratos de consultoría y asesoramiento científico con profesionales sanitarios o entidades integradas con profesionales sanitarios

El Código de Farmaindustria regula la contratación de profesionales sanitarios de forma individual o en grupos, para la prestación de servicios de asesoramiento o consultoría tales como ponencias en reuniones como conferenciantes o moderador, actividades de formación, reuniones de experto, etc. que impliquen el abono de una remuneración y/o gastos de desplazamiento y manutención. Dichos acuerdos deberán cumplir con las siguientes condiciones:

- existencia de un contrato escrito que especifique la naturaleza de los servicios a prestar.
- identificación de la legítima necesidad de los servicios;
- los criterios utilizados para seleccionar a los consultores están directamente relacionados con la necesidad identificada, y la persona

In their written contracts with consultants, companies are strongly encouraged to include provisions regarding the obligation of the consultant to declare that he or she is a consultant to the company whenever he or she writes or speaks in public about a matter that is the subject of the agreement or any other issue relating to that company. Similarly, companies that employ, on a part-time basis, healthcare professionals that are still practicing their profession are strongly encouraged to ensure that such persons have an obligation to declare his or her employment arrangement with the company whenever he or she writes or speaks in public about a matter that is the subject of the employment or any other issue relating to that company.

The Fenin Code provides for the contracting of health professionals for providing services such as research, advising, consultation, training, studies and conferences, subject to the following requirements:

- Formalization of a written contract, which specifies the services to be provided and the relevant remuneration.
- Remuneration to healthcare professionals for studies, conferences, data-collection or collection of any other type of information available in a healthcare center must be acknowledged and approved by the center at the relevant levels of responsibility.
- Remuneration must be in line with markedt value. It will be subject to taxation and/or withholding, as provided by law, and will be paid for the agreed services or products actually provided. Such services or products should contribute advantages to the medical community.
- In the event hospital resources are used and a remuneration to healthcare professionals exists, the medical center must be a party to the contract.
- The provision of services may not be dependent on any obligation to the use or acquisition of products or services.

responsable de su selección posee el *expertise* necesario para evaluar si los profesionales cumplen esos criterios;

- el número de profesionales sanitarios no supere el número que razonablemente sería necesario para lograr el objetivo;
- la compañía contratante debe mantener un soporte documental de los servicios prestados por los consultores y dar a esos servicios el uso que estaba previsto;
- como ya se ha indicado con anterioridad, la prestación de este tipo de servicios por parte del profesional sanitario no debe constituir un incentivo para la recomendación, prescripción, compra, suministro, venta o administración de un determinado medicamento;
- la remuneración del profesional sanitario deberá obedecer a criterios de mercado y ser acorde con el tiempo empleado, el trabajo realizado y las responsabilidades asumidas, y deberá estar adecuadamente formalizada. Señalar que la remuneración deberá ser dineraria, sólo se permiten remuneraciones en especie si han sido autorizadas de forma previa por la USD.
- cuando el profesional sanitario participe en un evento en calidad de asesor o consultor resultarán de aplicación las condiciones establecidas en materia de hospitalidad (Artículo 11 del Código de Farmaindustria).

Cuando la contratación de este tipo de servicios para un mismo proyecto o actividad conlleve la participación remunerada de al menos 20 profesionales sanitarios, el laboratorio deberá comunicarlo previamente a su inicio. La falta de comunicación de estos servicios constituirá una infracción del Código de Farmaindustria.

Lo anterior es asimismo de aplicación cuando los acuerdos se establezcan con instituciones, fundaciones, sociedades científicas, organizaciones o asociaciones integradas por profesionales sanitarios .

El Código de Farmaindustria recomienda que las compañías farmacéuticas incluyan una cláusula en virtud de la cual el profesional sanitario se compromete a declarar que presta servicios de consultoría al laboratorio, cada vez que escriba o manifieste públicamente respecto de algún asunto objeto de su acuerdo o relacionado con la compañía. Igualmente recomienda que aquellas compañías farmacéuticas que empleen profesionales sanitarios a tiempo parcial (es decir, que ejerzan su profesión) se aseguren de que estos tengan la obligación de declarar su relación con dicho laboratorio, cada vez que escriba o se manifieste públicamente respecto de algún asunto objeto de dicha contratación o relacionados con la compañía.

Recommendations

First analyze the promotional practice the medical product company plans to out in order to identify and revise promotional practices which could be totally or partially outside the law.

Company's should develop a Compliance Program, an internal code for the company's personnel, both those engaged in promotional activities in the company's headquarters and the medical representatives. The code will classify and list the promotional practices the pharmaceutical company decides to engage in. The purpose of the code is to provide an internal control document which will allow the company's management to have on record the identification and classification of the promotional activities carried out, as well as to control and avoid possible liability caused by illegal promotion activities. It is advisable that this document identifies those actions which the pharmaceutical company authorizes, as well as all supporting documentation and the various levels of responsibility and approval involved in carrying them out.

El Código Fenin regula la contratación de profesionales sanitarios para la prestación de servicios tales como la investigación, el asesoramiento, la consultoría, la formación y la realización de estudios y ponencias, sujeto a los siguientes requisitos:

- Formalización de un contrato por escrito donde se especifiquen los servicios a prestar y la remuneración correspondiente.
- La remuneración de profesionales sanitarios por estudios, ponencias, recogida de datos o cualquier otro tipo de información disponible en un centro sanitario deberá contar con el conocimiento y, en su caso, aprobación del centro, a los niveles oportunos de responsabilidad.
- La remuneración será adecuada al valor de mercado, sujeta a las retenciones e impuestos que marque la ley, y se entregará a cambio de los servicios o productos pactados y efectivamente suministrados. Dichos servicios o productos deberán aportar ventajas a la comunidad científica.
- Si se utilizan los recursos de una institución sanitaria y media remuneración, dicha institución deberá ser parte en el contrato.
- Los servicios no podrán estar condicionados a ninguna obligación de uso o adquisición, pasada o futura, de productos o servicios.

Recomendaciones

La primera recomendación es realizar un análisis de las prácticas promocionales que lleva a cabo el laboratorio, a fin de identificar y reconducir prácticas promocionales que puedan no ajustarse en todo o en parte a la legalidad vigente.

Tras este análisis, es conveniente elaborar dentro del Programa de *Compliance* del laboratorio un Código interno dirigido al personal del laboratorio, tanto al personal dedicado a actividades de promoción en la sede de la empresa como al personal de visita médica, donde se clasifiquen y recojan las prácticas promocionales que el laboratorio decide y autoriza llevar a cabo. Su objetivo es obtener un documento de control interno que permita a la dirección de la empresa tener identificadas y clasificadas las acciones promocionales que se desarrollan, así como controlar y evitar las posibles responsabilidades derivadas de una actividad promocional ilícita. Es recomendable que dicho documento identifique las actuaciones que el laboratorio autoriza a llevar a cabo así como la documentación que debe sustentar dicha autorización, y los distintos niveles de responsabilidad y aprobación en su puesta en práctica.

Sverige

Stefan Brandt, Jenny Lundberg

Begränsningar enligt regler för marknadsföring av

läkemedel och medicintekniska produkter

Regelverket

Offentligrättsliga regler

Sverige har två lagar som reglerar läkemedelsindustrins marknadsföring av läkemedelsprodukter till hälso- och sjukvårdspersonal. Läkemedelslagen (1992:859) ("LäL") som innehåller vissa specifika bestämmelser och den generella lagen på marknadsföringsområdet, Marknadsföringslagen (2008:486) ("MFL"). MFL reglerar även marknadsföring av medicintekniska produkter vilka definieras i Lag (1993:584) om medicintekniska produkter ("LMTP").

LäL reviderades i maj 2006 med anledning av implementeringen av direktiv 2001/83/EG om upprättande av gemenskapsregler för humanläkemedel ("Direktivet"). Detta ledde till att bestämmelser infördes i LäL avseende marknadsföring av läkemedel till såväl hälso- och sjukvårdspersonal som till allmänheten. Förtydliganden finns i Läkemedelsverkets föreskrift om marknadsföring av humanläkemedel, LVFS 2009:6. Dessa regler genomför bestämmelserna om marknadsföring i Direktivet.

LäL innehåller ingen definition av vad som utgör marknadsföring. Däremot anges i LVFS 2009:6 om marknadsföring av humanläkemedel att marknadsföring av läkemedel ska avse varje form av information vid uppsökande försäljning, reklamkampanjer eller förmånserbjudanden som syftar till att främja förskrivning, leverans, försäljning eller konsumtion av läkemedel. LVFS 2009:6 anger vissa åtgärder som särskilt skall anses vara marknadsföring, såsom t.ex. läkemedelsreklam som riktas till allmänheten; läkemedelsreklam som riktas till personer som är behöriga att förskriva eller lämna ut läkemedel; besök av läkemedelsrepresentanter hos personer som är behöriga att förskriva läkemedel; och tillhandahållande av varuprover. LVFS 2009:6 anger därefter vissa åtgärder som *inte* skall anses vara marknadsföring av läkemedel, såsom t.ex. märkningen och utformningen av bipacksedlar; korrespondens som krävs för att besvara speciella frågor om ett särskilt läkemedel; och faktamässiga och informativa meddelanden och referensmaterial avseende t.ex. förändringar av förpackningar och varningar

Sweden

Stefan Brandt, Jenny Lundberg

The Regulatory Framework

Regulatory Rules

In Sweden, there are two separate pieces of legislation covering the pharmaceutical industry's marketing of pharmaceutical products to healthcare professionals (and others). The Pharmaceuticals Act (1992:859) (*Läkemedelslagen*) which contains certain specific provisions and the Marketing Practices Act (2008:486) (*Marknadsföringslagen,* "MPA") which relates to marketing in general. The MPA also governs marketing of medical devices as defined by the Medical Devices Act (1993:584) (*Lag om medicintekniska produkter,* "MDA").

The Pharmaceuticals Act was revised in May 2006 in order to implement Directive 2001/83/EC on the Community code relating to medicinal products for human use ("Directive"). The implementation introduced several provisions relating to marketing of pharmaceutical products to healthcare professionals as well as provisions regarding marketing to the general public. Clarifications of the Directive are made in the Medical Products Agency's Regulation (*Läkemedelsverkets föreskrifter*, "LVFS 2009:6") regarding advertisement of pharmaceuticals. These regulations implement the Directive.

The Pharmaceuticals Act does not include any definition of what constitutes advertising or marketing. However, according to LVFS 2009:6, the term "advertising of medicinal products" includes any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products. Thereafter, LVFS 2009.6 lists several measures which specifically should be included in the definition of marketing, such as advertising to the public; advertising of medicinal products to persons qualified to prescribe or supply them; visits by medical sales representatives to persons qualified to prescribe medicinal products and the supply of samples. In addition to this list, LVFS 2009:6 also lists several measures which shall be excluded from the scope of marketing, for instance, the labeling and the accompanying package leaflets; correspondence needed to answer a specific question about a particular

för ogynnsamma reaktioner som ingår i de allmänna försiktighetsåtgärderna i fråga om läkemedel.

Den svenska marknadsföringslagen, MFL, är tillämplig på marknadsföring av alla slags produkter. Begreppet "marknadsföring" definieras i MFL som "*reklam och andra åtgärder i näringsverksamhet som är ägnade att främja avsättningen av och tillgången till produkter*". Denna definition medför att försäljningen av en produkt i sig utgör en marknadsföringsåtgärd. Även verksamhet som har till syfte att främja avsättning av produkter faller inom definitionen. Att ge vetenskaplig information till sjukvårdspersonal kan således falla inom MFL:s tillämpningsområde. Detta innebär att Sverige har två olika definitioner av vad som utgör marknadsföring av läkemedel beroende på vilken lag som skall tillämpas.

Bortsett från MFL och LMTP finns det inga specifika lagar som reglerar marknadsföring av medicintekniska produkter. LMTP implementerar samtliga tre huvudsakliga europeiska direktiv på det medicintekniska området. Direktivens mer detaljerade regler återfinns i en förordning och i fyra kompletterande myndighetsföreskrifter. Därutöver gäller även vissa särskilda bestämmelser i Sverige för sprutor och kanyler. Bestämmelserna återfinns i en förordning, en kungörelse samt i myndighetsföreskrifter.

Medicintekniska produkter definieras i LMTP såsom produkter som enligt tillverkarens uppgift skall användas, separat eller i kombination med annat, för att hos människor enbart eller i huvudsak:

- påvisa, förebygga, övervaka behandla eller lindra sjukdom,
- påvisa, övervaka, behandla, lindra eller kompensera en skada eller ett funktionshinder,
- undersöka, ändra eller ersätta anatomin eller en fysiologisk process, eller
- kontrollera befruktning.

Om produkterna uppnår sina huvudsakligen avsedda verkningar med hjälp av farmakologiska, immunologiska eller metaboliska medel är de dock inte medicintekniska produkter enligt LMTP.

Utomrättsliga regler

Läkemedelsindustriföreningen,("LIF"), en branschorganisation för läkemedelsföretag, har utformat " Läkemedelsbranschens etiska regelverk", senast reviderad 8 december 2011, giltig sedan 1 jan 2012, ("LIF:s Regler"), i syfte att närmare ange läkemedelsföretagens ansvar för information om

medicinal product; and factual, informative announcements and reference material relating, for example, to packaging changes, adverse-reaction warnings as part of general drug precautions.

The general marketing law in Sweden, the MPA, applies whenever marketing any kind of product. Under the MPA, the term "advertising" is seen as part of the broader term "marketing," which is primarily defined as "publicity and other measures in business activity, which aim to promote the sale and supply of products." Consequently, the sale itself, even though entirely passive, is considered to be a marketing measure. In addition, measures which aim to promote the supply of products are included in the definition so that supplying scientific information to, for example, healthcare professionals could be considered as constituting advertising under the MPA. This means that Swedish legislation has two different definitions on what constitutes marketing of pharmaceutical products, depending on which law to apply.

Apart from the PMA, there are no specific laws governing the marketing of medical devices. The MDA implements all of the three main European directives concerning medical devices. Further particulars of the provisions are found in a regulation and in four complementary authority regulations. In addition, there are also certain provisions in Sweden concerning syringes and injection needles found in an ordinance and in authority regulations.

Medical devices are defined in the MDA as products that according to the manufacturere shall be used, separately or together with something else, to or on humans solely or essentially with the objective to:

- prove, prevent, monitor, treat or reduce illness;
- prove, prevent, monitor, treat, reduce or compensate a injury or a functional disorder;
- examine, change or replace the anatomy or a physiological process; or
- control fertilization.

Devices that achive their main intended effect through the use of pharmacologic, immunologic or metabolic substances are not medical devices within the meaning of the MDA.

Self-Regulatory Rules

The Swedish Association of the Pharmaceutical Industry ("LIF"), a trade organization for pharmaceutical companies, has established rules governing drug information in Sweden ("LIF Rules"). LIF's Rules aim to lay down more precisely the responsibility of the pharmaceutical industry for

läkemedel. Dessa regler utgör i praktiken den viktigaste källan i samspelet mellan läkemedelsföretag och hälso- och sjukvårdpersonal. Informationsreglerna bygger på dels gällande regelsystem inom nationell läkemedelslagstiftning respektive EU:s regler på området, dels på utomrättsliga normer, t.ex. Internationella Handelskammarens Grundregler för Reklam och den uppförandekod som antagits av the Pharmaceutical Industries Association inom EFTA (EIFPA Koden).

LIF:s Regler består av fyra kapitel; kapitel I som innehåller regler för läkemedelsinformation till hälso- och sjukvårdspersonal, kapitel II som rör överenskommelser om samverkansformer med hälso- och sjukvården och kapitel III som fastslår etiska regler för samarbete mellan läkemedelsföretag och organisationer/intresseorganisationer. Kapitel IV består av regler för icke - interventionsstudier. .

LIF är huvudman för två kontrollorgan, Informationsgranskningsmannen ("IGM"), och Nämnden för Läkemedelsinformation ("NBL"). Dessa har till uppgift att säkerställa att LIF:s Regler efterlevs. Organen behandlas mer utförligt nedan, men redan här skall nämnas att NBL kan avge vägledande uttalanden i informations- eller marknadsföringsfrågor av större betydelse. Detta kan ske i samband med behandling av ett visst ärende, men det kan också ske på begäran av LIF, IGM, läkemedelsföretag som är medlem i LIF, IML eller FGL, apoteket och sammanslutning av personer verksamma på det medicinska området eller av domstol och annan myndighet.

LIF:s Regler kompletteras med ett antal avtal mellan LIF och olika organisationer inom hälso- och sjukvårdssektorn. Dessa avtal skall reglera läkemedelsföretagens samverkan med representanter från de aktuella organisationerna såsom läkare och forskare avseende t.ex. konsultationer, produktinformation, seminarier och sponsring. De avtal som reglerar sådan samverkan är:

- Avtal om samverkan mellan läkemedelsföretag och sjukvårdspersonal/forskare;
- Överenskommelse om samverkansformer mellan läkemedelsbranschen och medarbetare på apotek;
- Överenskommelse med Sveriges läkarförbund -
- Överenskommelse om samverkansformer mellan läkemedelsföretag och handikapporganisationer.

Dessa avtal kallas nedan gemensamt för LIF Avtalen.

information on drugs, and, in practice, they provide the basis for the relationship between the pharmaceutical industry and healthcare professionals. LIF's Rules are based partly on codified laws, pharmaceutical legislation and other enactments or regulations issued by government agencies and partly on non-statutory provisions such as the International Code of Advertising Practice drawn up by the International Chamber of Commerce and the Code of Practice on the Promotion of Medicines adopted by EFTA's Pharmaceutical Industries Association ("EFPIA Code").
LIF's Rules are divided into four sections: section I contains rules regarding pharmaceutical information to healthcare professionals; section II are agreements on forms of cooperation with the healthcare sector; section III contains the ethical rules for cooperation between pharmaceutical companies and organizations; and section IV comprises the rules for non-intervention studies.

LIF's Rules also set out the duties of the Information Examiner ("IGM") and the Information Practices Committee ("NBL"). IGM and NBL have a duty to ensure that LIF's rules are followed. IGM's and NBL's areas of activity will be discussed more thoroughly below, but it should be mentioned here that NBL may issue a statement of guidance concerning an informational or marketing matter of major importance. This is possible in connection with the consideration of a particular case; and a statement of guidance can also be issued on the request of LIF, IGM, the Swedish Pharmacies, pharmaceutical companies which are members of LIF, associations of persons active in the medical field, or by a court or other public authority.

The LIF's rules are supplemented with several agreements entered into between LIF on the one hand and organizations from the medical sector on the other. These agreements regulate the cooperation between the pharmaceutical companies and representatives from the medical organizations, such as doctors and scientists, in respect of, for instance, consultations, product information, seminars, advisory boards and sponsoring. The agreements regulating such cooperation are as follows:

- Agreement on cooperation between pharmaceutical companies and healthcare professionals / researchers
- Agreement on forms of collaboration between the pharmaceutical industry and employees in pharmacies
- Agreement with the Swedish Medical Association
- Agreement on forms of collaboration between pharmaceutical companies and disability groups

Förutom nationella branschregler och avtal är de europeiska uppförandekoderna, EFPIA Koden och uppförandekoden antagen av the International Federation of Pharmaceutical Manufacturers Association ("IFPMA Koden")., tillämpliga i Sverige sedan den 1 januari 2006 respektive den 1 januari 2007. Bestämmelserna i dessa uppförandekoder är till stor del redan en del av LIF:s Regler och/eller LIF Avtalen, men vissa bestämmelser i koderna har ännu inte blivit en del av nationella branschregler eller avtal. Detta innebär att även dessa uppförandekoder måste iakttas vid marknadsföringen av läkemedel i Sverige. EFPIA Koden innehåller exempelvis riktlinjer för webbsidor som är tillgängliga för hälso- och sjukvårdsmedarbetare, patienter och för allmänheten.

Tillåtna och otillåtna åtgärder

Läkemedelslagen

LäL innehåller en bestämmelse som anger de allmänna kraven som marknadsföringen måste uppfylla. Dessutom innehåller lagen bestämmelser som reglerar vissa specifika marknadsföringsåtgärder.

Den allmänna bestämmelsen i § 21b anger att marknadsföringen av läkemedel skall vara aktuell, saklig och balanserad och främja en ändamålsenlig användning av produkten. Marknadsföringen skall dessutom inte vara vilseledande och skall i övrigt ske i enlighet med god sed för sådan marknadsföring.

God sed avseende marknadsföring av läkemedel innebär att läkemedelsföretagen måste följa antagna standarder på området såsom LIF:s Regler, EFPIA Koden, IFPMA Koden och Internationella Handelskammarens Grundregler för Reklam.

Det tredje stycket av bestämmelsen anger att man i marknadsföringen skall lämna sådan information som är av särskild betydelse för allmänheten eller för de personer som är behöriga att förskriva eller lämna ut läkemedel.

§ 21a i LäL innehåller ett uttryckligt förbud mot marknadsföring av läkemedel som inte godkänts för försäljning i Sverige.

Denna bestämmelse innehåller även vissa specifika regler avseende marknadsföring riktad till allmänheten. I korthet säger dessa regler att marknadsföring inte får riktas till barn och att det är förbjudet att marknadsföra receptbelagda läkemedel till allmänheten, med undantag för vaccinationskampanjer mot infektionssjukdomar.

The agreements above are jointly referred to below as the LIF Agreements.

In addition to the national self-regulatory industry rules and agreements, the European codes of practice (revised yearly), the EFPIA Code (1 January 2006) and the International Federation of Pharmaceutical Manufacturers Association's Code of Pharmaceutical Marketing Practices ("IFPMA Code") (1 January 2007). The rules in these codes are, to a great extent, already part of the LIF's Rules and/or the LIF Agreements, but some of the rules have not yet been adopted in any national self-regulatory industry rules or agreements. Therefore, these codes must also be taken into account when marketing pharmaceutical products in Sweden. The EFPIA Code does, for example, provide guidelines for internet websites available to healthcare professionals, patients and the general public.

Permitted and Prohibited Practices

The Pharmaceuticals Act

The Pharmaceuticals Act contains one provision that lays down the general requirements marketing activities must comply with. The Act also contains provisions which are directed to certain marketing activities.

The general provision in Section 21b states that the marketing of a pharmaceutical product shall be objective, up-to-date and balanced, and encourage appropriate use of the product. The marketing shall moreover not be misleading and shall always be consistent with generally accepted practices for such marketing.

Generally accepted practices in the marketing of pharmaceutical products means that pharmaceutical companies have to comply with established standards such as the LIF's Rules, the EFPIA Code, the IFPMA Code and the International Chamber of Commerce's International Code of Advertising Practice.

The third paragraph of the provision states that marketing shall provide such information that is of special importance to the general public or to the persons qualified to prescribe or supply products.

Section 21a in the Pharmaceuticals Act contains an explicit ban against marketing of pharmaceutical products which have not been granted a market authorization in Sweden.

LäL:s § 21c anger att det företag som fått ett godkännande för försäljning skall ha en funktion inom företaget med vetenskaplig kompetens som skall övervaka informationen om det läkemedel som är föremål för godkännandet.

Marknadsföringslagen

MFL:s materiella bestämmelser består av en generalklausul och en regelkatalog. Generalklausulen har följande innehåll:

"Marknadsföringen skall stämma överens med god marknadsföringssed."

Bestämmelsen uttrycker den grundläggande iden om rättvis marknadsföring

Regelkatalogen som är efter generalklausulen består av en rad konkretiserade bestämmelser när vissa typer av marknadsföringsåtgärder är tillåtna respektive förbjudna. Konkretiserade bestämmelser finns beträffande bl.a. reklamidentifiering, vilseledande reklam, vilseledande förpackningsstorlekar, konkursutförsäljningar, utförsäljningar och realisationer, obeställda produkter samt förmånserbjudanden.

Som framgår av generalklausulens ordalydelse, reglerar denna alla marknadsföringsåtgärder, inklusive de situationer som täcks av regelkatalogen. Om en åtgärd faller in under någon av regelkatalogens bestämmelser är dock fler sanktioner tillämpliga än om åtgärden endast faller in under generalklausulen.

Lagen om medicintekniska produkter

Som redogjorts för ovan finns inte någon specifik lag som reglerar marknadsföring av medicintekniska produkter. Frågan om vilken produktinformation medicintekniska företag är skyldiga att tillhandahålla vid marknadsföring av sina produkter får därför bestämmas från fall till fall. Var god notera att beroende på vilken typ av medicinskteknisk produkt som kommer ifråga kan tillstånd krävas för att föra ut produkten på den svenska marknaden. Tillstånd beviljas av Läkemedelsverket.

Regler om läkemedelsinformation

Som nämnts ovan är LIF:s Regler uppdelade i fyra kapitelavdelningar. I det följande kommenteras endast kapitel I, "Regler för läkemedelsinformation till hälso- och sjukvårdspersonal".

This provision also contains certain rules regarding marketing to the general public. These rules state in short, that marketing may not be directed towards children and that it is prohibited to market prescription pharmaceuticals to the general public, except for vaccination campaigns regarding infectious diseases.

Section 21c states that a holder of a market authorization shall have a function within the company with scientific competence to supervise the information regarding the pharmaceutical product subject to authorization.

The Marketing Practices Act

The MPA's material rules consist of a general rule and a number of specific rules for certain practices. The general rule in section 5 states the following:

"Marketing practices shall be consistent with generally accepted marketing practice."

The provision expresses the basic idea of fair marketing practices.

The specific rules give concrete form to a number of marketing practices and indicate when they are allowed and when they are not. The specific rules contain provisions regarding, for instance, identification in advertisements, misleading advertising, misleading packaging dimensions, clearance sales, discount sales, unsolicited products, and special offers.

The general rule in section 5 covers all marketing practices, including situations covered by the specific rules. However, if a practice is covered by any of the specific rules, then its breach gives rise to additional sanctions than would be the case if it was covered only by the general rule.

The Medical Devices Act

As stated above, the MDA does not contain any specific rules on the marketing of medical devices. Therefore, the question regarding what product information a company is obliged to provide has to be decided on a case by case basis. That being said, please note that, depending on the type of medical device, market authorization may be required in order to place a medical device on the market. Such authorization is granted by the Medicinal Products Agency.

Avdelningen är indelad i följande underavdelningar:

- Avdelning I (1) "Allmänna förhållningsregler för informationens innehåll och utformning". Denna underavdelning innehåller riktlinjer i förhållande till informationens saklighet, vederhäftighet, identifierbarhet, aktualitet, dokumentation och dess åberopande, jämförande information och misskreditering;
- Avdelning I (2) "Allmänna förhållningsregler om informationens spridning". I denna underavdelning anges krav på selektivitet. Informationen skall endast riktas till mottagare som kan antas ha behov av eller intresse för denna. Information som innehåller någon form av varningsinformation skall endast utsändas i form av särskilt meddelande.
- Avdelning I (3) "Särskilda förhållningsregler för vissa informationsmedel m.m." I denna underavdelning definieras skriftlig respektive muntlig information och de förhållningsregler som skall tillämpas i respektive situation samt regler avseende tillhandahållandet av läkemedelsprover, hjälpmedel och presentartiklar.
- Avdelning I (4) "Ansvarsregler". Ansvarsreglerna innehåller regler om ansvarets omfattning, ansvarsbärare och bevisskyldighet.

Gåvoartiklar, representation och sammankomster

Gåvoartiklar

Tillhandahållandet av gåvoartiklar till hälso- och sjukvårdspersonal behandlas i Direktivet men den svenska lagstiftaren har valt att inte implementerat några sådana bestämmelser i den svenska lagstiftningen. Detta ämne behandlas istället i de utomrättsliga reglerna, såsom LIF:s Regler, EFPIA Koden och IFPMA Koden.

LIF:s Regler innehåller följande bestämmelse avseende gåvoartiklar:

> "Gåvoartiklar får utdelas endast med stor återhållsamhet och får endast avse artiklar av ringa värde och som är relevanta (dvs. har medicinsk anknytning) för yrkesutövaren. Med ringa värde avses högst ett belopp som vid var tid är fastställt av LIFs styrelse. På gåvan får inte anges annat än läkemedelsföretagets namn eller namnet på företagets ombud i Sverige och namnet på läkemedlet eller dess generiska namn eller dess varumärke. Annat tryck får ej förekomma."

LIF's Rules

As mentioned above, LIF's Rules are divided into four sections. For the purpose of this handbook, only Section I, (rules governing drug information to healthcare personnel) will be discussed.

The section is divided into different subsections:

- Section I (1) General rules of conduct related to the contents and form of information: In this section, more specific guidelines are given in relation to objectivity, truthful presentation, identification, current knowledge, documentation and references, comparisons, and denigration.
- Section I (2) General rules of conduct in disseminating information: The information shall be distributed selectively. Drug information ought to be directed only towards those who may be presumed to need, or to have an interest in, the information in question. Information containing some kind of warning statement shall be dispatched in the form of a separate communication.
- Section I (3) Special rules of conduct for certain information, etc.: This sub-section defines written and oral drug information and special rules of conduct applying to certain information, and also regulating the provision of drug samples, aids and promotional gifts.
- Section I (4) Responsibility rules: These rules contain provisions on the scope of responsibility, the bearer of responsibility, and the burden of proof.

Gifts, Seminars, Hospitality and Entertainment

Gifts

The provision of gifts to healthcare personnel is addressed in the Directive but the Swedish legislator has not implemented any such rules in the Swedish legislation. Instead, the subject is regulated in the self-regulatory rules, such as the LIF's Rules, the EFPIA Code and the IFPMA Code.

LIF's Rules contain the following provision regarding gifts:

"Gifts may be distributed only with great restraint and may only relate to items of negligible value and that are relevant (i.e., medical-related) to professionals. With negligible value means an amount that at the given time is determined by the LIF Board at the highest. Such articles shall bear the name of the pharmaceutical company or of it's representative in Sweden. In

Det anges också att inga gåvor eller ekonomiska förmåner får tillhandahållas, erbjudas eller utlovas till hälso- och sjukvårdspersonal/på apotek som ett incitament att rekommendera, förskriva, köpa, tillhandahålla, sälja eller administrera läkemedel. Detta överensstämmer med bestämmelserna i EFPIA Koden.

EFPIA Koden anger att inga gåvoartiklar, ekonomiska förmåner eller naturaförmåner får ges, erbjudas eller utlovas till en medarbetare inom hälso- och sjukvården som ett incitament för att förskriva, leverera, sälja eller administrera ett läkemedel. Där läkemedel marknadsförs mot hälso- och sjukvårdspersonal får dock gåvoartiklar, ekonomiska förmåner och naturaförmåner ges, erbjudas eller utlovas under förutsättning att gåvan är av obetydligt värde och att den är relevant för personens yrkesutövning.

IFPMA Koden anger att gåvoartiklar får tillhandahållas om gåvan är av obetydligt värde och relevant för hälso- och sjukvårdsmedarbetarens yrkesutövning. LIF har angivit att sådana gåvoartiklar och liknande gåvor som tillåts enligt bestämmelserna i uppförandekoderna ovan inte skall ha ett marknadsvärde som överstiger 100 kronor.

Utöver gåvoartiklarna ovan anger IFPMA Koden att om nationell lag tillåter så är det även tillåtet att tillhandahålla en hälso- och sjukvårdsmedarbetare med en gåva av obetydligt värde som inte är relaterad till yrkesutövningen, under förutsättning att detta sker sällan och att gåvan ges för att uppmärksamma en betydande nationell, kulturell eller religiös högtid. LIF har angett att sådana personliga gåvor som ges enligt denna bestämmelse inte skall ha ett värde som överstiger 100 kronor.

I Sverige finns ett antal överenskommelser om samverkan som har ingåtts mellan dels olika organisationer inom den privata och offentliga hälso- och sjukvårdssektorn såsom läkare och forskare och dels Swedish Medtech, en branschorganisation för de medicintekniska företagen i Sverige, samt Swedish Labtech, laboratorieleverantörernas branschförening. Enligt Samverkansavtalet är det förbjudet för företag att erbjuda medarbetare inom hälso- och sjukvården förmåner, gåvor eller annan ersättning. Förbudet torde även gälla gåvor till medicinska institutioner eftersom sådana gåvor får anses utgöra indirekta gåvor till institutionens medarbetare.

Sammankomster

LIF Avtalen reglerar bland annat hälso- och sjukvårdspersonals medverkan i vetenskapliga sammankomster och liknande anordnade av olika läkemedelsföretag. Det följer av LIF Avtalen att sådana sammankomster

addition, or instead of the company's or representative's name, a trademark used by the company may be shown. No other markings is permitted."

It is also stated that no gifts or financial benefits may be provided, offered or promised to the healthcare professional / pharmacist as an inducement to recommend, prescribe, purchase, supply, sell or administer a medical product. This is consistent with the provisions of the EFPIA Code.

The EFPIA Code states that no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to a healthcare professional as an inducement to prescribe, supply, sell or administer a medicinal product. However, where medicinal products are being promoted to healthcare professionals, gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons if the gifts are inexpensive and relevant to the practice of medicine or pharmacy. The IFPMA Code states that promotional aids or reminder items may be provided if the gift is of minimal value and relevant to the practice of the healthcare professional. LIF has stated that the value of such promotional aids and similar gifts permitted under these provisions in the EFPIA Code and IFPMA Code should not exceed SEK100.

In addition to the promotional aids and other gifts described above, the IFPMA Code also states that it is permissible, if allowed under local law, to provide healthcare professionals with an inexpensive gift not related to the practice of medicine on an infrequent basis in acknowledgement of significant national, cultural or religious holidays. LIF has stated that the value of such personal gifts should not exceed SEK100.

With regard to medical devices, according to the cooperation agreements (agreements entered into between different organizations within the private and public health and medical care sector like doctors and researchers on one side and Swedish Medtech, a trade organization for the Swedish medical devices companies, and Swedish Labtech, the laboratory suppliers trade organization, on the other), it is not permitted for medical device companies to offer benefits, gifts or other compensation to healthcare professionals. Gifts offered to medical institutions that could be considered as indirect gifts to the healthcare professionals working within the institution, accordingly, are also prohibited.

Seminars

The LIF Rules regulate, among other activities, healthcare professionals' participation in medical conferences and similar events arranged by

skall hållas på deltagarnas arbetsplats eller så nära denna som möjligt. Sammankomster får endast äga rum på andra platser om särskilda skäl av pedagogisk, praktisk, ekonomisk eller liknande natur föreligger. Sammankomster utanför Sverige är endast tillåtna i direkt anslutning till internationell utbildning och internationell vetenskaplig sammankomst om majoriteten av den deltagande hälso- och sjukvårdspersonalen inte är från Sverige och om motsvarande sammankomst inte kan hållas i Sverige.

Inbjudningar och erbjudanden från läkemedelsföretag avseende internationella sammankomster skall enbart ges till sjukvårdshuvudmannen, som sedan får avgöra om det finns några lämpliga medarbetare som bör deltaga i sammankomsten i fråga. Inbjudningar skall med andra ord inte skickas direkt till den enskilda hälso- och sjukvårdsmedarbetaren. Av inbjudan skall det klart framgå tid och plats för sammankomsten samt eventuella sidoarrangemang. Den tidsmässiga omfattningen av och innehållet i det yrkesinriktade programmet skall också tydligt framgå. Syftet med detta är att sjukvårdshuvudmannen skall kunna ta ställning till sammankomstens relevans för medarbetarens kompetenshöjning.

LIF Avtalen innehåller även utförliga regler om vad som får erbjudas en hälso- och sjukvårdsmedarbetare under och i samband med sammankomster och kongresser. Ett läkemedelsföretag får exempelvis aldrig svara för en större del av en hälso- och sjukvårdsmedarbetares kostnad än hela konferensavgiften samt 50 procent av deltagarens kostnad för resa, kost och logi. Vidare får inga sociala aktiviteter eller fritidsaktiviteter tillhandahållas eller erbjudas i samband med sammankomster eller i umgänget i övrigt.

Läkemedelsföretagen får dock bekosta sammanträdeslokaler, föredragshållare, studiematerial och liknande som är nödvändigt för sammankomstens genomförande.

Valet av plats för seminarier, kongresser, sammankomster och liknande regleras även i EFPIA Koden. LIF anger i sin tolkning av EFPIA Koden att läkemedelsföretagen bör undvika att använda platser som är kända för sina fritidsaktiviteter eller som på något annat sätt uppfattas som exklusiva, t.ex. vintersportorter, motorsportsevenemang eller golfturneringar. Detsamma gäller för städer under eller i samband med större internationella evenemang.

Möjligheterna att bekosta kost och logi är mycket begränsade. Enligt Samverkansavtalet är det förbjudet för ett medicintekniskt företag att bekosta sammankomster som anordnas i samband med förberedelse eller genomförande av en offentlig upphandling av produkter som erbjuds av företaget. Beträffande övriga sammankomster är det endast tillåtet att delvis

pharmaceutical companies. According to the LIF Rules, conferences shall normally be carried out at the participants' place of work or as near it as possible. Conferences may be held in other locations only where pedagogical, practical, economic or other similar reasons so dictate. Conferences outside Sweden are only permitted in direct connection with international training and scientific conferences if the majority of the participating professionals are not from Sweden and equivalent sessions cannot be held within Sweden.

Invitations and offers from pharmaceutical companies regarding international scientific conferences or congresses shall be made to the healthcare professionals' employer, who will determine whether there are any suitable candidates to participate in the congress. The invitations shall, in other words, not be sent directly to an individual healthcare professional. The time and location and any additional activities involved with the conference shall be clearly set out in the invitation. The duration and content of the agenda shall also be apparent. The aim is that the employer should be able to determine the relevance of the conference for the professional's training and development.

The LIF Rules contain extensive regulations on what can be provided for the healthcare professionals during and in connection with conferences and congresses. For instance, pharmaceutical companies may never compensate the participants for more than the entire conference fee and 50 percent of the cost of travel, food and accommodation, and that no social or recreational activities may be provided or offered in connection with the conferences or related events.

The pharmaceutical companies may, however, pay for conference facilities, speakers, and study materials and similar items which are necessary to carry out the conference or congress.

The choice of venues for seminars, congresses, and conferences and similar events is regulated in the EFPIA Code. LIF states in its interpretation of the EFPIA Code that pharmaceutical companies should avoid using venues that are known for leisure activities, or in other ways viewed as exclusive, e.g., winter sports resorts, motoring events or golf tournaments. The same applies to cities during or in connection with major international events.

With regard to medical devices, the abilityto provide for hospitality is limited. According to the cooperation agreements, it is prohibited for a medical devices company to pay for meetings in connection with preparations or executions of public procurements concerning products being

bekosta resa, kost och logi samt konferensavgift. En förutsättning är dock att sammankomsten sker i fortbildningssyfte och att såväl sammankomst som resa, kost och logi präglas av måttfullhet och kan granskas öppet. Deltagarna eller deras arbetsgivare skall alltid svara för en skälig andel av kostnaderna, vilket innebär att ett företag aldrig får svara för en större del av kostnaderna än hela konferensavgiften eller av halva kostnaden för resa, kost och logi.

Alla måltider vid sammankomster skall präglas av stor måttfullhet. Alkoholhaltiga drycker får endast erbjudas i begränsad omfattning och enbart som måltidsdryck. Sprit får överhuvudtaget inte förekomma. Varken i samband med sammankomster eller umgänget i övrigt får övriga sociala aktiviteter eller fritidsaktiviteter erbjudas.

Befrämjande åtgärder

Läkemedelsprover

LIF:s Regler hänvisar i fråga om läkemedelsprover till vad som anges i Läkemedelsverkets föreskrifter.

Enligt Läkemedelsverkets föreskrift LVFS 2009:6 om marknadsföring av humanläkemedel får läkemedelsprover lämnas till den som har tillstånd att bedriva öppenvårdsapotek, öppenvårdsapotekets läkemedelsansvarig, detaljhandlare som har rätt att sälja läkemedel samt till farmaceut utsedd av vårdgivaren vid ett sjukhusapotek. Läkemedelsprover får endast lämnas ut som ett svar på en skriftlig beställning som daterats och undertecknats. Beställningarna måste sparas och arkiveras av läkemedelsföretaget och läkemedelsföretaget måste även kontrollera att beställaren är behörig att förskriva eller lämna ut läkemedel. Läkemedelsprover måste även vara märkta med texten “Gratis läkemedelsprov, inte för försäljning” eller någon annan formulering med motsvarande innebörd och uppgift om utgångsdatum, och skriftlig information som sammanfattar läkemedlets egenskaper bifogas.

Läkemedelsprover skall lämnas ut med stor återhållsamhet. Endast en förpackning av minsta storlek per produkt får lämnas ut varje år till en och samma person. Läkemedelsprover av receptbelagda humanläkemedel får endast avse nya produkter. En produkt är att anse som ny om den har varit allmänt tillgänglig i mindre än två år. Ny styrka eller beredningsform utan ny indikation är inte att anse som en ny produkt..

Läkemedel som är narkotika enligt Läkemedelsverkets föreskrifter (LVFS 1997:12) om förteckningar över narkotika får inte lämnas ut som läkemedelsprov.

supplied by the company. Regarding other meetings, companies are permitted to partly subsidize the conference participant's travel, food, and accommodation costs and conference fees. However, a requirement hereof is that the conference and such travel, food, and accommodation are made with the purpose to educate, are moderate, and can be publicly examined. The participant or the participant's employer shall always be responsible for paying a reasonable proportion of the costs, which means that the company may never be responsible for a larger proportion of the costs of the entire conference fee or half the costs of travel, food, and accommodation costs.

All meals provided at conferences must be very modest. Alcoholic drinks may only be offered in limited quantities and only with food. Spirits may not be offered at all. Neither in conjunction with conferences or other interactions may separate social or recreational activities be provided.

Promotional Activities

Samples

In this area, LIF's Rules refer to the regulations issued by the government agency, the Medical Products Agency.

According to the Medical Products Agency's Regulation LVFS 2009:6 on the distribution of medical samples, free samples of medicinal products can be provided to persons qualified to prescribe the product, and to the head of a pharmacy, a retailor which has the right to supply pharmaceuticals, as well as a pharmacist appointed by the nursing ward of a hospital pharmacy. The sample may only be supplied in response to a written request which has been signed and dated. The request must be kept and filed by the pharmaceutical company and the pharmaceutical company must also check that the person sending the request is authorized to prescribe or dispense medicinal products. The sample must also be marked with "medical sample, not for sale" or other formulations with the same content, as well as the expiry date, and must be accompanied with a written summary of the medicinal product's characteristics.

Samples shall be distributed only with great restraint. Only one package of the smallest size can be supplied each year to the same recipient. Samples may only be distributed of new products. New product means that the product has not been available on the public market for more than two years.

Pharmaceuticals which are classified as narcotics according to the *Läkemedelsverkets* regulations are not allowed to be supplied in samples.

Möjligheten att dela ut varuprover av medicintekniska produkter finns inte uttryckligen reglerad i svensk rätt, men torde vara mycket begränsad. LIF:s Regler som ovan redogjorts för kommer att reglera situationen.

Konsekvenser av att regelverket inte efterlevs

Läkemedelslagen

Läkemedelsverket är den myndighet som har tillsyn över efterlevnaden av LäL. Läkemedelsverket har rätt att på begäran få den information samt meddela de förelägganden och förbud som behövs för efterlevnaden av LäL och de föreskrifter som meddelats med stöd av denna lag. Sådana förfrågningar, förelägganden och förbud kan förenas med vite.

Marknadsföringslagen.

Sanktionerna enligt MFL kan indelas i tre huvudtyper enligt följande:

- förbud vid vite och ålägganden vid vite,
- marknadsstörningsavgift, och
- skadestånd

Förbud vid vite är en generell sanktion och kan användas både vid överträdelser av generalklausulen och av katalogreglerna. Ett förbud innebär att en näringsidkare vid vite förbjuds att fortsätta eller upprepa en åtgärd som befunnits strida mot marknadsföringslagen. Åläggande vid vite kan innebära att en näringsidkare förpliktas lämna information i ett visst avseende.

Om käranden i mål enligt MFL kan visa sannolika skäl för sin talan, kan domstolen meddela interimistiskt förbud eller åläggande. Dessa förbud och ålägganden kan förenas med vite.

Vid brott mot någon av reglerna i regelkatalogen kan domstolen utdöma en marknadsstörningsavgift. Avgiften skall fastställas till mellan 5 000 kronor och 5 000 000 kronor. Avgiften får dock inte överstiga 10 procent av näringsidkarens årsomsättning under föregående räkenskapsår.

Skadestånd enligt MFL kan utdömas vid överträdelse av regelkatalogen eller vid överträdelse av redan meddelade förbud enligt marknadsföringslagen. Överträdelsen skall ha skett uppsåtligen eller av oaktsamhet. Skadeståndregleringen i MFL ger ersättning för ren förmögenhetsskada, t.ex. utebliven vinst eller goodwillförlust. Det finns även möjlighet för domstolen att ta hänsyn till omständigheter av annan än ekonomisk art.

The possibility to hand out samples of medical devices is not explicitly regulated by Swedish law. Hence, the LIF's Rules referred to above will govern the situation.

Consequences of Breach

The Pharmaceuticals Act

The Swedish Medical Products Agency is the authority that supervises compliance with the Pharmaceuticals Act. The Medical Products Agency is entitled to demand such information, and issue such orders and prohibitions necessary to ensure the compliance with the Pharmaceutical Act and the regulations issued based on the act in question. Such demands, orders and prohibitions can be backed by fines.

The Marketing Practices Act

Sanctions under the MPA can be divided into three main types:

- Prohibitions backed by fines and orders backed by fines
- Fines for disruptive marketing practices
- Damages

A prohibition backed by a fine is the main sanction under the MPA. Such a prohibition implies that an undertaking is prohibited from continuing with a measure that has been found contrary to the MPA. An order could mean that an activity is ordered to give information in a certain way.

If a claimant can demonstrate probable cause for his or her claim, the court may make a provisional prohibition or order; these injunctions and orders may be backed by fines.

Where there are breaches of specific rules, the court may impose a fine for disruptive marketing practices. The fine shall be a minimum of SEK5,000 and a maximum of SEK5,000,000. However, the fine may never exceed 10 percent of the undertaking's yearly turnover for the previous financial year.

Damages can be imposed for breaches of specific rules or in cases of breach of previous prohibitions under the MPA. The breach must have been caused intentionally or negligently. Damages under the MPA cover purely financial loss, for example, loss of goodwill, and there is even the possibility that the court may take into consideration circumstances which are not of an economic nature.

I syfte att verkligen säkerställa att vilseledande marknadsföring upphör, kan domstol vid överträdelser av regelkatalogens bestämmelser och vid överträdelser av vitesförbud besluta om utplånande av vilseledande framställningar.

Lagen om medicintekniska produkter

Läkemedelsverket är central myndighet för tillsyn och efterlevnaden av LMTP. Läkemedelsverket har rätt att på begäran få den information samt meddela de förelägganden och förbud som behövs för efterlevnaden av LMTP. Sådana förelägganden och förbud kan förenas med vite.

I LMTP stadgas att den som med uppsåt eller av oaktsamhet släpper ut en medicinteknisk produkt på marknaden utan att produkten uppfyller de krav och villkor som ställs på produkten i LMTP eller de föreskrifter som meddelats med stöd av LMTP skall dömas till böter eller fängelse i upp till ett år. Även en person som tar produkten i bruk kan drabbas av samma påföljd.

En tillverkare som underlåter att, i tillämpliga fall, anlita ett anmält organ för att medverka i utvärderingen av en medicinteknisk produkt kan komma att dömas till böter eller fängelse i upp till ett år.

LIF:s Regler

IGM och NBL är två organ som verkar inom det egenåtgärdssystem som LIF upprätthåller inom läkemedelsbranschen. Av Stadgar för Läkemedelsindustrins Informationsgranskningsman och Nämnden för Bedömning av Läkemedelsinformation framgår bland annat följande.

IGM och NBL har till uppgift att verka för att läkemedelsföretag i sin produkt- och företagsinformation samt i övrigt i sin marknadsföring och sitt marknadsuppträdande beaktar LIF:s Regler, tillämpliga rättsliga regler och allmänna utomrättsliga normer om god affärssed inom näringslivet, samt i övrigt iakttar god branschsed.

IGM:s och NBL:s verksamhetsinriktning omfattar främst marknadsbevakning och ärendebedömning. Härutöver får NBL avge vägledande uttalanden, d.v.s. i förtydligande syfte ange vad som är eller bör anses vara god branschsed i ett visst avseende.

IGM har till uppgift att pröva informationsåtgärder beträffande humanläkemedel samt andra marknadsföringsåtgärder och

Where there is a breach of specific rules or where there is breach of a prohibition backed by a fine, the court may order the removal of representations which are misleading.

The Medical Devices Act

The Swedish Medical Products Agency is the authority that supervises compliance with the MDA. The Medical Products Agency is entitled to demand such information, and issue such orders and prohibitions necessary to ensure compliance with the MDA. Such demands, orders and prohibitions can be subject to fines.

In the MDA, it is stated that any person who, intentionally or negligently, places a medical device on the market without the product meeting the demands and conditions set forth by the MDA and the regulations issued based on the act in question, shall be fined or sentenced to imprisonment for a period of up to one year.

A manufacturer that omits hiring a notified body (when this is necessary) to participate in the evaluation of a medical device can be fined or sentenced to imprisonment for a period of up to one year.

LIF's Rules

IGM and NBL are engaged in LIF's self-regulation. The Statutes of the Pharmaceutical Industry's Information Examiner and the Information Practices Committee contain the following principal provisions.

The task of IGM and NBL is to ensure that, regarding their products and company information and other aspects of their marketing activities and conduct, pharmaceutical companies observe LIF's Rules, relevant legal statutory provisions, and general non-statutory criteria for good business practice in the industry, and that they otherwise comply with good industrial practice.

IGM's and NBL's overall activity consists primarily of monitoring the market and assessing cases. In addition, NBL may issue statements of guidance explaining what is or ought to be considered good industrial practice in any particular case.

IGM's task is to consider informational measures concerning medicinal products for human use and other marketing activities concerning medicinal

marknadsaktiviteter avseende humanläkemedel, som IGM finner anledning ifrågasätta vid sin marknadsbevakning eller som i anmälan till IGM ifrågasätts av någon som har talerätt.

NBL har till uppgift att pröva besvär över beslut som IGM meddelat eller ärenden som anmälts av myndighet där MBL utgör första instans. NBL skall även prova informationsåtgärder beträffande annat än humanläkemedel, som i anmälan till NBL ifrågasatts av någon som har talerätt.

Talerätt

Rätt att hos IGM påtala informationsåtgärd eller annan marknadsföringsåtgärd eller marknadsaktivitet som ett läkemedelsföretag vidtagit eller som annan vidtagit för företagets räkning, tillkommer enskild person, företag, sammanslutning samt LIF:s Compliance Officer under vissa omständigheter.

Rätt att hos NBL påtala vidtagen informationsåtgärd eller annan marknadsföringsåtgärd eller marknadsaktivitet tillkommer IGM, enskild person, företag, sammanslutning eller myndighet.

Avgifter hos IGM och NBL

Om IGM i slutligt beslut finner att vidtagen informationsåtgärd eller annan marknadsföringsåtgärd eller marknadsaktivitet är oförenlig med god branschsed, skall företaget ifråga normalt utge IGM-avgift.

I anmälningsärenden, där IGM finner att anmärkning inte skall riktas mot den påtalade åtgärden, skall anmälaren, om denne är eller företräder ett konkurrerande läkemedelsföretag, utge IGM-avgift.

Om NBL, efter att part anfört besvär över IGM:s beslut, ändrar IGM:s beslut att påföra ett läkemedelsföretag avgift, bortfaller skyldighet för läkemedelsföretaget att utge IGM-avgift. I sådana fall skall i normala fall i stället motparten, om detta är ett läkemedelsföretag, betala NBL-avgift. Om NBL inte ändrar IGM:s beslut påförs det kritiserade bolaget normalt NBL-avgift.

Avgifterna hos IGM och NBL är maximalt 500 000 kronor.

products intended for human use, which IGM finds cause to question in the course of monitoring the market, or which is questioned in a report to IGM.

NBL considers appeals against decisions taken by IGM and cases reported by a public authority, where these are considered by NBL at first instance. NBL also considers cases concerning informational measures relating to matters other than medicinal products for human use, which, in a report to NBL, have been challenged by a party that is entitled to litigate.

Right To Litigate

The right to complain to IGM about an informational measure, which a pharmaceutical company has itself adopted or which some other party has adopted on its behalf, is held by a private person, a company or an association or under some circumstances, LIF's Compliance Officer.

The right to complain to NBL is held by IGM, a private person, a company, an association, or a public authority.

IGM and NBL Charges

If, in making its decision, IGM finds that the pharmaceutical company in question has adopted an informational measure, marketing measure or activity which is incompatible with good industrial practice, the company shall normally pay an IGM charge.

If, in making its decision in a reported case, IGM finds that criticism may not be leveled at the informational measure about which a complaint has been received, and if the complainant is – or represents – a rival pharmaceutical company, then this company shall normally pay an IGM charge.

If NBL, following a complaint over IGM's decision, changes IGM's decision to impose a pharmaceutical company with an IGM charge, the obligation to pay the charge is set aside. In such cases, generally, the complainant, if this is a pharmaceutical company, shall pay an NBL charge. If NBL upholds IGM's decision, the criticized company shall in general pay an NBL charge.

Both IGM and NBL charges are set to a maximum of SEK500,000.

“Codes of Conduct” (Uppförandekod)

I och med att LIF:s Regler och LIF Avtalen bygger på gällande rättsliga regelsystem och en mängd utomrättsliga normer som ger uttryck för god branschsed, utgör LIF:s Regler och LIF Avtalen för svenskt vidkommande en “sammanställning” av de viktigaste “Codes of Conduct” på området.

Straff-och (Civil)rättsligt ansvar

Enligt brottsbalken kan arbetstagare som för sig själv eller annan tar emot, låter åt sig utlova, eller begär muta eller annan otillbörlig belöning för sin tjänsteutövning, dömas för mutbrott. För att utgöra mutbrott måste belöningen eller förmånen anses otillbörlig. Enligt brottsbalkens förarbeten skall bedömningen av vad som anses vara otillbörligt basera sig på förhållanden i det enskilda fallet. Om man kan fastslå att det finns en vilja att förmå mottagaren av förmånen att göra någonting som denne annars inte skulle ha gjort och som skulle vara till förmån för förmånsgivaren, anses förmånen som otillbörlig. Att förse en medarbetare inom hälso- och sjukvården med gåvor eller liknande belöningar, med avsikt att öka receptförskrivningen av ett visst läkemedel, varigenom hälso- och sjukvårdsmedarbetaren skulle välja bort andra konkurrerande läkemedel utgör mutbrott. Lagen godkänner emellertid konferenser och seminarier i utbildningssyfte och stipendier för forskning som utgörande anständiga förmåner. Enligt förarbetena till paragrafen om mutbrott är det avgörande huruvida förmånen har ett omedelbart samband med och utgör en naturlig och användbar del av mottagarens arbete. Om så är fallet, anses förmånen tillbörlig.

Marknadsföringsåtgärder som liknar muta men som inte utgör mutbrott enligt brottsbalken kan utgöra en överträdelse av generalklausulen i marknadsföringslagen (se Tillåtna och otillåtna åtgärder ovan).

Överenskommelser med hälso-och sjukvårdspersonal

Med undantag för LIF Avtalen som nämnts ovan, finns det ett antal andra avtal inom detta område som ingåtts av LIF.

Mellan LIF och Sveriges kommuner och landsting finns ett avtal benämnt “Huvudöverenskommelse om kliniska prövningar/icke-interventionsstudier av läkemedel”. Syftet med denna överenskommelse är att ange förutsättningarna för parternas samarbete kring klinisk prövning/icke-interventionsstudie av läkemedel som initierats av läkemedelsindustrin och

Professional Codes of Conduct

Given the fact that LIF's Rules and the LIF Agreements are based on codified laws and a certain number of self-regulatory codes on good trade practice, LIF's Rules and the LIF Agreements can be said to represent a compilation of the most important codes of conduct in this area.

Liability Under Criminal and Civil Law

Under the Swedish Penal Code, to receive or to ask for awards in connection with fulfilling professional duties may constitute bribery. To amount to a bribe, the reward or benefit must be considered improper. According to the preparatory works of the statute, the determination of what is to be considered improper is to be based on the circumstances of each specific situation. If it can be established that there is an intention to induce the receiver of the benefit to do something which he or she would not otherwise have done, and which would be to the advantage of the party providing the benefit, the benefit is seen as improper. It seems clear that to provide a healthcare professional with gifts or similar awards, intended to promote prescriptions of a pharmaceutical product, thereby seeking to induce the healthcare professional to select that product before other competing products, would constitute a bribe. However, the legislator has specifically recognized that educational conferences, seminars and grants for research normally constitute proper benefits. According to the preparatory works of the statute on bribery, the test is whether or not the benefit has an immediate connection with, and is a natural and useful ingredient of, the professional duties of the receiver. If this is the case, the benefit is considered proper.

Marketing practices that resemble bribery but do not constitute a crime under the Penal Code could be a violation of the general rule in section 4 of the Marketing Practices Act (see Permitted and prohibited practices above).

Contracts with Healthcare Professionals and Medical Institutions

Apart from the LIF Agreements mentioned above, there are a few other agreements entered into by LIF in this area.

LIF and the Swedish municipality and county councils have entered into a Main Agreement Concerning the Clinical Trial of Medicines. The purpose of this agreement is to state the preconditions for cooperation between the parties in clinical trials of medicines initiated by the pharmaceutical industry,

att utgöra utgångspunkten för avtalet mellan företag och berörd sjukvårdshuvudman. En förutsättning för en klinisk prövning är godkännande från etikprövningsnämnd respektive Läkemedelsverket. Överenskommelsen omfattar kliniska prövningar/icke-interventionsstudie som helt eller delvis finansieras av företag och reglerar förutsättningarna för kliniska prövningar/icke-interventionsstudier samt påbörjandet, genomförandet och avslutandet av kliniska prövningar.

LIF har även upprättat etiska regler avseende samarbetet mellan LIF:s medlemsföretag och organisationer/intresseorganisationer. Med organisationer och intresseorganisationer avses handikappförbund, patientföreningar och anhörigföreningar samt andra intresseorganisationer som bedriver opinionsbildning inom hälso- och sjukvårdsområdet, såsom pensionärsorganisationer, Cancerfonden, Röda Korset, Hjärt-Lungfonden m.fl. Syftet med de etiska reglerna är att säkerställa dels att samarbetet mellan organisationerna och LIF:s medlemsföretag sker på ett ansvarsfullt och meningsfullt sätt, och dels att samarbetet, information och utbildning genomförs på ett sådant sätt att parternas oberoende ställning i förhållande till varandra inte rubbas eller kan ifrågasättas från juridisk eller etisk synpunkt. De etiska reglerna kompletteras med en avtalsmall som kan användas när ett läkemedelsföretag sluter avtal med en organisation eller intresseorganisation.

Rådgivning

Med beaktande av det komplexa regelverk som föreligger på detta område, är det av största vikt att rådgivning till klienter baserar sig på och anpassas till den marknadsföringsåtgärd eller annan åtgärd som klienten avser att vidta.

and to provide the starting point for agreement between the company and the health principal concerned. Subject to the Medical Products Agency's approval of the trial, the agreement covers the conduct of clinical trials of medicines which are partly, or completely, financed by companies.

Furthermore, the agreement contains provisions on preconditions for clinical trials, the start of clinical trials, the conduct of clinical trials and an advisory body.

LIF has also adopted ethical rules as to cooperation between LIF member companies and user organizations/interest groups. Organizations and interest groups mean disability organizations, patient associations and relatives' associations and other interest organizations which form opinion within the health service, such as pensioners' organizations, the Swedish Cancer Society, the Swedish Red Cross and the Swedish Heart-Lung Foundation. The purpose of the ethical rules is to ensure that cooperation between organizations and LIF member companies takes place in a responsible and meaningful manner, and that the cooperation, information and training are also conducted in such a manner that the parties' independence from one another is not jeopardized or questioned from either legal or ethical standpoints. The ethical rules are supplemented by an agreement template which can be used when pharmaceutical companies enters into an agreement with an organization or interest group.

Recommendations

Because of the complexity of the regulatory framework, medical product companies should carefully consider their advertising and other marketing measures.

Schweiz

Peter Reinert

Einleitung

Wie auch Unternehmen in anderen Branchen sind Pharmaunternehmen bestrebt, die Umsätze aus dem Verkauf der von ihnen hergestellten und vertriebenen Arzneimitteln und Medizinprodukten zu fördern. Bei der Förderung der Verkaufstätigkeit sind die Schranken der Rechtsordnung zu wahren. So verbietet das Korruptionsstrafrecht die Gewährung eines nicht gebührenden Vorteils an einen Beamten und die Gewährung eines solchen Vorteils ist auch gegenüber einer Privatperson grundsätzlich strafbar, sofern dessen Arbeitgeber oder Auftraggeber der Vorteilsgewährung nicht zustimmt.

Beim Vertrieb von Arzneimitteln und Medizinprodukten gelten noch weitere Einschränkungen, welche namentlich sicherstellen, dass die Personen, welche Arzneimittel oder Medizinprodukte abgeben oder verschreiben, sich nicht durch finanzielle Anreize in ihrem Abgabe- bzw. Verschreibungsverhalten beeinflussen lassen. Dies erfolgt einerseits durch das grundsätzliche Verbot der Annahme geldwerter Leistungen, aber auch durch die Verpflichtung, gewährte Rabatte an den Patienten bzw. dessen Krankenversicherer weiterzugeben.

Der regulatorische Rahmen

Mit dem Inkrafttreten des Bundesgesetzes über die Heilmittel vom 15. Dezember 2000 (“Heilmittelgesetz”; “HMG”) am 1. Januar 2002 wurde das schweizerische Heilmittelrecht vereinheitlicht. Bis zu diesem Zeitpunkt war praktisch das gesamte Heilmittelrecht – mit Ausnahme der schon damals bundesrechtlich geregelten Medizinprodukte – durch kantonales Recht bzw. durch interkantonale Bestimmungen geregelt.

Die Werbevorschriften finden sich insbesondere in der Verordnung über die Arzneimittelwerbung (“Arzneimittel-Werbeverordnung”; “AWV”) vom 17. Oktober 2001. Daneben enthält Art. 33 HMG Bestimmungen über das Versprechen und Annehmen geldwerter Vorteile. Sowohl die Arzneimittel-Werbeverordnung als auch Art. 33 HMG gelten lediglich für Arzneimittel, nicht auch für Medizinprodukte. Immerhin ermächtigt Art. 51 HMG den

Switzerland

Peter Reinert

Introduction

Like advertising in other industries, medical promotions strive to maximize the turnover resulting from the sale of pharmaceuticals and medical devices that they manufacture or distribute. The marketing has to respect the limits imposed by law. Anti-corruption law prohibits the grant of an undue advantage to an official, and the grant of such an advantage is basically also subject to criminal sanctions if granted to a private person, unless such person's employer or principal approves the advantage.

When selling pharmaceuticals and medical devices, further restrictions apply to ensure, in particular, that persons who supply or prescribe pharmaceuticals or medical devices are not influenced when supplying or prescribing pharmaceuticals or medical devices by financial incentives. This is secured by a general prohibition on accepting any pecuniary advantage, but also by the obligation to pass on any rebates to the patients and their health insurance.

The Regulatory Framework

On 1 January 2002, when the Federal Act on Pharmaceuticals and Medicinal Products (*Bundesgesetz über Arzneimittel und Medizinprodukte*; hereinafter referred to as the "Act") of 15 December 2000 entered into force, Swiss pharmaceutical law was unified. Up to this date, almost the entire pharmaceutical regime, with the exception of medicinal products which were then already regulated by federal law, was regulated by cantonal law or intercantonal regulations.

The advertising rules are in the first place set out in the Ordinance on the Advertising of Pharmaceuticals (*Verordnung über die Arzneimittelwerbung*; "Ordinance") of 17 October 2001. In addition, the Act contains provisions on the promise and acceptance of pecuniary advantages. The Ordinance as well as Article 33 of the Act exclusively apply to pharmaceuticals but not to medicinal products. The Act now at least authorizes the Swiss federal government to issue an ordinance regulating the advertisement of medicinal products. So far, the federal government has not used that power.

Bundesrat zum Erlass von Werbevorschriften auch für Medizinprodukte auf dem Verordnungswege. Bis heute hat der Bundesrat von dieser Kompetenz allerdings keinen Gebrauch gemacht.

Art. 33 HMG verbietet die Gewährung, das Anbieten oder das Versprechen geldwerter Vorteile an Personen, die Arzneimittel verschreiben oder abgeben, aber auch an Organisationen, die solche Personen beschäftigen, sofern diese Vorteile als Gegenleistungen für die Verschreibung oder die Abgabe eines Arzneimittels gewährt werden. Das Verbot ist beidseitig, richtet sich also auch an die Fachpersonen, welche solche geldwerten Vorteile weder fordern noch annehmen dürfen. Art. 33 HMG ist auf sämtliche Situationen anwendbar, in denen das berufliche Verhalten einer Person, die Arzneimittel verschreibt oder abgibt, durch wirtschaftliche Anreize beeinflusst werden könnte. Da ein Grossist weder Arzneimittel abgibt noch verschreibt, hat er keinen Einfluss auf den Entscheid über die Behandlung des Patienten, weshalb die Beziehung zwischen Herstellerin und Grossist nicht unter Art. 33 HMG fällt. Erfasst sind dagegen auch all jene Personen, die ermächtigt sind, Arzneimittel selbständig anzuwenden, wie dies beispielsweise für Hebammen, nicht aber für Assistenten der Fall ist. Ebenfalls nicht unter Art. 33 HMG fallen Arzneimittel, die an jeder Verkaufsstelle frei verkäuflich sind, also keiner Beratungspflicht unterliegen (d.h. Arzneimittel der Kategorie E).

Gemäss Art. 33 Abs. 3 HMG sind (i) geldwerte Vorteile von bescheidenem Wert, die für die medizinische oder pharmazeutische Praxis von Belang sind, sowie (ii) handelsübliche und betriebswirtschaftlich gerechtfertigte Rabatte, die sich direkt auf den Preis auswirken, zulässig. Die genaue Bedeutung dieser zweiten Ausnahme ist umstritten: Immerhin wird allgemein anerkannt, dass es sich um zwei Alternativen handelt: Das schweizerische Heilmittelinstitut Swissmedic, welches für die Durchsetzung von Art. 33 HMG zu sorgen hat, hat in ihrer Publikation zur "Zulässigkeit von Rabatten im Rahmen von Artikel 33 Absatz 3 Buchstabe b des Heilmittelgesetzes" (Swissmedic Journal 11/2003, S. 980 ff.) explizit festgehalten, dass es sich hier um zwei alternative und nicht kumulative Rechtfertigungsgründe handelt.

Zulässig sind damit einerseits betriebswirtschaftlich gerechtfertigte Vergünstigungen, andererseits aber auch darüber hinausgehende handelsübliche Vergünstigungen. Als betriebswirtschaftlich gerechtfertigt gelten Vergünstigungen, die es einem Marktteilnehmer ermöglichen, in einen bestimmten Markt einzudringen, sich den Bedingungen eines bestimmten Marktes anzupassen oder die Wettbewerbsfähigkeit seines Produktes

The Act prohibits the grant, offer or promise of pecuniary advantages to persons who prescribe or supply pharmaceuticals, and also to organizations that employ such persons, provided that such advantages are given as a consideration for the prescription or the supply of a pharmaceutical. The prohibition is directed to both sides, and addresses not only the healthcare industry but also the professional, who may neither ask for nor accept such pecuniary advantages. The Act applies to all situations in which the occupational behavior of a person who prescribes or supplies pharmaceuticals might be influenced by economic incentives. Due to the fact that a wholesaler neither prescribes nor supplies pharmaceuticals, the wholesaler has no influence on the decision on how the patient shall be treated. Therefore, the relationship between manufacturer and wholesaler is not covered by the Act.

However, all persons who are authorized to supply pharmaceuticals on their own, for example, midwives, but not assistants, fall under the prohibition of the Act. Pharmaceuticals that can be sold at any sales outlet without any obligation to advise the patient (pharmaceuticals of category E) are likewise not covered by the Act.

According to the Act, pecuniary advantages of modest value that are relevant for the medicinal or pharmaceutical practice, as well as rebates that are commonly granted in trade and rebates that are economically justified provided they have an effect on the price, are permissible. The meaning of the latter exception has been deleted. At least, it is commonly acknowledged that two alternative forms of advantages are allowed. Swissmedic, the Swiss pharmaceutical regulator which has the task of enforcing the Act, has, in its publication on the permissibility of rebates in the context of Article 33 paragraph 3 lit. b of the Act (*Zulässigkeit von Rabatten im Rahmen von Artikel 33 Absatz 3 Buchstabe b des Heilmittelgesetzes*), explicitly acknowledged that the two forms are alternative rather than cumulative.

Therefore, the following two alternative advantages are permissible: On the one side, rebates that are economically justified or permissible; and on the other side, rebates and advantages that are commonly granted in trade. Advantages which allow a party to penetrate a certain market, to adapt to the conditions of a particular market, or to secure the competitiveness of its products are considered economically justified. Besides rebates in the context of the market launch of a new product, rebates that are granted for a limited period of time when a competitor enters the market are considered economically-justified rebates. Further, economically-justified rebates are

sicherzustellen. Neben Rabatten im Rahmen der Markteinführung eines neuen Produktes handelt es sich hier auch um vorübergehend gewährte Rabatte anlässlich des Auftretens eines neuen Konkurrenten. Zu denken ist weiter etwa an Skonti für die Zahlung innert einer kurzen Frist oder Mengenrabatte, die durch effektive Kosteneinsparungen seitens des Verkäufers begründet sind sowie Vergünstigungen, die für die Benutzung eines bestimmten Bestellmodus' – wie etwa elektronischen Bestellungen - gewährt werden.

Ein darüber hinausgehender Rabatt stellt nach Ansicht von Swissmedic dann eine handelsübliche Vergünstigung dar, wenn er während eines gewissen Zeitraumes im Rahmen der Beziehungen zwischen Medikamentenherstellern und medizinischen Fachpersonen gewährt wurde, so dass letztere davon ausgehen können, auch weiterhin davon zu profitieren. Indem der handelsübliche Rabatt vorhersehbar ist, verliert seinen Einfluss auf die Kaufentscheidung der medizinischen Fachperson, da der Nettopreis (Bruttopreis abzüglich des handelsüblichen Rabatts) als Grundpreis angesehen wird und einzige Bezugsgrösse bildet. Erforderlich ist immerhin, dass der Bruttopreis unabhängig von der Person des Kunden nie angewendet wird.

Von vorne herein keinen geldwerten Vorteil stellen Zahlungen dar, die der Hersteller einem Abnehmer für die Übernahme gewisser Aufgaben zahlt. Nach Ansicht der Swissmedic ist immerhin erforderlich, dass die Änderung in der üblichen Pflichtenverteilung allein im Interesse der vorteilsgewährenden Vertragsparteien liegt. Dies ist etwa dann der Fall, wenn ein Apotheker die Arzneimittel selbst beim Grossisten abholt, statt sie sich liefern zu lassen. Hat die Gegenleistung aber (auch) für den Hersteller oder den Grossisten einen Wert, wird die entsprechende Gegenleistung regelmässig als betriebswirtschaftlich gerechtfertigter Rabatt im Sinne von Art. 33 Abs. 3 HMG qualifizieren.

Art. 33 Abs. 3 HMG verlangt, dass sich handelsübliche und betriebswirtschaftlich gerechtfertigte Rabatte direkt auf den Preis auswirken. Dies muss nach der wohl zutreffenden Ansicht der Swissmedic unabhängig davon gelten, ob die Krankenversicherung die Kosten des Arzneimittels übernimmt. Deshalb sind Rückvergütungen am Ende einer bestimmten Rechnungsperiode unzulässig, da eine Weitergabe an die Patienten und die Versicherer in der Regel ausgeschlossen ist. Eine Ausnahme besteht immerhin im stationären Spitalbereich, weil dort die Weitergabe von Rabatten immer indirekt über die Spitalpauschale erfolgt.

discounts granted for payment within a short payment term or quantity rebates that are justified by actual cost savings on the side of the seller, as well as rebates which are granted for the use of a particular order mode such as electronic orders.

According to Swissmedic, rebates exceeding such advantages constitute rebates commonly granted in trade if they are granted during a certain time period in the context of the relationship between pharmaceutical companies and healthcare professionals in such a way that the healthcare professionals (can be well assumed) to benefit from such rebates in the future. Due to the fact that the rebate commonly granted in trade is predictable, it loses its influence on the purchase decision of the healthcare professional because the net price (gross price minus rebate commonly granted in trade) is considered to be the base price and constitutes the only reference price. It is, however, required that the gross price will, irrespective of the customer, never be applied.

Payments by which the manufacturer pays a consideration to the customer for assuming certain tasks do not constitute a pecuniary advantage from the outset. According to Swissmedic, it is at least required that the change in the ordinary distribution of tasks is in the sole interest of the party that grants the rebate. This is, for example, the case if a pharmacist himself collects the pharmaceuticals at the wholesaler's premises rather than have the wholesaler deliver them to the pharmacy. If, however, the consideration (also) has value for the manufacturer or the wholesaler, the corresponding consideration will regularly qualify as a rebate that is economically justified in the sense of the Act.

The Act requires that the rebate commonly granted in trade or that is economically justified has a direct impact on the price. According to Swissmedic, this has to be the case irrespective of whether the health insurance pays for the costs of the pharmaceutical. Therefore, rebates granted only at the end of a certain period are not permissible because it is generally excluded that the rebate can be passed on to the patients and the health insurances, respectively. An exception applies at least in connection with inpatient treatment because the rebates are always indirectly passed on via the hospital lump sum agreed between health insurances and hospitals.

In the author's opinion, no obligation exists to pass on such rebates to the extent rebates are economically justified because they are motivated by the cost savings of the supplier. It obviously was not the intent of the legislator to abandon any interest on the part of the service recipient in acting in an

Soweit Vergünstigungen betriebswirtschaftlich gerechtfertigt sind, namentlich durch Einsparungen seitens des Lieferanten begründet sind, besteht meines Erachtens keine Pflicht zur Weitergabe dieser Rabatte. Es war klarerweise nicht die Absicht des Gesetzgebers, jegliches Interesse des Leistungsempfängers an einem betriebswirtschaftlich sinnvollen und kosteneffizienten Verhalten im Keim zu ersticken. Dies leuchtet dort ohne weiteres ein, wo der Vergütungsempfänger selbst gewisse Gegenleistungen erbringt, etwa durch vorzeitige Zahlung bei Skonti oder bei der Verschiebung der Lagerhaltungskosten vom Verkäufer zum Käufer, indem dieser weniger, dafür grössere Mengen bestellt und dafür Mengenrabatte erhält. Auch Art. 33 HMG gebietet keine solche Weitergabe, da Art. 33 HMG lediglich verhindern will, dass sich Rabatte auf das Verschreibungs- oder Abgabeverhalten auswirken könnten, was in derartigen Konstellationen ausgeschlossen sein dürfte, da der Leistungsempfänger eine Gegenleistung erbracht hat. Fraglich ist daher, ob in solchen Fällen überhaupt von einem geldwerten Vorteil gesprochen werden kann, da ja eine Gegenleistung erbracht wird.

Als Vorteil von bescheidenem Wert, der zulässig ist, sofern er für die medizinische oder pharmazeutische Praxis von Belang ist, gilt gemäss dem in der parlamentarischen Beratung abgegebenen Votum einer Parlamentarierin ein Betrag bis zu CHF 300 pro Empfänger, Jahr und Firma. Massgebend ist dabei der Wert, den der Vorteilsempfänger zu zahlen hätte. Unerheblich sind dagegen die unter Umständen bedeutend tieferen Selbstkosten des vorteilsgewährenden Unternehmens. Nicht anwendbar ist die Schwelle von CHF 300 dagegen bezüglich Einladungen zu Kongressen.

Gemäss Gesetzestext ist die Gewährung geldwerter Vorteile nur dann verboten, wenn sie für die Verschreibung oder die Abgabe eines Arzneimittels erfolgt. Erhält also beispielsweise ein Apotheker zu Weihnachten eine Schachtel Pralinen oder ein Arzt einen nicht allzu teuren Wein, dürfte die Kausalität zwischen der Vorteilsgewährung und der Abgabe bzw. der Verschreibung eines Arzneimittels nicht gegeben sein. Die Grenzen sind aber auch hier fliessend, da ein sozial nicht adäquates Geschenk wohl nur deshalb gemacht wird, um das Verschreibungs- bzw. Abgabeverhalten der beschenkten Fachperson zu beeinflussen. Die Swissmedic verlangt für die Anwendung von Art. 33 HMG ebenfalls einen gewissen Zusammenhang zwischen Vorteilsgewährung und der Verschreibung oder Abgabe von Arzneimitteln. Ihrer Ansicht nach genügt es jedoch, dass dieser Zusammenhang nur schwach ausgeprägt oder gar versteckt ist und sich unter Umständen auch aus den Begleitumständen herleiten lässt. Dies wäre nach Ansicht der Swissmedic beispielsweise bereits dann der Fall, wenn an einen

economically sensible and cost-efficient way. This is obvious where the recipient of the rebate himself, to a certain extent, provides a certain consideration, for example, by prematurely paying an invoice to obtain a discount or by shifting the storage costs from the seller to the buyer due to the fact that the buyer procures less frequently, but in bigger quantities. Article 33 of the Act does not ask that such rebates be passed on, because this provision exclusively wants to avoid rebates having an effect on the prescription or supply of pharmaceuticals, which is likely excluded under such circumstances. It is also questionable whether, indeed, a pecuniary advantage exists at all, because a consideration exists.

According to the debate in parliament, an amount of up to CHF300 to one recipient, year and company can be considered an advantage of limited value which is permissible provided the advantage is of relevance for the medicinal or pharmaceutical practice. The price which the recipient would have to pay to obtain the advantage, and which might be much higher than the one the party who grants the advantage has to pay, is decisive as to whether the threshold is met. The threshold of CHF300 is, however, not applicable to invitations to congresses.

The wording of the Act only prohibits the grant of pecuniary advantages if they are given as a consideration of the prescription or the supply of a pharmaceutical. Therefore, if, for example, a pharmacist gets a box of chocolates or a physician a bottle of inexpensive wine at Christmas, the causal link between the grant of the advantage and the supply and prescription of the pharmaceutical is arguably not given. However, this situation is not very clear because a present that is not socially adequate will generally only be made to influence the prescription or supply of a pharmaceutical by the professional receiving the gift. Swissmedic also requires a certain connection between the grant of an advantage and the prescription or supply of pharmaceuticals for the application of Article 33 of the Act. However, according to Swissmedic, it is sufficient that this connection is only very weak or even concealed and if it can only be inferred from the circumstances. According to Swissmedic, that would, for example, be the case if healthcare professionals were invited by a pharmaceutical company to a congress or were accompanied to such congress by more employees of the pharmaceutical company than required for merely organizational reasons. Swissmedic argues that such context already qualifies as advertising of healthcare professionals and that advertising in connection with the grant of an advantage qualifies as a prohibited influence. In the author's opinion, this view is very questionable.

Kongress eingeladene Medizinalpersonen von mehr Mitarbeitenden des Pharmaunternehmens begleitet werden, als dies aus rein organisatorischen Gründen erforderlich wäre. Solche Kontakte würden als Fachwerbung qualifizieren und eine Werbung im Zusammenhang mit einer Vorteilsgewährung genügt nach Ansicht der Swissmedic bereits für eine unzulässige Beeinflussung; eine meines Erachtens äusserst fragliche Auffassung.

Der Bundesrat hat im Oktober 2009 ein Vernehmlassungsverfahren zur ordentlichen Revision des Heilmittelgesetzes durchgeführt. Die vorgeschlagene Änderung sieht den Ersatz von Art. 33 HMG durch einen weitgehend identischen neuen Art. 57a HMG vor. Dieser soll nun neu auch auf Medizinprodukte, mit Ausnahme bestimmter, vom Bundesrat festgelegter Kategorien anwendbar sein, dafür aber nur noch auf verschreibungspflichtige Arzneimittel, so dass neu Arzneimittel der Abgabekategorien C und D (d.h. Arzneimittel, die nur nach Fachberatung in Apotheken, Drogerien oder durch selbst dispensierende Ärzte abgegeben werden dürfen) nicht mehr vom Verbot der Vorteilsgewährung erfasst wären. Zudem soll ein neuer Art. 57c HMG Personen, die Heilmittel verschreiben, abgeben oder anwenden sowie Organisation, die solche Personen beschäftigen, verpflichten, ihre Kunden zu informieren über (i) eigene Beteiligungen an Unternehmen, die Heilmittel herstellen oder in Verkehr bringen, (ii) Beteiligungen solcher Unternehmen an der eigenen medizinischen oder pharmazeutischen Praxis oder Organisation sowie (iii) Tätigkeiten in Führungs-, Aufsichts-, Berater- und ähnlichen Gremien solcher Unternehmen sowie generell über die Tätigkeit als Berater oder Experte für solche Unternehmen. Für den Vollzug der Art. 57a - 57c HMG soll nicht mehr wie bisher die Swissmedic, sondern das Bundesamt für Gesundheit zuständig sein. Diese neue Kompetenzzuordnung dürfte für eine konsequentere Durchsetzung der Bestimmungen über die Vorteilsgewährung sorgen, da Swissmedic diesen Bereich nicht als ihre Kernaufgabe ansah. Die Botschaft des Bundesrates an das Parlament dürfte in der zweiten Hälfte des Jahres 2012 erfolgen, so dass bis zum Inkrafttreten der geplanten Revisionsvorlage noch ein paar Jahre vergehen dürften.

Hinzuweisen ist in diesem Zusammenhang auch auf Art. 56 Abs. 3 des Bundesgesetzes über die Krankenversicherung ("KVG") vom 18. März 1994, wonach die Fachperson solche Rabatte an den Patienten oder dessen Krankenversicherer weiterzugeben hat. Diese Verpflichtung gilt allerdings nur im Anwendungsbereich des KVG, d.h. nur für solche Arzneimittel (aber auch Medizinprodukte), die kassenpflichtig sind. Das Bundesamt für Sozialversicherung hat zu diesem Thema drei Empfehlungen erlassen: Die Empfehlung vom 15. März 2002 betreffend die Weitergabe der beim Einkauf

The Federal Government sent a proposal for an amendment of the Act to interested stakeholders in October 2009. The suggested proposal provides for a substitution of the relevant part of the Act by a new article. These two provisions are, to a large extent, identical. However, the new provision shall now also apply to medical devices, with the exception of certain categories of medical devices which shall be designated by the Federal Government. On the other hand, the new Article shall only cover prescription drugs, which would mean that OTC pharmaceuticals of categories C and D (i.e., OTC products which can only be supplied after consultation by a healthcare professional, and exclusively in drug stores or directly by physicians who have the right to supply pharmaceuticals) would no longer be covered by the prohibition on granting advantages. Furthermore, a new Article of the Act shall oblige persons who prescribe or supply therapeutic products as well as organizations which employ such persons to inform their customers of their own ownership in undertakings which manufacture or market therapeutic products; any ownership of such undertakings in their own medical or pharmaceutical practice or organization; their activities in any management or supervisory body, advisory boards and other bodies of such undertakings; as well as any advisory or expert activity for such undertakings. The enforcement of the relevant parts of the Act shall no longer be the task of Swissmedic, but of the Federal Office for Public Health. This new assignment of competence will likely trigger stricter enforcement, because Swissmedic did not consider the enforcement of the prohibition to grant advantages to constitute one of its core tasks. The Federal Government is supposed to submit the proposal of the new Act to the Parliament in the second half of 2012. Therefore, a few years will lapse before the planned amendment will enter into force.

In this context, the Federal Act on Health Insurance (*Bundesgesetz über die Krankenversicherung*; "KVG") of 18 March 1994 has to be mentioned. According to this provision, a professional has to pass on such rebates to the patients or their health insurers. This obligation, however, exists exclusively within the scope of application of the KVG, i.e., only for pharmaceuticals (also medicinal products) whose costs have to be borne by the health insurers. The Federal Office for Social Security has issued three official recommendations with respect to this topic:

- The Recommendation of 15 March 2002 concerning the passing on of rebates obtained when buying pharmaceuticals for consumption in inpatient treatment (*Empfehlung betreffend die Weitergabe der beim Einkauf verwendungsfertiger Arzneimittel erhaltenenVergünstigungen im stationären Spitalbereich*);

verwendungsfertiger Arzneimittel erhaltenen Vergünstigungen im stationären Spitalbereich, die Empfehlung vom 11. Juli 2002 betreffend die Weitergabe der beim Einkauf verwendungsfertiger Arzneimittel erhaltenen Vergünstigungen im ambulanten Bereich und die Empfehlung vom 20. Dezember 2002 betreffend den Umgang mit und die Weitergabe von geldwerten Vorteilen, insbesondere im Zusammenhang mit Weiter- und Fortbildungen.

Erlaubte und verbotene Praktiken

Geschenke, Seminare, Einladungen und Unterhaltung

Wie bereits oben ausgeführt wurde, dürfen Geschenke an Personen, die Arzneimittel verschreiben oder abgeben oder an Organisationen, die solche Personen beschäftigen, in keinem Fall den Betrag von CHF 300 pro Empfänger, Jahr und Firma übersteigen. Im Einzelfall ist jedoch zu prüfen, ob der Maximalbetrag nicht tiefer anzusetzen ist. Nach Meinung dieses Autors ist hier eine Sozialadäquanz zu fordern, d.h. es ist erheblich, aus welchem Anlass ein Geschenk gewährt wird. Ein Geschenk zu einem 60. Geburtstag wird anders beurteilt werden müssen als ein Geschenk im Anschluss an ein ganz gewöhnliches Verkaufsgespräch. Im letztgenannten Fall dürfte insbesondere auch der verpönte Zusammenhang des Geschenkes mit dem Verschreibungs- bzw. Abgabeverhalten nahe liegen, während dies im erstgenannten Fall zumindest fraglich sein kann. Art. 33 HMG verlangt immerhin, dass das Geschenk für die medizinische bzw. pharmazeutische Praxis von Belang sein muss. Immerhin ist denkbar, dass andere sozialadäquate Geschenke – wie etwa eine Flasche Wein zu einer Promotion – vor Art. 33 HMG standhalten, da jeglicher Einfluss auf die Verschreibung und Abgabe von Arzneimitteln ausgeschlossen werden kann.

Die Teilnahme an Aus- und Fortbildungsveranstaltungen dürfen weder direkt noch indirekt mit der Verschreibung, der Abgabe oder dem Einkauf von Arzneimitteln abhängen.

Swissmedic hat im Swissmedic Journal 1/2006 unter dem Titel “Zum Verbot des Versprechens und Annehmens geldwerter Vorteile gemäss Art. 33 des Heilmittelgesetzes, insb. in Zusammenhang mit der Unterstützung der Weiter- und Fortbildung von Medizinalpersonen durch die Pharmaindustrie” festgehalten, wie Swissmedic die Unterstützung der Weiter- und Fortbildung von Medizinalpersonen unter dem Blickwinkel von Art.33 HMG beurteilt. Danach sind Veranstaltungen, die länger dauern als einen halben Tag oder einen umfangreicheren Repräsentationsaufwand aufweisen als eine Pausenverpflegung (bei Veranstaltungen von zwei- bis vierstündiger Dauer)

- the Recommendation of 11 July 2002 concerning the passing on of rebates received when buying pharmaceuticals ready for consumption outside hospitals (*Empfehlung betreffend die Weitergabe der beim Einkauf verwendungsfertiger Arzneimittel erhaltenen Vergünstigungen im ambulanten Spitalbereich*); and,
- the Recommendation of 20 September 2002 concerning the behavior and passing on of pecuniary advantages, particularly in the context of professional development activities (*Empfehlung betreffend den Umgang mit und die Weitergabe von geldwerten Vorteilen, insbesondere im Zusammenhang mit Weiter- und Fortbildungen*).

Permitted and Prohibited Practices

Gifts, Seminars, Hospitality and Entertainment

As set out above, gifts given to persons who prescribe or supply pharmaceuticals, or to organizations that employ such persons may under no circumstances exceed CHF300 per recipient, year and company. It has to be assessed on a case by case basis whether the maximum amount of the gift should be even lower. This author is of the opinion that the gift has to be socially adequate. This means that it is important why a gift is given. A gift given on the occasion of a 60th birthday will have to be considered differently than a gift given at the end of an ordinary discussion on the sale of products. In the latter case, the existence of an illegal causal link between the gift and the prescription or supply, respectively, is likely, while it is at least questionable whether such link is also given in the first case. The application of the Act at least requires that the gift is of importance to medical or pharmaceutical practice. Gifts that are socially adequate, such as a bottle of wine at the occasion of a promotion of a doctor, could comply with the Act because any influence on the prescription and supply of pharmaceuticals can be excluded.

The participation in professional development events may neither directly nor indirectly be contingent upon the prescription, the supply or the purchase of pharmaceuticals.

Under the title “Re prohibition on promising or accepting pecuniary advantages according to Article 33 of the Act, particularly in connection with the support of the professional education of healthcare professionals by the pharmaceutical industry” (*ZumVerbot desVersprechens und Annehmens geldwerterVorteile gemäss Art. 33 des Heilmittelgesetzes, insb. in Zusammenhang mit der Unterstützung derWeiter- und Fortbildung von Medizinalpersonen durch die Pharmaindustrie*) that it published in 2006, Swissmedic stated how it will classify the support of the professional

bzw. ein vorgängiges oder anschliessendes einfaches Mittag- oder Abendessen (bei halbtägigen Veranstaltungen), nur dann mit Art. 33 HMG vereinbar, wenn die eingeladenen Medizinalpersonen einen Selbstkostenbeitrag leisten. Die Höhe dieses Selbstkostenbeitrags ist von verschiedenen Faktoren, wie insbesondere Ort und Dauer sowie Inhalt der Veranstaltung, Inhalt und Umfang des notwendigen Repräsentationsaufwandes, dem Grad einer allfälligen Abhängigkeit der Veranstaltungsorganisation von den Vorteilsgebern sowie der persönlichen Eigenschaft der Vorteilsempfänger abhängig. Grundsätzlich ist aber mindestens ein Drittel der Kosten von den Teilnehmern selbst zu bezahlen. Für Medizinalpersonen in Weiterbildung kann dieser Anteil auf 20% der Kosten reduziert werden und unter bestimmten Umständen kann von der Leistung eines Selbstkostenbeitrages sogar völlig befreit werden. Das Rahmenprogramm einer Veranstaltung darf sodann nicht mehr als 20% des finanziellen und zeitlichen Umfangs der gesamten Veranstaltung ausmachen. Es muss zudem unmittelbar vor, während oder unmittelbar nach der Veranstaltung angeboten werden und dessen einzelne Elemente dürfen gleichzeitig angebotene Teile der wissenschaftlichen Veranstaltung nicht konkurrenzieren. Erfüllen Elemente des Rahmenprogramms diese Voraussetzungen nicht, sind sie von den Teilnehmern vollumfänglich selbst zu bezahlen. Dies gilt auch für den nicht notwendigen Aufwand für Reise, Unterkunft und Verpflegung.
Unzulässig ist klarerweise die Bezahlung von Flügen für Ehegatten, objektiv nicht gerechtfertigter Kosten wie beispielsweise für First Class und nach – zumindest hinsichtlich Interkontinentalflüge diskutabler - Auffassung der Swissmedic auch Business Class Flüge.

Weshalb Medizinalpersonen bei einer eintägigen Weiterbildung in der Schweiz zwingend einen Selbstkostenbeitrag zu leisten haben, leuchtet nicht wirklich ein, zumal den Ärzten infolge des Arbeitsausfalles und weiterlaufender Betriebskosten der Praxis nicht unerhebliche Kosten entstehen, die ihnen selbstverständlich nicht ersetzt werden dürfen. Ein Selbstkostenbeitrag muss meines Erachtens namentlich dann nicht verlangt werden, wenn bei einem eintägigen Anlass nur ein Mittagessen und Pausenverpflegung geboten werden, da die Medizinalperson keinen grösseren Vorteil erhält als der bei einem halbtägigen Anlass erlaubte. Im Übrigen ist nicht einzusehen, weshalb ein Aussendienstmitarbeiter einen Arzt grundsätzlich zu einem Mittagessen einladen darf, derselbe Arzt aber einen Kostenbeitrag zu zahlen hat, wenn das Mittagessen nicht anlässlich eines Vertreterbesuchs erfolgt, sondern anlässlich einer eintägigen wissenschaftlichen Veranstaltung.

development of healthcare professionals under the Act. According to this statement, events that last longer than half a day or have a larger expense than a light meal during breaks (in a case of events between two to four hours) or a preceding or subsequent simple lunch or dinner (in case of half-day events) are only in line with the Act if the invited healthcare professionals pay cost contribution. The amount of the cost contribution depends on various factors like the place, duration and content of the event, the content and extent of the required representation expense, the degree of dependence of the event organization on the supporting entities, if any, as well as the personal qualification of the recipient of the advantage. As a general rule, however, the participants have to bear at least one third of the entire cost. For healthcare professionals in education, this contribution can be reduced down to 20 percent of the costs and, under certain circumstances, they can even be released altogether from the payment of cost contribution. Furthermore, the side program of an event must not exceed 20 percent of the entire cost or time of the entire event. Furthermore, the side program needs to be offered immediately before, during or immediately after the event, and the side program's individual elements must not compete with parts of the scientific event that are scheduled at the same time. If elements of the side program do not meet these criteria, they have to be fully paid by the participants. This also applies with respect to any expense for travel, accommodation and meals that are not required.

Clearly, neither the payment of the flight costs for spouses nor the reimbursement of costs that are not objectively justified like first class tickets or, in Swissmedic's view (which is at least discussable with respect to intercontinental flights), business class flights, are allowed.

To ask healthcare professionals to make a cost contribution if they attend a one-day educational event within Switzerland does not really make sense. This is particularly true because the physicians, due to the fact that they cannot work and that the running costs of their practice continue to run, already incur quite considerable costs which, of course, must not be compensated. Furthermore, it is difficult to see why a sales representative might invite a doctor for lunch but the very same doctor has to make cost contribute if the lunch is not granted in the context of a visit of the sales representative but at the occasion of a one-day scientific event.

The Ordinance states that the expense in connection with scientific seminars needs to be in a reasonable amount and needs to be secondary compared to the main purpose of the event. Participation expenses may not relate to persons who are not authorized to prescribe or supply pharmaceuticals.

Art. 11 Abs. 1 AWV statuiert, dass der Repräsentationsaufwand im Zusammenhang mit wissenschaftlichen Kongressen in einem vertretbaren Rahmen bleiben und in Bezug auf den Hauptzweck der Veranstaltung von untergeordneter Bedeutung sein muss. Er darf sich nicht auf Personen beziehen, welche nicht zur Verschreibung, Abgabe oder zur eigenverantwortlichen beruflichen Anwendung von Arzneimitteln berechtigte Fachpersonen sind.

Promotionsveranstaltungen

Art. 11 AWV verlangt, dass der Repräsentationsaufwand im Zusammenhang mit Promotionsveranstaltungen in einem vertretbaren Rahmen bleibt und in Bezug auf den Hauptzweck der Veranstaltung von untergeordneter Bedeutung ist. Insbesondere darf er sich nicht auf andere als im Gesundheitswesen tätige Personen beziehen. Es ist daher nicht erlaubt, den Ehepartner einer Fachperson ebenfalls an einen Kongress einzuladen. Eine Unterhaltung der teilnehmenden Ärzte an einem Fachkongress ist dagegen nicht grundsätzlich verboten, muss aber gegenüber der berufsbezogenen und wissenschaftlichen Veranstaltung klar in den Hintergrund treten. Dies bezieht sich sowohl auf die Kosten als auch auf den Zeitrahmen, den eine solche Unterhaltung einnimmt.

Unklar ist das Verhältnis von Art. 11 AWV zu Art. 33 HMG, der die Gewährung geldwerter Vorteile grundsätzlich verbietet. Da die Unterhaltung für die medizinische oder pharmazeutische Praxis nicht von Belang ist, könnte sie – zumindest nach dem Wortlaut von Art. 33 HMG – auch nicht von der Ausnahmebestimmung des Abs. 3 profitieren. Solange sich die Unterhaltung aber in sehr bescheidenem Rahmen bewegt, dürfte sie das Verschreibungsverhalten der Fachpersonen nicht beeinflussen. Da der Zweck von Art. 33 HMG darin besteht, eine Beeinflussung des Verschreibungsverhaltens durch unsachliche Anreize zu verhindern, steht meines Erachtens Art. 33 HMG einer solchen Unterhaltung von Ärzten anlässlich von Promotionsveranstaltungen nichts im Wege. Dies wird auch seitens der Swissmedic anerkannt, lässt sie doch ein Rahmenprogramm zu. Unter Rahmenprogramm versteht die Swissmedic dabei lediglich denjenigen Repräsentationsaufwand, der nicht notwendige Leistungen umfasst, die im Umfeld einer Veranstaltung erbracht werden. Immerhin muss eine Medizinalperson gemäss Auffassung der Swissmedic nur dann nicht die gesamten Kosten des Rahmenprogramms bezahlen, wenn sämtliche Elemente desselben unmittelbar vor, während oder unmittelbar nach der Veranstaltung angeboten werden, der damit verbundene finanzielle und zeitliche Umfang 20% des Gesamtaufwandes für die Veranstaltung bzw. ihrer Gesamtdauer

Promotional Activities

The Ordinance requires that the expenses connected toa promotional activity always needs to be of a reasonable amount and need to be of minor importance compared to the main purpose of the event. In particular, the expense may not relate to persons other than persons active in the healthcare business. Therefore, the invitation of a spouse of a healthcare professional to a congress is prohibited. Entertaining physicians at events is not generally prohibited, but needs to be clearly of minor importance compared to the scientific and business-related event, both in terms of costs as well as the duration of such entertainment.

The relationship between the Ordinance and the Act, which in principle, prohibits the grant of pecuniary advantages is not entirely clear. Due to the fact that entertainment is not relevant to a medicinal or pharmaceutical practice, it cannot – at least based on the wording of the Act – benefit from the exemption of the Act. However, as long as the entertainment is very modest, it is unlikely to have an influence on prescriptions by the healthcare professional. In view of the fact that the purpose of the Act is to avoid any influence on prescription activities by irrelevant incentives, this provision, in this author's opinion, does not prohibit secondary and modest entertainment. Swissmedic also allows for a social program. According to Swissmedic, a social program is limited to the representational expense, which relates to performances rendered in the context of an event but are not necessary for such event. In Swissmedic's opinion, a healthcare professional is not required to pay for the entire cost of the social program only if all elements of such social programs are offered immediately prior to, during or immediately after the event and if the related time or financial expense of the social program does not exceed 20 percent of the entire cost or duration of the scientific event, and if the agenda of the social program does not compete with parts of the scientific event that are scheduled at the same time. An exception applies for social program that are organized by the congress organization itself and are covered by the registration fee or paid by the congress organization itself.

Samples

According to the Ordinance, samples may be granted to healthcare professionals only in a small number and upon written request. In principle, not more than five packages may be given to healthcare professionals, but this number further reduces if the packages are of significant value.

nicht übersteigt und die einzelnen Elemente des Rahmenprogramms gleichzeitig angebotene Teile der wissenschaftlichen Veranstaltungen nicht konkurrenzieren (wobei immerhin für das seitens der Kongressorganisation selbst offerierte Rahmenprogramm, das durch die Teilnahmegebühr abgedeckt oder von der Kongressorganisation selbst bezahlt wird, eine Ausnahme gilt).

Muster

Gemäss Art. 10 AWV dürfen an *Fachpersonen* Muster nur in kleiner Anzahl und auf schriftliche Anforderung hin abgegeben werden. An Fachpersonen dürfen grundsätzlich nicht mehr als fünf Packungen abgegeben werden, wobei sich die Zahl abzugebender Packungen reduziert, wenn diese von erheblichem Wert sind. Muster dürfen nicht grösser sein als die kleinste im Handel befindliche Originalpackung. Das Muster muss deutlich sichtbar und dauerhaft als solches gekennzeichnet sein. Es muss die erforderlichen Angaben für die äussere Packung sowie eine genehmigte Packungsbeilage enthalten. Bei Arzneimitteln ohne Packungsbeilage gilt der zuletzt genehmigte Text auf der äusseren Packung. Mit der Musterpackung muss die von Swissmedic zuletzt genehmigte Arzneimittelinformation abgegeben werden. Ist diese im Arzneimittel-Kompendium, im Tierarzneimittel-Kompendium oder in einer von Swissmedic als gleichwertig anerkannten Publikation bereits veröffentlicht, genügt der Hinweis auf diese Publikation. Die sanitätspolizeilich verantwortliche Vertriebsfirma hat zudem sicherzustellen, dass über die Abgabe von Mustern Buch geführt wird.

Die Abgabe von Mustern *an das Publikum* ist für Arzneimittel der Abgabekategorien C, D und E, also nicht verschreibungspflichtige Arzneimittel, möglich. Muster für Humanarzneimittel dürfen allerdings höchstens eine empfohlene Tagesdosis enthalten, müssen deutlich sichtbar und dauerhaft als Muster gekennzeichnet sein und den Anforderungen der Swissmedic an die Angaben und Texte auf Behältern und Packungsmaterial entsprechen. Muster von Arzneimitteln der Abgabekategorien C und D (also nicht verschreibungspflichtigen Arzneimitteln, für die eine Fachberatung erforderlich ist) dürfen dem Publikum nur von den entsprechenden Abgabestellen abgegeben werden (z.B. Apotheken für die Abgabekategorie C). Sie dürfen nicht zur Selbstbedienung angeboten werden. Schliesslich dürfen Muster nicht verkauft werden (Art. 19 Abs. 4 AWV).

Furthermore, samples may not be bigger than the smallest original package admitted on the market. The sample, furthermore, needs to be clearly and permanently marked as such. It needs to contain the latest information normally required for pharmaceuticals. The sample has to be accompanied by the information leaflet that was approved by Swissmedic. If the information leaflet has already been published in the compendium of pharmaceuticals, the compendium of veterinary pharmaceuticals or in another publication that was recognized by Swissmedic as being equivalent, a reference to such publication is sufficient. Furthermore, the firm that is responsible for the distribution has to make sure that the grant of samples is recorded in writing.

The grant of samples to the public is possible for pharmaceuticals of categories C, D and E, i.e., for OTC drugs. Samples that are given to the public, however, have to be limited to the dosage recommended for one single day and have clearly visible directions and be permanently marked as samples. In addition, they have to meet the requirements set by Swissmedic regarding the supply and the information on the packaging. Samples of pharmaceuticals of categories C and D (i.e., OTC-products which require consultation by a healthcare professional) may only be handed out to the public at the appropriate outlets (e.g., drugstores for category C). Self-service is not allowed. Finally, samples must not be sold.

Consequences of Breach

Swissmedic can order a company that seriously or repeatedly violates the Ordinance to submit, during an appropriate period of time, all drafts for any planned promotion, including, in this author's opinion, invitations to healthcare professionals in the form designated by Swissmedic, prior to publishing them for review and prior approval. The company responsible for the distribution has to bear the cost of this review.

According to the Act, the intentional violation of the provisions concerning advertisement for pharmaceuticals can be sanctioned by a fine of up to CHF50,000. If the person who violated those provisions acted on a commercial basis, he can be sanctioned by imprisonment of up to six months and incur a pecuniary fine. A negligent violation can be sanctioned with a fine of up to CHF10,000. In principle, the natural person who committed the illegal act is subject to criminal sanctions. The principal or employer who deliberately or negligently and in violation of a legal obligation does not prevent such a violation from being committed by their employee, mandatee or representative, or does not eliminate its effects, is subject to the same criminal sanctions as the person who is acting on his behalf. If the principal

Folgen einer Verletzung

Swissmedic kann eine Firma, welche schwer oder wiederholt gegen die AWV verstösst, verpflichten, während einer angemessenen Dauer sämtliche Entwürfe für die geplante Werbung – und damit gemäss Erachtens dieses Autors auch Einladungen an Medizinalpersonen – in der von Swissmedic bezeichneten Form vor dem Erscheinen zur Begutachtung und Genehmigung vorzulegen, wobei die Vertriebsfirma die Kosten dieser Begutachtung zu tragen hat.

Gemäss Artikel 87 Absatz 1 lit. b HMG wird mit Busse bis zu CHF 50'000.-- bestraft, wer vorsätzlich gegen die Bestimmungen über die Werbung für Arzneimittel verstösst. Unter diese Bestimmungen fallen insbesondere auch die Regeln über die Vorteilsgewährung an Medizinalpersonen gemäss Art. 33 HMG. Wer gewerbsmässig handelt, kann gar mit Freiheitsstrafe bis zu 6 Monaten und Geldstrafe bestraft werden. Die fahrlässige Begehung wird mit Busse bis zu CHF 10'000.-- bestraft. Strafbar ist grundsätzlich diejenige natürliche Person, welche die Tat verübt hat. Der Geschäftsherr, Arbeitgeber, Vertretene oder Auftraggeber, der es vorsätzlich oder fahrlässig in Verletzung einer Rechtspflicht unterlässt, eine Widerhandlung eines Untergebenen, Beauftragten oder Vertreters abzuwenden oder in ihren Wirkungen aufzuheben, untersteht den Strafbestimmungen, die für den handelnden Täter gelten. Ist der Geschäftsherr, Arbeitgeber, Auftraggeber oder Vertretene eine juristische Person oder eine Personengesamtheit ohne Rechtspersönlichkeit, so sind die schuldigen Organe strafbar. Fällt eine Busse von höchstens CHF 5'000.-- in Betracht und würde die Ermittlung der strafbaren Personen Untersuchungsmassnahmen bedingen, die im Hinblick auf die verwirkte Strafe unverhältnismässig wären, kann von einer Verfolgung dieser Personen Umgang genommen und an ihrer Stelle die juristische Person oder die Personengesamtheit ohne Rechtspersönlichkeit zur Bezahlung der Busse verurteilt werden.

Gestützt auf Art. 100^{quater} StGB ist grundsätzlich sogar denkbar, dass das Unternehmen mit einer Busse bis zu CHF 5 Millionen bestraft wird. Voraussetzung ist allerdings, dass die strafbare gewerbsmässige Handlung wegen mangelhafter Organisation des Unternehmens keiner bestimmten natürlichen Person zugerechnet werden kann, so dass das Vergehen dem Unternehmen, in dem der Verstoss gegen Art. 33 HMG erfolgte, zugerechnet wird.

or the employer is a legal person, the corporate body who should have acted is subject to the criminal sanctions. If the sanction is a fine not exceeding CHF5,000 and if finding the person who is responsible would necessitate an investigation that would be disporportionale considering the sanction, the judge can instead order the legal entity to pay the fine in lieu of the sanction against such person.

Under the Swiss Criminal Code, the pharmaceutical company may be liable for a fine of up to CHF5,000,000, if punishable act can, not be imputed to a specific individual.

Professional Codes of Conduct

Code of Business Conduct of the Pharmaceutical Industry in Switzerland

The associations of the pharmaceutical industry in Switzerland, the Swiss Society of Chemical Industries ("SSCI"), ASSGP, Intergenerika, Interpharma and Vereinigung Pharmafirmen in der Schweiz ("VIPS") on 4 December 2003 adopted the Code of Business Conduct of the pharmaceutical industry in Switzerland ("Pharma Code"). The contracting associations shall encourage so that their members, and manufacturing and trading companies in the pharmaceutical industry to comply with the Pharma Code and sign the relevant declaration. Such a declaration can also be signed by companies who manufacture or distribute pharmaceuticals in Switzerland, even though they are not members of any of the named associations. Companies that agree to observe the Pharma Code have to respect the regulation concerning the procedure in case of violations of the Pharma Code and, in principle, must not bring the matter in front of Swissmedic for a violation of the healthcare law or in front of a court for unfair competition as long as such a procedure is still running. The Pharma Code applies to the promotion of pharmaceutical products aimed at healthcare professionals, to information provided to healthcare professionals on pharmaceuticals, to events in that context and also to the professional development of healthcare professionals. The Pharma Code also regulates the sponsoring of clinical trials with pharmaceuticals.

The Pharma Code regulates the grant of samples. Samples may be supplied to healthcare professionals to familiarize them with the corresponding pharmaceutical products and to enable them to gain experience with the products in practice.

Verhaltensrichtlinien der Berufsverbände

Verhaltenskodex der pharmazeutischen Industrie in der Schweiz

Die Verbände der pharmazeutischen Industrie in der Schweiz, die scienceindustrie (vormals SGCI Chemie Pharma Schweiz), die ASSGP, die Intergenerika, die Interpharma und die vips Vereinigung Pharmafirmen in der Schweiz haben am 4. Dezember 2003 den Verhaltenskodex der pharmazeutischen Industrie in der Schweiz ("Pharmakodex") erlassen. Der Pharmakodex wurde seither mehrmals revidiert, letztmals am 1. November 2011. Die vertragsschliessenden Verbände setzen sich dafür ein, dass sich die ihnen angeschlossenen Herstellungs- und Vertriebsunternehmen der pharmazeutischen Branche dazu verpflichten, den Pharmakodex einzuhalten und die entsprechende Erklärung zu unterzeichnen. Eine solche Erklärung können aber auch Unternehmen abgeben, die Arzneimittel in der Schweiz herstellen und vertreiben und keinem der genannten Verbände angehören. Unternehmen, die sich auf die Einhaltung des Pharmakodexes verpflichten, respektieren bei Verfahren wegen Verstössen gegen den Pharmakodex die entsprechende Vollzugsregelung und verzichten, solange ein entsprechendes Verfahren durchgeführt wird, grundsätzlich darauf, dieselbe Angelegenheit zugleich bei Swissmedic wegen Verletzung des Heilmittelrechts oder bei einem Gericht wegen unlauteren Wettbewerbs anhängig zu machen. Der Pharmakodex regelt die Fachwerbung für Arzneimittel, die Information der Fachpersonen über Arzneimittel sowie die entsprechenden Veranstaltungen und die Weiter- und Fortbildung von Fachpersonen. Der Pharmakodex regelt auch das Sponsoring klinischer Versuche mit Arzneimitteln.

Ziff. 147 Pharmakodex regelt die Abgabe der Muster. Muster dürfen Medizinalpersonen abgeben werden, damit diese das entsprechende Arzneimittel kennen lernen und in der Praxis damit Erfahrungen machen können.

Gemäss Ziff. 211 Pharmakodex sind Symposien, Kongresse und ähnliche Veranstaltungen anerkannte Mittel zur Verbreitung von Wissen und Erfahrung. Hauptzweck dieser Anlässe muss die Vermittlung wissenschaftlicher oder fachlicher Information sein. Der zeitliche Aufwand muss denjenigen für das Rahmenprogramm deutlich überwiegen. Der finanzielle Aufwand für die Veranstaltung soll etwa dem entsprechen, was der Durchschnitt der Teilnehmer von sich aus aufzuwenden bereit wären, wenn sie selbst dafür zu bezahlen hätten.

The Pharma Code states that symposia, congresses and similar events are recognized means for the dissemination of knowledge and experience. The main purpose of such events has to be the imparting of scientific or professional information. The time allotted to scientific and professional education has to clearly outweigh the time for entertainment and hospitality. The financial investment for the event should equate to what the average of the participants would pay if they had to pay themselves for this event. The invitation of healthcare professionals who are not employed by the company that organizes or financially supports the event as participants or speakers may not depend on the suggestion, prescription or supply of certain pharmaceuticals.

Companies may pay adequate fees for speakers and reimburse the expenses they incur by participating in the event, including travel expenses. On the other hand, companies must not pay travel and accommodation costs of persons who merely accompany healthcare professionals to the event.

In principle, companies have to ask the healthcare professionals who participate in an event for an adequate contribution to the costs to secure their independence. These rules equally apply to events that are financially supported by companies. With respect only to events taking place in Switzerland that last for less than one day, no contribution to the costs has to be asked. However, Swissmedic is of the (questionable) opinion that a cost contribution is due even if the event lasts for more than half a day. Companies may neither entirely nor partially reimburse or have reimbursed the cost contributions of the participants.

If companies financially sponsor professional development events that are offered or organized by medical associations, universities, hospitals, healthcare professionals or other institutions, the fact that such an event is financially supported and the identity of the sponsoring companies must be clearly mentioned in the announcement of the event, during the event itself and in publications concerning the event. The sponsoring amounts have to be paid to an account of the organizer that is specifically designed for the event and out of which all speakers and all expenses in connection with the organization and the event itself are paid. The topics of the program have to be designated by the organizer.

The Pharma Code requires that the financial sponsoring of clinical trials be regulated in a written agreement. The agreement has to be duly signed by the company which finances the clinical trial as a sponsor, the healthcare professional who is mainly responsible for the clinical trial, and

Die Einladung von Fachpersonen, die nicht für das veranstaltende oder finanziell unterstützende Unternehmen tätig sind, als Teilnehmer oder Referenten an Veranstaltungen darf nicht von der Empfehlung, Verschreibung oder Abgabe bestimmter Arzneimittel abhängig gemacht werden.

Die Unternehmen können den Referenten angemessene Honorare bezahlen und die ihnen mit der Teilnahme an der Veranstaltung entstehenden Auslagen einschliesslich Reisekosten vergüten. Dagegen dürfen Unternehmen Personen, welche an die Veranstaltung eingeladene Medizinalpersonen begleiten, die mit der Teilnahme an der Veranstaltung verbundenen Reise- und Unterkunftskosten nicht bezahlen. Unternehmen haben von den an einer Veranstaltung teilnehmenden Fachpersonen im Interesse der Unabhängigkeit derselben grundsätzlich einen angemessenen Kostenbeitrag zu verlangen. Diese Regeln gelten auch für Veranstaltungen, die von Unternehmen finanziell unterstützt werden. Lediglich bei Veranstaltungen in der Schweiz, die weniger als einen Tag dauern, kann von einem Kostenbeitrag abgesehen werden. Wie bereits oben ausgeführt, vertritt allerdings Swissmedic die (fragwürdige) Ansicht, dass ein Selbstkostenbeitrag schon dann zu leisten ist, wenn die Veranstaltung länger als einen halben Tag dauert. Die Unternehmen dürfen den Teilnehmern die Kostenbeiträge weder ganz noch teilweise zurückerstatten oder zurückerstatten lassen.

Unterstützen Unternehmen Weiter- und Fortbildungsveranstaltungen, die von Fachgesellschaften, Universitäten, Kliniken, Fachpersonen oder andern Institutionen angeboten oder durchgeführt werden, finanziell, muss bei der Ankündigung der Veranstaltung, an dieser selbst und in Publikationen darüber die Tatsache der finanziellen Unterstützung sowie die Identität der unterstützenden Unternehmen deutlich erkennbar sein. Die Unterstützungsbeiträge sind auf ein speziell dafür bestimmtes Konto des Veranstalters zu überweisen, aus dem die Referenten und sämtliche Aufwendungen für die Organisation und Durchführung der Veranstaltung bezahlt werden. Die Themen der Veranstaltung sind durch den Veranstalter zu bestimmen. Sie sind objektiv und nach dem aktuellen Stand der wissenschaftlichen Erkenntnis zu behandeln.

Der Pharmakodex verlangt, dass die finanzielle Unterstützung klinischer Versuche durch Unternehmen in einem schriftlichen Vertrag zu regeln ist. Die Verträge müssen vom Unternehmen, die den klinischen Versuch als Sponsor finanziert, der Fachperson, die den klinischen Versuch

the institution in which the clinical trial takes place. The consideration for clinical trials which have been carried out in cooperation with institutions has to be paid to an account of the institution with which the clinical trial is carried out. This account has to be audited by an independent person.

The company which sponsors the clinical trial has emphasize the fact that the responsible investigator and his or her employees carry out the clinical trial independently from the interests of the sponsoring company and that they do not have any financial interest in the results of the trial. Obviously, a clinical trial may neither directly nor indirectly be made contingent upon the purchase of pharmaceuticals or other products for therapeutic need or upon certain purchase conditions. The results of clinical trials have, to be published, and in any publication, the fact that the trial was sponsored and the undertakings which sponsored the clinical trial must be mentioned. Furthermore, the relevance of the results has to be assessed taking into account the significance of an illness as well as the clinical and financial expense of the investigated measure.

The Pharma Code also governs the relationship with patient organizations and requests the pharmaceutical undertakings as from the end of the first quarter 2013 to make a list of all patient organizations publicly available to which the undertaking has promised the performance of significant services and to publish the aggregate amounts paid to each patient organization.

The life science industries asked a healthcare professional independent of any member firm to lead the secretariat of the Pharma Code. The Secretariat is responsible for the objective supervision of the advertisement of pharmaceuticals and the information on pharmaceuticals made or initiated by companies as well as for the termination, withdrawal or correction of advertisements and information directed to healthcare professionals by undertakings that clearly violated the Pharma Code. The Secretariat furthermore acts as a mediator to settle disputes between the companies that are involved in a proceeding concerning a suspected violation. Furthermore, the secretariat of the Pharma Code investigates any violation of the Pharma Code.

If an undertaking does not comply with the requirements of the Secretariat within the set deadline, or refuses to accept requirements or if it does not keep its promise to amend a violation, the Secretariat of the Pharma Code, without delay, refers the matter to Swissmedic for final decision.

hauptverantwortlich durchführt und der Institution, in der der klinische Versuch durchgeführt wird, rechtsgültig unterzeichnet werden. Die Abgeltung für klinische Versuche, die im Rahmen von Institutionen durchgeführt werden, muss auf ein Konto der Institution überwiesen werden, bei der der klinische Versuch durchgeführt wird. Das Konto muss von einer neutralen Stelle revidiert werden.

Das Unternehmen, das den klinischen Versuch sponsert, hat darauf zu achten, dass der verantwortliche Prüfer und seine Mitarbeiter den Versuch unabhängig von den Interessen des Sponsors durchführen und kein finanzielles Interesse an den Untersuchungsergebnissen haben. Die Durchführung von klinischen Versuchen darf selbstverständlich weder direkt noch indirekt vom Kauf von Arzneimitteln oder anderen Produkten für den therapeutischen Bedarf oder bestimmten Einkaufskonditionen abhängig gemacht werden. Die Ergebnisse klinischer Versuche sind grundsätzlich zu veröffentlichen und in der Veröffentlichung ist auf die Tatsache der Unterstützung und die sie gewährenden Unternehmen hinzuweisen. Auch ist die Relevanz der Ergebnisse unter Berücksichtigung der Bedeutung einer Krankheit sowie des klinischen und finanziellen Aufwands der untersuchten Massnahme zu bewerten.

Der Pharmakodex regelt auch die Beziehung zu Patientenorganisationen und verpflichtet die Pharmaunternehmen ab dem Ende des 1. Quartals 2013, eine Liste der Patientenorganisationen öffentlich zugänglich zu machen, denen sie die Erbringung bedeutender Dienstleistungen zugesichert haben und die pro Patientenorganisation bezahlten Gesamtbeträge zu veröffentlichen.

Scienceindustries beauftragt eine geeignete firmenunabhängige Fachperson mit der Führung des Pharmakodex-Sekretariates. Dieses sorgt für die objektive Überwachung der von den Unternehmen durchgeführten oder veranlassten Fachwerbung für Arzneimittel und Information über Arzneimittel sowie dafür, dass Unternehmen, die nachweislich gegen den Pharmakodex verstossen haben, die entsprechende Fachwerbung oder Information absetzen, zurückziehen oder korrigieren und hilft bei der einvernehmlichen Beilegung von Meinungsverschiedenheiten unter den an einem Verfahren hinsichtlich eines vermuteten Verstosses beteiligten Unternehmen. Das Pharmakodex-Sekretariat untersucht zudem Verstösse gegen den Pharmakodex.

Folgt das Unternehmen der Anordnung des Pharmakodex-Sekretariates innerhalb der gesetzten Frist nicht oder weigert es sich, dieser zu folgen oder hält es sich nicht an seine Zusicherung, einen Verstoss zu korrigieren, so

Association of the Federal Trade and Industry Associations of the Medical Device Technology ("FASMED")

The Association of the Swiss Trade and Industry Association of the Medical Device Technology ("FASMED") on 26 May 2010 issued the FASMED Code of Conduct which replaced the former Code of Business Conduct of 2003. It applies to the members and their interactions with professionals admitted to practice a profession in Switzerland or elsewhere.

The FASMED Code of Business Conduct is based on four basic principles. The separation principle prohibits any interaction to influence the decision of professionals with regard to products or to make such interaction dependent on the use of the products. According to the transparency principle, the interaction has to be transparent and consistent with local laws, regulations and professional rules. The equivalence principle requires that whenever a member engages a professional to perform a service for or on behalf of the member, the compensation paid for the services rendered must be reasonable and in line with its fair market value. The documentation principle requires that a written agreement be entered into for interactions. Such agreement has to include provisions on the purpose of the interaction, the services to be performed, the compensation and reimbursement of expenses. The intended activities have to be substantiated and evidenced by activity reports or the like. The documentation principle also requires that all documents be retained by the member.

The FASMED Code of Business Conduct prohibits members from directly or indirectly making, offering or promising payments of money or other non-cash benefits to professionals so that they will use the products, or to obtain orders or other benefits.

Agreed services and consideration shall be shown on the invoice or otherwise documented in writing. Non-cash benefits of nominal value which are of relevance to the medical or pharmaceutical practice as well as customary and commercially-justified discounts, which directly affecting, the prize are permissible.

The FASMED Code of Business Conduct prohibits members to directly or indirectly make, offer or promise monetary payments or pecuniary advantages to employees of medical institutions or other healthcare organizations to obtain orders or other advantages. Any performance and the consideration thereof agreed upon in the context of transactions creating a

überweist das Pharmakodex- Sekretariat die Angelegenheit umgehend Swissmedic zur Beurteilung und Erledigung.

Dachverband der Schweizerischen Handels- und Industrievereinigungen der Medizintechnik ("FASMED")

Der Dachverband der Schweizerischen Handels- und Industrievereinigung der Medizintechnik ("FASMED"), die Vereinigung der Medizinprodukte-Hersteller hat am 26. Mai 2010 den FASMED Code of Business Conduct erlassen, welcher den bisherigen Code of Business Conduct 2003 ersetzte. Dieser wendet sich an Mitglieder und ist anwendbar auf deren Interaktionen mit Fachpersonen, die in der Schweiz oder im Ausland zur Berufsausübung zugelassen sind.

Der FASMED Code of Business Conduct statuiert vier Grundprinzipien: Das Prinzip der Trennung verbietet es, die Interaktion durch unzulässige Vorteilsgewährung dafür zu missbrauchen, Entscheidungen der Fachpersonen betreffend den Produkten zu beeinflussen oder von der Verwendung der Produkte abhängig zu machen. Das Prinzip der Transparenz verlangt, dass die Interaktion transparent und im Einklang mit örtlichen Gesetzen, Rechtsvorschriften und Berufsordnungen ist. Gemäss dem Prinzip der Äquivalenz muss sodann die Entschädigung, die einer Fachperson für eine Leistung für oder im Auftrag eines Mitglieds bezahlt wird, angemessen sein und einem fairen Marktwert entsprechen. Das Prinzip der Dokumentation verlangt schliesslich, dass der Interaktion eine schriftliche Vereinbarung zugrunde liegen muss, welche unter anderem den Zweck der Interaktion, die zu erbringenden Leistungen, die Entschädigung und den Auslagenersatz regelt. Die vorgesehenen Aktivitäten müssen substantiiert und durch Tätigkeitsberichte oder Ähnliches belegt sein. Weiter verlangt das Prinzip die Aufbewahrung der entsprechenden Dokumente.

Der FASMED Code of Business Conduct verbietet es Mitgliedern, Fachpersonen direkt oder indirekt Geldzahlungen oder andere geldwerte Vorteile zu gewähren, anzubieten oder zu versprechen, damit diese die Produkte verwenden oder Aufträge oder andere Vorteile zu erhalten. Vereinbarte Leistungen und Gegenleistungen sind auf der Rechnung auszuweisen oder in sonstiger Weise schriftlich zu dokumentieren.

Der FASMED Code of Business Conduct verbietet es Herstellern und Vertreibern von Medizinprodukten, zwecks Einholung von Aufträgen oder um anderer Vorteile willen Mitarbeitern von medizinischen Einrichtungen und sonstigen Leistungserbringern unmittelbar oder mittelbar Geldzahlungen

turnover have to be documented on the invoice or otherwise have to be documented in writing to the medical organization. Rebates that are common in trade and economically justified are permissible provided that they directly have an impact on the price.

Members may offer product training and advanced trainings for professionals in order to facilitate the safe and effective use of their products. The event has to be, however, held in an appropriate setting. Members may offer participants reasonable meals in conjunction with the event and also overnight accommodation for training and advanced training events. Additional hospitality may be appropriate. Hospitality should not reasonable financial limits and should be secondary to the purpose of the event from the standpoint of time and subject matter.

If permitted under the guidelines of professional associations and organizations responsible for such conferences, members may support independent, educational, scientific or guideline-drafting conferences that promote scientific expertise, medical advances and provision of effective healthcare. Members may, in particular, absorb the costs of participation by a particular professional; though costs should be limited to the participation fee and reasonable and actual meals, travel, and lodging costs arising in connection with the participation in the conference. Prior written consent of the hospital administration, the professional's superior or any other responsible agency, with complete disclosure of the purpose and scope of the sponsoring, should be obtained. Members may also provide direct financial support to the organizer in order to reduce the costs of the participants. The organizer must make a written request, and the support must be paid directly to the organizer or educational institution. Members may be involved in specifying the content of the event only to the extent of recommending speakers or commenting on the program upon appropriate request.

Consulting agreements with healthcare professionals may only be entered into when a legitimate need for the corresponding service has been identified in advance. The consultant has to be selected based on his or her qualifications and specialized knowledge in the field of the defined project, and not based on his or her use of the products. Prior written consent of the hospital administration, the professional's superior or any other responsible agency, with complete disclosure of the purpose and scope of the consulting agreement, have to be obtained.

Members may make donations for exclusively charitable or non-profit purposes, provided that the recipient is allowed to accept such donations

oder geldwerte Vorteile anzubieten oder zu gewähren. Vereinbarte Leistungen und Gegenleistungen sind auf der Rechnung auszuweisen oder in sonstiger Weise schriftlich zu dokumentieren. Handelsübliche und betriebswirtschaftlich gerechtfertigte Rabatte, die sich direkt auf die Preise auswirken, sind zulässig.

Mitglieder dürfen Fachpersonen Produkttraining und Aus- bzw. Weiterbildung anbieten, um den sicheren und wirksamen Gebrauch der Produkte zu erleichtern. Die Veranstaltung hat jedoch in einem angemessenen Umfeld stattzufinden. Mitglieder dürfen den Teilnehmenden im Zusammenhang mit der Veranstaltung angemessene Mahlzeiten und bei Aus- bzw. Weiterbildungsveranstaltungen auch Übernachtungsmöglichkeiten anbieten. Weitere Gastfreundlichkeit kann angemessen sein. Jede Gastfreundlichkeit muss sich jedoch in einem angemessenen finanziellen Rahmen bewegen und dem Zweck der Veranstaltung in zeitlicher und thematischer Sicht untergeordnet sein. Mitglieder können auch für die angemessenen und tatsächlichen Kosten für Reise und Unterkunft der Teilnehmer aufkommen.

Mitglieder können unabhängige, bildende, wissenschaftliche oder Richtlinien-gestaltende Konferenzen, welche das wissenschaftliche Fachwissen, den medizinischen Fortschritt und die Bereitstellung effektiver Gesundheitsfürsorge fördern, unterstützen soweit diese gemäss den Richtlinien von Berufsverbänden oder Organisationen solcher Konferenzen zulässig sind. Die Mitglieder können auch die Kosten der Teilnahme einer bestimmten Fachperson übernehmen, wobei sich die Übernahme auf die Teilnahmegebühr sowie angemessene und tatsächliche Kosten für Mahlzeiten, Reise und Unterkunft, die im Zusammenhang mit der Teilnahme an der Konferenz entstehen, beschränken muss. Die vorgängige schriftliche Zustimmung der Spitaladministration, des Vorgesetzten der Fachperson oder einer anderen zuständigen Behörde sollte unter vollständiger Offenlegung des Zwecks und Umfangs des Sponsorings eingeholt werden. Mitglieder dürfen auch den Organisator direkt finanziell unterstützen, um die Kosten der Teilnehmer zu reduzieren. Der Organisator hat eine schriftliche Anfrage zu stellen und die Unterstützung ist direkt an den Organisator oder das Ausbildungsinstitut zu zahlen. Die Mitglieder dürfen bei der Bestimmung des Inhalts der Veranstaltung nur insofern involviert sein, als sie auf entsprechende Anfrage Referenten empfehlen oder das Programm kommentieren.

Beratungsvereinbarungen mit Fachpersonen dürfen nur dann geschlossen werden, wenn vorab ein legitimer Bedarf für die entsprechenden Leistungen

under applicable law. However, donations must not be tied to the use of the products in any way. Furthermore, donations may not be made at the request of a professional unless the professional is an employee of an organization and makes the request on behalf of the organization. The professional's preferred organization should not be supported thereby at the request of such professional. Furthermore members should not have control over the actual use of their donations.

Members may make research grants to support independent medical research. Research grants are permissible to support customer-initiated studies that concern clinical or non-clinical research in areas in which the member has a legitimate interest. All requests for such grants must be made in writing, naming the type and goal of the research activity. No support should be granted until the written agreement is signed. Complete disclosure to the hospital administration or the professional's superior or any other responsible agency is necessary, and the recipient should promise to mention the support of the research by the member in all oral and written presentations of the results.

Liability Under Criminal (and Civil) Law

The Regulatory Framework

The grant of advantages to professors at universities, physicians and pharmacists at hospitals, or other personnel of hospitals could violate the Swiss criminal law relating to corruption. The relevant provisions are embodied in the Swiss Criminal Code (*Schweizerisches Strafgesetzbuch*; "StGB"). Article 323ter StGB prohibits, among others, offering, promising or granting to an official any advantage in favor of such official or any third person that is not due in connection with the official's public activity as a consideration for an activity or an omission that is against the official's duties or is in the official's discretion. From this bribery, the grant of an advantage as described in StGB has to be distinguished. Whoever offers, promises or grants to an official, in view of the exercise of a public function, an advantage that is not due may be sentenced under this provision.

Therefore, not only gifts to a large number of officials, but also specific goodwill payments that do not relate to a specific activity of the official, constitute criminal offences. Nevertheless, only grants that aim at influencing the official are covered. Therefore, the advantage has to be apt to influence the exercise of the public function of an official. StGB states that advantages that the official may accept under the provisions to which he or she is subject,

identifiziert wurde. Der Berater ist auf der Grundlage seiner Qualifikationen und Fachkenntnisse im Bereich des definierten Projektes auszuwählen und nicht aufgrund seiner Verwendung von Produkten. Die vorgängige schriftliche Zustimmung der Spitaladministration, des Vorgesetzten der Fachperson oder einer anderen zuständigen Behörde ist unter vollständiger Offenlegung des Zwecks und Umfangs der Beratungsvereinbarung einzuholen.

Mitglieder können Spenden für ausschliesslich wohltätige oder gemeinnützige Zwecke ausrichten, soweit der Empfänger solche Spenden gemäss dem anwendbaren Recht annehmen darf. Die Spenden dürfen jedoch in keiner Weise an die Verwendung der Produkte geknüpft sein. Auch dürfen Spenden nicht als Antwort auf die Anfrage einer Fachperson gemacht werden. Eine Ausnahme besteht dann, wenn die Fachperson ein Mitarbeiter dieser Organisation ist und die Anfrage im Auftrag der Organisation stellt. Damit sollte auf die Anfrage einer Fachperson nicht die bevorzugte Organisation dieser Fachperson unterstützt werden. Die Mitglieder sollten auch keine Kontrolle über die tatsächliche Verwendung ihrer Spenden haben.

Mitglieder können Forschungszuschüsse gewähren, um die unabhängige medizinische Forschung zu unterstützen. Zulässig sind auch Forschungszuschüsse zur Unterstützung von Kunden-initiierter Studien, die klinische oder nicht-klinische Forschung in Gebieten betreffen, in welchen das Mitglied ein legitimes Interesse hat. Alle Anfragen für solche Zuschüsse müssen schriftlich erfolgen und die Art und das Ziel der Forschungsaktivitäten nennen. Bis zur Unterzeichnung der schriftlichen Vereinbarung sollte keine Unterstützung gewährt werden. Vollständige Offenlegung gegenüber der Spitaladministration oder dem Vorgesetzten der Fachperson oder einer anderen zuständigen Behörde ist notwendig und der Empfänger soll sich verpflichten, die Unterstützung der Forschung durch das Mitglied in allen mündlichen und schriftlichen Präsentationen der Resultate zu erwähnen.

Verantwortlichkeit unter Strafrecht und Zivilrecht

Der regulatorische Rahmen

Die Vorteilsgewährung gegenüber Universitätsprofessoren, Chef- und Assistenzärzten, Spitalapothekern oder sonstigem Spitalpersonal kann gegen das schweizerische Korruptionsstrafrecht verstossen. Die entsprechenden Bestimmungen finden sich in Art. 322ter bis 322^{octies} des Schweizerischen Strafgesetzbuches ("StGB"). Art. 322ter StGB stellt unter anderem unter Strafe, wer einem Beamten in Zusammenhang mit dessen amtlicher Tätigkeit

as well as small and socially common advantages, are not covered by the criminal provision. These provisions only relate to officials. The notion of an official is defined in the StGB and covers institutional as well as functional officials. Therefore, it does not matter in which role the functional official fulfils the public entity. It is however essential that the official carries out a public task. Private persons who discharge a public task equally qualify as officials. Therefore, all healthcare professionals who are employed by a public hospital will likely qualify as officials whether their employment is one under public or private law. Physicians who practice on their own are, on the other hand, clearly not covered by the provisions of the criminal law on corruption unless they perform a public task besides their private activity. Also, wholesalers and employees of pharmacies and drugstores do not fall under the term of an official in the sense of the Swiss criminal code. It is always required, however, that such persons do not perform any public task besides their private activities, and receive advantages in this context. Private physicians who treat their patients in private and also in public hospitals do not discharge any public function. While it is true that safeguarding the public health is a public task, one cannot, for this sole reason, categorize any physician as an official. Rather, categorization as an official requires that the person in question is acting as a representative of public rights and duties, and that the activity in question is discharged on behalf of and not merely instead of the state. Due to the fact that Swiss corruption law aims to protect the objectivity and integrity of public activity, the functional connection has to be stronger the weaker the institutional incorporation into the state organization is. It is, therefore, decisive that a task can be imputed to the state, because only in this case is the integrity and the objectivity of the administration endangered. A physician who renders emergency services in a public or private hospital, therefore, does not qualify as such an official because his or her activity is not perceived as the activity of the state and because the physician neither performs an official task nor is embedded in the public administration.

The grant of an advantage to healthcare professionals who do not qualify as officials in the sense of the criminal law may constitute an act of unfair competition in the sense of the Federal Act on Unfair Competition (*Bundesgesetz über den unlauterenWettbewerb*; "UWG"). According to this provision, whoever offers, promises or grants to an employee, shareholder, an agent or another auxiliary person of a third party within the private sector entity in connection with the recipient's occupational or business activity as a consideration for an activity or an omission that contravenes the recipient's duties or which is in the recipient's discretion engages in unfair competition. ("Employer") any undue advantage to the recipient or another person or The

für eine pflichtwidrige oder eine im Ermessen stehende Handlung oder Unterlassung zu dessen Gunsten oder zu Gunsten eines Dritten einen nicht gebührenden Vorteil anbietet, verspricht oder gewährt. Von dieser Bestechung zu unterscheiden ist die in Art. 322^{quinquies} StGB enthaltene Vorteilsgewährung. Dieser macht sich unter anderem strafbar, wer einem Beamten im Hinblick auf die Amtsführung einen nicht gebührenden Vorteil anbietet, verspricht oder gewährt. Während also die eigentliche Bestechung den Bezug zu einer bestimmten oder zumindest bestimmbaren Handlung oder Unterlassung voraussetzt, genügt für den Tatbestand der Vorteilsgewährung (auch "Anfüttern" genannt), dass der Vorteil nicht für eine bestimmbare Gegenleistung erfolgt, sondern für die Amtsführung als solche. Strafrechtlich verpönt sind damit auch Streugeschenke oder gezielte Goodwill-Zahlungen, denen keine konkrete Gegenleistung zuzuordnen ist. Immerhin werden nur solche Zuwendungen erfasst, die eine Beeinflussung des Amtsträgers anvisieren. Der Vorteil muss also geeignet sein, auf die Amtsführung des Empfängers einzuwirken. Art. 322^{octies} Ziff. 2 StGB stellt klar, dass dienstrechtlich erlaubte sowie geringfügige, sozial übliche Vorteile von der Strafbarkeit nicht erfasst werden.

Die Art. 322ter ff. StGB erfassten im hier interessierenden Zusammenhang lediglich die Beamten. Der Beamtenbegriff erfasst sowohl institutionelle wie auch funktionale Beamte. Es kommt mithin nicht darauf an, in welcher Rechtsform der funktionale Beamte für das Gemeinwesen tätig ist. Entscheidend ist vielmehr, dass er Staatsaufgaben wahrnimmt. Private, welche öffentliche Aufgaben erfüllen, gelten als Beamte. Damit fallen wohl sämtliche Medizinalpersonen, welche sich in einem Dienstverhältnis zu einem staatlichen Spital befinden, unabhängig davon, ob dieses Dienstverhältnis öffentlich rechtlich oder zivilrechtlich ausgestaltet ist, unter den Beamtenbegriff. Frei praktizierende Ärzte werden dagegen klarerweise von den Bestimmungen des Korruptionsstrafrechtes nicht erfasst, sofern sie daneben nicht irgendeine staatliche Aufgabe erfüllen. Auch Grossisten, frei praktizierende Apotheker und Drogisten fallen grundsätzlich nicht unter den Beamtenbegriff des Schweizerischen Strafgesetzbuches. Vorausgesetzt ist immer, dass diese Personen nicht neben ihrer privatwirtschaftlichen Tätigkeit noch irgendwelche staatlichen Aufgaben erfüllen und in diesem Zusammenhang Vorteile erhalten.

Keine staatliche Aufgabe erfüllen aber auch Privatärzte, die ihre Privatpatienten als Belegärzte in Privatkliniken, aber auch in öffentlichen Spitälern behandeln. Die Wahrung der Volksgesundheit ist zwar an sich eine staatliche Aufgabe; es ginge meines Erachtens jedoch zu weit, aus diesem Grunde jeden Arzt als Beamten zu qualifizieren. Für das Vorliegen der

person acting on behalf of the Employer who asks for or accepts such an undue advantage is engages in an act of unfair competition. If the Employer, however, accepted the advantage or if the advantage is only of limited value and socially adequate, there is no undue advantage and, therefore, no unfair competition exists.

Permitted and Prohibited Activities

Bribery as well as the grant of advantages are contingent upon the offer, promise or grant of an advantage that is not due. Any legal, economic or personal advantage of the recipient qualifies as an advantage. Besides actual cash payments, the grant of any property, the right to use a certain property, for example the donation of precious objects, the lending of a car free of charge, the grant of rebates or an invitation to travel, but also the renouncement of a pecuniary claims, for example a waiver of claims, constitute an advantage. A certain transaction can qualify as an advantage if the parties' respective performances are not equivalent. The grant of advantages is permissible provided that the advantages are minor and socially adequate. The report that the Swiss federal government submitted to parliament in connection with the amendment of the criminal code gives the example of a bunch of flowers given to a nurse. Such a present primarily has the function of honoring honest services rendered in the past and does not intend to influence the future discharge of the public function. On the other hand, it is prohibited to invite officials who will have to decide on a public procurement in the future, even if for the time being no specific decisions are pending. Besides the amount of the advantage, which may only under very exceptional circumstances amount to CHF300 but will, in general, need to be much lower, the specific circumstances of the case are relevant. For example, in a case of a pending public procurement procedure, almost no advantage will be acceptable, while the standards will be somewhat lower if an advantage is granted without any concrete public service being expected in the future.

It has recently become common in the context of financing public tasks by third parties or through sponsorships, that public institutions ask private persons to finance certain public functions. In this case, private persons take over a public task and declare this fact openly, or could at least declare it openly and take over those public tasks voluntarily and in a responsible manner. This case has to be distinguished from the case where officials receive advantages as a consideration for their discharge of a public function or even for activities in violation of their tasks. Also, if the principal physician of a public hospital receives a profit because he prefers the

Beamteneigenschaft ist vielmehr erforderlich, dass die fragliche Person als Sachwalter staatlicher Rechte und Pflichten nach aussen hin auftritt und dass die fragliche Tätigkeit für und nicht bloss anstelle des Staates ausgeübt wird. Da das schweizerische Korruptionsstrafrecht das allgemeine Vertrauen in die Objektivität und Sachlichkeit staatlichen Handelns schützen will, muss die funktionelle Bindung umso stärker sein, je schwächer die institutionelle Eingliederung ist. Entscheidend ist, dass die Aufgabe dem Gemeinwesen zugerechnet werden kann, da nur in diesem Fall die Integrität und Sachlichkeit der Verwaltung gefährdet sein kann. Der in einem öffentlichen oder privaten Spital Notfalldienst leistende Arzt qualifiziert daher meines Erachtens nicht per se als Beamter, da seine Tätigkeit nicht als staatliche Tätigkeit wahrgenommen wird und er weder eine amtliche Aufgabe erfüllt, noch in die öffentliche Verwaltung eingegliedert ist.

Die Vorteilsgewährung an Medizinalpersonen, welche nicht als Beamte im strafrechtlichen Sinne qualifizieren, kann eine unlautere Wettbewerbshandlung gemäss Art. 4a UWG darstellen. Gemäss dieser Bestimmung handelt unlauter, wer einem Arbeitnehmer, einem Gesellschafter, einem Beauftragten oder einer andern Hilfsperson eines Dritten im privaten Sektor im Zusammenhang mit dessen dienstlicher oder geschäftlicher Tätigkeit für eine pflichtwidrige oder eine im Ermessen stehende Handlung oder Unterlassung zu dessen Gunsten oder zu Gunsten eines Dritten einen nicht gebührenden Vorteil anbietet, verspricht oder gewährt. Auch die im Dienste des Dritten stehende Person, die sich im Zusammenhang mit ihrer dienstlichen oder geschäftlichen Tätigkeit für eine pflichtwidrige oder eine im Ermessen stehende Handlung oder Unterlassung für sich oder einen Dritten einen nicht gebührenden Vorteil fordert, sich versprechen lässt oder annimmt, handelt unlauter. Hat der Dritte jedoch den Vorteil genehmigt oder handelt es sich um bloss geringfügige, sozial übliche Vorteile, liegt kein nicht gebührender Vorteil und damit keine unlautere Wettbewerbshandlung vor.

Erlaubte und verbotene Aktivitäten

Sowohl die Bestechung als auch die Vorteilsgewährung stellen auf das Anbieten, Versprechen oder Gewähren eines nicht gebührenden Vorteils ab. Als Vorteil gilt jede objektiv messbare, rechtliche, wirtschaftliche oder auch persönliche Besserstellung des Zuwendungsempfängers. Neben eigentlichen Geldleistungen fallen auch Sach- und Nutzzuwendungen, so etwa die Zuwendung wertvoller Gegenstände, die Überlassung eines Leihwagens, die Gewährung von Rabatten oder die Bezahlung einer Reise, aber auch der Verzicht auf geldwerte Leistungen, wie beispielsweise ein Schulderlass, unter

products of a specific company when buying pharmaceuticals for the hospital, there is a clear case of bribery rather than sponsoring. Transparency is an important criterion to distinguish bribery from sponsoring or financing of public tasks by third parties. There is *prima facie* evidence that (permissible) sponsoring exists where it has been made public, while prohibited sponsoring is generally kept secret. Obviously, sponsorships may not be dependant on a certain turnover level.

In summary, one should be very reluctant to grant advantages to persons who qualify as officials in the sense of StGB. In particular, one should refrain from inviting such persons to events unless they are delivering a speech. In such a case, the advantages that such speakers obtain have to be in line with market conditions and have to be adequate. An invitation may only be contemplated if it enables reasonable professional development and thus can qualify as sponsoring of a public task. In this event, however, the consent of the competent authorities (e.g., the administration of the hospital) has to be obtained in advance, and the invitation has to be disclosed.

Public Procurement and Fraud

The principles set out above apply equally in the context of public procurement. The grant of an advantage that is not justified in this context always qualifies as bribery in the sense of StGB and not only as a mere grant of a certain advantage.

Sanctions

The bribery of Swiss officials under the StGB can be sanctioned by imprisonment of up to five years or a pecuniary fine. The grant of certain advantages under the StGB can be sanctioned with imprisonment of up to three years or a pecuniary fine. If both the illicit act as well as the fault are so small that a punishment would not be appropriate, the competent authority renounces the prosecution, the filing of the criminal complaint with the court or the punishment.

At least in those cases where a causal link exists between the prohibited grant of an advantage in a contract between the healthcare professional or the medical institution on the one side and the distributor on the other side, the legal grant of the advantage triggers the nullity of such an agreement.

If the grant of an advantage to a healthcare professional constitutes an act of unfair competition, the responsible person not only has to pay damages, but also has to make restitution to the victim for any profit derived from such

den Vorteilsbegriff. Als Vorteil ist auch ein Geschäft zu qualifizieren, wenn sich Leistung und Gegenleistung wirtschaftlich nicht entsprechen. Nicht gebührend ist ein Vorteil, zu dessen Annahme der Amtsträger nicht berechtigt ist. Vorteilszuwendungen sind zulässig, sofern sie geringfügig und sozial üblich sind. Die Botschaft des Bundesrates an das Parlament erwähnt hier etwa den Blumenstrauss für die Krankenschwester, welcher primär die Funktion hat, vergangene treue Dienstleistungen zu belohnen und nicht die künftige Amtsführung zu beeinflussen. Verboten wäre dagegen eine bezahlte Vergnügungsreise von Entscheidungsträgern, selbst wenn im Moment keine konkreten Entscheide anstehen. Neben der Höhe des Vorteils, der wohl nur in ganz seltenen Fällen einmal den Betrag von CHF 300.-- erreichen, regelmässig aber bedeutend tiefer liegen dürfte, kommt es auch auf die konkreten Umstände an. Eine Zuwendung im Umfeld eines hängigen Vergabeverfahrens ist zweifellos kritischer zu beurteilen als eine Vorteilsgewährung ohne näheren zeitlichen Bezug zu einer konkreten Amtshandlung.

Inzwischen ist es im Rahmen der Drittmittelfinanzierung oder des Sponsorings üblich geworden, dass auch öffentlich-rechtliche Institutionen Private um die Mitfinanzierung von Staatsaufgaben angehen. Es geht hier um die offen deklarierte oder ohne weiteres deklarierbare, verantwortungsvolle, freiwillige Übernahme einer öffentlichen Aufgabe durch Private. Es geht also nicht darum, Beamten private Vorteile für ihre Amtsführung und schon gar nicht für pflichtwidrige Handlungen zukommen zu lassen. Erhält allerdings ein Chefarzt einer Klinik private Gewinnbeteiligungen dafür, dass er beim Einkauf von Medikamenten für die Institution ein Unternehmen bevorzugt, liegt klarerweise Bestechung und kein Sponsoring vor. Im Bereich der Drittmittelfinanzierung bzw. des Sponsorings ist die Transparenz ein wichtiges Kriterium. Vermutungsweise liegt (zulässiges) Sponsoring dort vor, wo dieses publik gemacht wird, während (verbotene) Bestechung geheim gehalten wird. Klarerweise darf Sponsoring auch nicht vom Erreichen bestimmter Umsätze abhängig gemacht werden.

Zusammenfassend ergibt sich, dass Personen, welche als Beamte im Sinne von Art. 110 Ziff. 4 StGB qualifizieren, nur äusserst zurückhaltend Vorteile zugewendet werden sollen. Insbesondere sollte darauf verzichtet werden, solche Personen an Veranstaltungen einzuladen, es sei denn, diese Personen würden als Redner auftreten, wobei die ihnen insgesamt zukommenden Vorteile marktkonform und angemessen sein müssen. Eine Einladung kommt nur in Frage, wenn sie eine sinnvolle Weiterbildung ermöglicht und so als Sponsoring einer Staatsaufgabe qualifiziert werden kann. In diesem Falle ist

unfair activity, if any. The intentional unfair competition can, upon request, furthermore be sanctioned with imprisonment of up to three years or a pecuniary fine.

Contracts with Healthcare Professionals and Medical Institutions

To the extent that the mutual rights and obligations arising out of contracts with healthcare professionals or medical institutions are of equal economic value, no further problems arise in principle. If, however, the performance that the healthcare professional or medical institution receives clearly outweighs the consideration that such healthcare professional or institution has to give based on that contract, there is a grant of an advantage. Reference is made to the details given above.

In addition, the disciplinary rules to which an official or an employed healthcare professional is subject might require that prior approval be obtained from the supervisory authority or the employer before the official or healthcare professional may enter into a contract and, e.g., agree to deliver a speech, to participate in a clinical study or to render consultancy services.

Recommendations

The permissibility of any grant of advantage or benefit to a healthcare professional must be diligently checked in advance. In general, the pharmaceutical companies should be rather reluctant in that respect, particularly with respect to the grant of advantages to persons who discharge public functions like physicians or pharmacists employed by public hospitals. The advantages may be reduced by asking the healthcare professionals to give consideration. If the healthcare professional's performance is compensated at market value, no grant of an advantage exists which could give rise to any concerns. To the extent that not only minor advantages are granted, the grant should be made public, because transparency is a strong indication that sponsoring or financing of public tasks by private means rather than corruption are at issue. Of course, internal hospital regulations, if any, also have to be observed and the consent of the employer or the hospital administration obtained.

In the case of sponsoring, one has to assess whether, indeed, a public task should be financed. If this is the case, the responsible superior (in particular the hospital administration) has to be contacted and consent to the sponsoring. At the same time, one will have to ensure that the payments

aber vorgängig die Zustimmung der zuständigen Amtsstelle (z.B. Spitalverwaltung) einzuholen und die Einladung offenzulegen.

Öffentliches Beschaffungswesen und Betrug

Die soeben erläuterten Regeln gelten auch im Bereich des öffentlichen Beschaffungswesens. Eine unerlaubte Vorteilszuwendung erscheint in diesem Zusammenhang immer als eine Bestechung im Sinne von Art. 322ter StGB und nicht als blosse Vorteilsgewährung im Sinne von Art. 322^{quinquies} StGB.

Sanktionen

Die Bestechung schweizerischer Amtsträger im Sinne von Art. 322ter StGB wird mit Freiheitsstrafe bis zu fünf Jahren oder Geldstrafe bestraft. Die Vorteilsgewährung im Sinne von Art. 322^{quinquies} StGB wird mit Freiheitsstrafe bis zu drei Jahren oder Geldstrafe bestraft. Sind sowohl die Schwere der Tat als auch die Schuld derart gering, dass eine Strafe unangemessen wäre, so sieht die zuständige Behörde von der Strafverfolgung, der Überweisung an das Gericht oder der Bestrafung ab.

Zumindest da, wo Kausalität zwischen der unerlaubten Vorteilshingabe und dem Vertragsschluss zwischen der Medizinalperson oder der von ihr vertretenen medizinischen Institution einerseits und der Vertriebsfirma andererseits gegeben ist, führt die rechtswidrige Vorteilshingabe zur (zivilrechtlichen) Nichtigkeit des Vertrages.

Stellt die Vorteilsgewährung an Medizinalpersonen eine unlautere Wettbewerbshandlung dar, hat der Täter nicht bloss Schadenersatz zu leisten, sondern dem Verletzten auch einen allfälligen Gewinn herauszugeben (Art. 9 Abs. 3 UWG). Der vorsätzlich unlautere Wettbewerb kann auf Antrag überdies gestützt auf Art. 23 UWG mit Freiheitsstrafe bis zu drei Jahren oder Geldstrafe bestraft werden.

Verträge mit Medizinalpersonen und medizinischen Institutionen

Solange Leistung und Gegenleistung bei Verträgen mit Medizinalpersonen oder medizinischen Institutionen gleichwertig sind, stellen sich grundsätzlich keine weiteren Probleme. Steht dagegen die einer Medizinalperson oder medizinischen Institution gewährte Leistung in einem Missverhältnis zur erbrachten Gegenleistung, liegt eine Vorteilsgewährung vor. Damit kommen sowohl Art. 33 HMG, als auch die Strafbestimmungen von Art. 87 Abs. 1 lit.

made are, indeed, used to perform the state activities in question. Cash has to be exclusively paid to official accounts of the state or to research accounts of departments or divisions that have been approved and are controlled by the competent governmental authorities. Payments made to officials, but also to associations or other legal entities that are not clearly controlled by the state, strongly discouraged. Only if the institutions in question are independent from officials can such institutions be financially supported. However, in this case, neither a sponsoring nor the financing of a public task by private third parties are at issue, but rather a donation to an organization, which may not be made with a view influencing any activity of an official.

Due to the fact that the KVG asks that rebates be passed on to the patient or the health insurer, and due to the fact that a violation of this obligation constitutes a criminal act, it is recommended to ask for the written declaration of the recipient of the advantage, i.e., the hospital or the physician, according to which the hospital or the physician guarantees to live up to its obligation to pass on the advantages.With regards to hospitals, the obligation to account for the prices actually paid and to live up to the KVG as well as the Ordinance on the Assessment of Costs and the Performance by Hospitals and Nursery Homes in Health Insurance (*Verordnung über die Kostenermittlung und die Leistungserfassung durch Spitäler, Geburtshäuser und Pflegeheime der Krankenversicherung*) of 3 July 2002 is sufficient, at least to the extent of inpatient treatment.

b HMG und Art. 322terff. StGB sowie Art. 23 Abs. 1 UWG zur Anwendung. Es kann diesbezüglich auf die obgenannten Ausführungen verwiesen werden.

Die disziplinar- oder arbeitsrechtlichen Regeln, denen ein Beamter oder eine Medizinalperson unterworfen ist, können überdies die vorgängige Zustimmung der Aufsichtsbehörde oder des Arbeitgebers zum Abschluss eines Vertrages erfordern. Die vorgängige Zustimmung kann etwa für den Vertrag, eine Rede zu halten, an einer klinischen Studie teilzunehmen oder Beratungsleistungen zu erbringen, erforderlich sein.

Empfehlungen

Vorteilshingaben an Medizinalpersonen sind jeweils vorgängig sorgfältig zu prüfen. Grundsätzlich sollten sich die Marktteilnehmer hier Zurückhaltung auferlegen. Dies gilt insbesondere hinsichtlich der Vorteilsgewährung an Personen, die öffentliche Aufgaben erfüllen, wie Spitalärzte oder Spitalapotheker. Die Vorteile können dadurch reduziert werden, dass von den Medizinalpersonen Gegenleistungen verlangt werden. Werden diese Leistungen zu marktkonformen Bedingungen abgegolten, liegt gar keine Vorteilsgewährung mehr vor, die Anlass zu Bedenken geben könnte. Soweit nicht bloss geringfügige Vorteile gewährt werden, sollte die Vorteilsgewährung publik gemacht werden, da die Transparenz gegen das Vorliegen einer strafbaren Bestechung spricht. Selbstverständlich sind auch allfällige spitalinterne Weisungen einzuhalten bzw. die Zustimmung des Arbeitgebers bzw. der Spitalleitung einzuholen.

Im Falle des Sponsorings ist abzuklären, ob tatsächlich die Finanzierung einer staatlichen Aufgabe zur Diskussion steht. Ist dies der Fall, ist die vorgesetzte Stelle (insbesondere die Spitalverwaltung) zu kontaktieren und von ihr das Einverständnis zur Drittmittelfinanzierung einzuholen. Gleichzeitig ist sicherzustellen, dass die ausgerichteten Beträge tatsächlich dazu verwendet werden, die betreffende staatliche Aufgabe zu erfüllen. Geldbeträge sind ausnahmslos auf die offiziellen Konten der Gemeinwesen oder der von den zuständigen staatlichen Stellen genehmigten und kontrollierten Forschungskonten ihrer Departemente oder Abteilung einzuzahlen. Von jeglicher Zahlung an Beamte selbst, aber auch an Vereine oder andere juristische Personen, die nicht klarerweise staatlich beherrscht sind, ist grundsätzlich abzuraten. Nur wenn die betreffenden Institutionen von Beamten unabhängig sind, können solche Institutionen allenfalls unterstützt werden. In diesem Fall liegt jedoch weder ein Sponsoring noch eine Drittmittelfinanzierung einer staatlichen Aufgabe vor, sondern eine

Spende an eine Organisation, die nicht im Hinblick auf die Amtsführung eines Beamten erfolgen darf.

Da Art. 56 KVG die Weitergabe von Rabatten an den Leistungsempfänger statuiert und die Verletzung dieser Pflicht strafbar ist, empfiehlt es sich, eine Erklärung des Vorteilsempfängers, das heisst des Spitals oder Arztes zu verlangen, wonach sich dieser verpflichtet, seiner Pflicht zur Weitergabe der Vergünstigung nachzukommen. Bei Spitälern genügt – zumindest im stationären Bereich – die Verpflichtung, die effektiv bezahlten Preise im Sinne von Art. 49 Abs. 6 KVG sowie der Verordnung über die Kostenermittlung und die Leistungserfassung durch Spitäler, Geburtshäuser und Pflegeheime der Krankenversicherung vom 3. Juli 2002 auszuweisen.

Türkiye

Haşmet Ozan Güner

Beşeri Tıbbi Ürünlerin Tanıtımına İlişkin Kurallar

Giriş

Beşeri tıbbi ürünlerin tanıtımı Türkiye'deki sıcak gündem maddelerinden biridir. Hükümleri 31 Aralık 2011 'den itibaren kısım kısım yürürlüğe giren ve tüm hükümleri ile birlikte 1 Ocak 2013 'te yürürlüğe girmiş olacak olan Beşeri Tıbbi Ürünlerin Tanıtım Faaliyetleri Hakkında Yönetmelik (28037 sayılı Resmi Gazete) ("İlaç Tanıtım Yönetmeliği") ilaçların tanıtımına ilişkin önemli değişiklikler getirmiştir.

3 Mart 2011 tarihinde yürürlüğe giren 6112 sayılı Radyo ve Televizyonların Kuruluş ve Yayın Hizmetleri Hakkında Kanun'un ("Radyo TV Kanunu") reçetesiz ilaçların radyo ve televizyonda reklamının yapılmasına izin vermektedir. Türkiye Eczacılar Birliği buna karşı çıkarak bu düzenlemenin bunun 1262 sayılı İspençiyari ve Tıbbi Müstahzarlar Kanunu'na ("İlaç Kanunu") aykırı olduğunu ve toplum sağlığında bozulmaya yol açacağını ileri sürmektedir.

Kamu görevlisi olarak çalışan hekimlerin ve diş doktorlarının başka faaliyetler sürdürmesini yasaklamak amacıyla bir çok kanunda değişiklik yapan "tam gün yasası" Türk Tabipler Birliği'nin muhalefetiyle karşılaşmış ve Anayasa Mahkemesi tarafından iptal edilmiştir.

El kitabının bu bölümü Türkiye'de ilaçların reklam ve tanıtımına ilişkin kuralları yürürlükteki kanun ve düzenlemeler ışığında açıklamaktadır.

Hukuki Çerçeve

Beşeri tıbbi ürünlerin tanıtılması ve pazarlanması, Türkiye'de kanunlar, Sağlık Bakanlığı tarafından çıkartılan yönetmelikler ve ilaç sanayii ve Türkiye Tabipleri Birliği tarafından hazırlanan ilkeler ve kılavuzlarda düzenlenmektedir.

Özellikle, İlaç Kanunu'nun 13. maddesi beşeri tıbbi ürünlerin tanıtımı ve pazarlanmasına ilişkin genel ilkeleri belirtmektedir. İlaç Tanıtım Yönetmeliği ise beşeri tıbbi ürünlere yönelik izin verilen tanıtım faaliyetlerinin ayrıntılarını ortaya koymaktadır.

Turkey

Hasmet Ozan Guner

Restrictions Under the Pharmaceutical Advertising Law

Introduction

Promotion of pharmaceutical products is a hot topic in Turkey. With the new Regulation on the Promotion of the Pharmaceutical Products for Human Use (Official Gazette no. 28037) (the "Pharma Promotion Regulation"), the provisions of which have gradually started to enter into force on 31 December 2011 and will be in fully force as of 1 January 2013, introduced essential changes to the promotion rules for medicines.

The new Law no. 6112 on the Establishment and Broadcasting of Radio and Television (the "Broadcasting Law"), which entered into force on 3 March 2011, permits the advertising of non-prescription pharmaceutical products on radio and television. This faces opposition from the Turkish Pharmacists Association, and is claimed to be in contradiction with Turkish Law no. 1262 on Pharmaceutical Medicinal Preparations ("Pharma Law"), and would negatively effect public health.

The "full-time law" amending various laws in order to prohibit medical doctors and dentists who are public servants from carrying out other activities also faced opposition from the Turkish Medical Doctors Association, and has been recently revoked by the Turkish Constitutional Court.

This section of this handbook explains the Turkish rules on the advertising and promotion of pharmaceutical products in light of the currently-in-force laws and regulations.

The Regulatory Framework

The advertising and promotion of pharmaceutical products for human use are regulated in Turkey by the laws, regulations adopted by the Ministry of Health, and guidelines adopted by the pharmaceutical industry and the Turkish Medical Doctors Association.

In particular, Article 13 of the Pharma Law sets out the general principles for the advertising and promotion of pharmaceutical products. Pharma Promotion Regulation provides the details of the authorized promotional activities for pharmaceutical products.

Buna ek olarak, bu tip faaliyetler açısından aşağıdakiler gibi etik ilkeleri ve mesleki kılavuzlar bulunmaktadır:

- Araştırmacı İlaç Firmaları Derneği'nin İyi Tanıtım ve İyi İletişim İlkeleri;
- İlaç Endüstrisi İşverenler Sendikası tarafından hazırlanan İlaç Tanıtım İlkeleri Ve Sağlık Mensuplarıyla İlişkiler Hakkında Yönetmelik
- Türkiye İlaç Sanayi Derneği'nin İlaç Tanıtım İlkeleri Kılavuzu
- Türk Tabipleri Birliği'nin Hekim ve İlaç Tanıtım İlkeleri ve Hekim-Endüstri İlişkisi Bildirgesi

Yukarıdaki etik ilkeleri ve mesleki kılavuzlar yalnızca bunları yayınlayan derneklerin üyeleri için bağlayıcıdır.

İlaç Kanunu'nun 13. maddesi beşeri tıbbi ürünlerin tanıtımı ve pazarlanması için aşağıdaki ilkeleri ortaya koymaktadır:

- İlaçların iyileştirici özelliklerini yanlış tanıtan veya abartan tanıtımlar yasaktır.
- Reçeteli ilaçların tanıtımı yalnızca tıbbi mecmualarda Sağlık Bakanlığı'nın önceden verilmiş onayı ile yapılabilir.
- İlacın bilimsel özellikleri hakkında hazırlanmış olan filmler yalnızca Sağlık Bakanlığı'nın onayıyla ve onun tayin edeceği yerlerde gösterilebilir. İlaç Tanıtım Yönetmeliği Madde 5/4 uyarınca, sağlık meslek mensupları Sağlık Bakanlığı'nın izni olmadıkça bu ürünlerin tanıtımında rol alamazlar.

Türk hukukunda reçetesiz ilaçların kamuya tanıtımının yapılıp yapılamayacağı belirsiz bir konudur. 3 Mart 2011 tarihinde yürürlüğe giren Radyo TV Kanunu'nun 11/2 maddesi reçeteli ilaçlara ilişkin ticari iletişimleri yasaklamaktadır. Bu hükme göre, "*Reçeteye tabi ilaçlar ve tedaviler hakkında ticarî iletişim yapılamaz*". İlgili kanunun aşağıda yer verilen 11/3 maddesi bazı sınırlamalarla birlikte reçetesiz ilaçların tanıtımına izin vermektedir: "*Reçeteye tabi olmayan ilaçlar ve tedavilerin reklamları dürüstlük ilkesi çerçevesinde, gerçeği yansıtan ve doğrulanması mümkün unsurlardan oluşacak şekilde hazırlanır*." Ayrıca Türkiye Radyo-Televizyon Kurumu Reklâm Yönetmeliği (27331 sayılı Resmi Gazete) Madde 5/f reçeteli ilaçların tanıtımını yasaklamaktadır, fakat reçetesiz ilaçların tanıtımına ilişkin herhangi bir kural veya kısıtlamaya yer vermemektedir.

Additionally, there are codes of conduct and professional guidelines for such activities, such as:

- The Research-based Pharmaceutical Companies Association's Good Promotion and Good Communication Principles
- The Pharmaceutical Industry Employers Syndicate's Regulation on the Promotion of the Pharmaceutical Products and Communications with the Health Care Professionals (HCPs)
- The Turkish Pharmaceutical Industry Association's Pharmaceutical Products Promotion Guidelines
- The Turkish Medical Doctors Association's Principles on the Medical Doctors and Promotion of Pharmaceutical Products, and Declaration on the Medical Doctor - Industry Relationship

The above codes of conduct and professional guidelines are binding only on the members of the issuing associations.

Article 13 of the Pharma Code states the following principles for the advertising and promotion of pharmaceutical products:

- Advertisements which misrepresent or exaggerate the curative properties of medicines are prohibited.
- Advertisements of prescription medicines can only be published in medical magazines, with prior approval by the Ministry of Health.
- Motion pictures on the scientific properties of a medicine can be demonstrated only in places approved by the Ministry of Health. According to Article 5/4 of the Pharma Promotion Regulation, HCPs can appear in these motion pictures only with the prior approval of the Ministry of Health.

The advertising of non-prescription pharmaceutical products to the public remains an unclear issue in Turkish law. Article 11/2 of the Broadcasting Law, which entered into force on 3 March 2011, prohibits the advertising of prescription medicines. According to this provision, "The commercial communication related to the prescription medicines and treatments are prohibited." Article 11/3 of the same law, which reads as follows, permits the advertising of non-prescribed medicines with some restrictions: "The advertising of the non-prescription medicines and treatments must be prepared within the framework of good faith principles, as to include elements that are accurate and that may be verified." Furthermore, Article 5/f of the Turkish Radio and Television Authority Advertisement Regulation

Diğer taraftan İlaç Tanıtım Yönetmeliği Madde 5/3 reçeteli veya reçetesiz ilaçlar arasında ayrım yapmaksızın beşeri tıbbi ürünlerin topluma tanıtımını ve pazarlamasını yasaklamaktadır.

Türkiye'de gerçekleştirilen uluslararası konferanslar sırasındaki tanıtım faaliyetleri hariç olmak üzere, tanıtım faaliyetleri yalnızca Türkiye'de ruhsatlandırılmış olan beşeri tıbbi ürünler açısından yapılabilir (İlaç Tanıtım Yönetmeliği, Madde 6/2).

Yukarıdaki sınırlamalara tâbi olarak, beşeri ve tıbbi ürünler şu şekilde tanıtılabilir:

- Sağlık meslek mensuplarına dağıtılan/satılan yayınlarla veya bilimsel içerikli tıbbi-mesleki dergilerde yer alan yayınlarla, ve
- Hekim, diş hekimi ve eczacıya ürün tanıtım elemanları tarafından ziyaret yapılarak ve ürünlerin uygulanması ve yan etkileri gibi konularda diğer sağlık meslek mensupları bilgilendirilerek (İlaç Tanıtım Yönetmeliği, Madde 5/1).

Tanıtım faaliyetleri,

- ürünün kısa ürün bilgisi ile uygun olmalıdır,
- ürünün terapötik değeri hakkında sağlık meslek mensuplarının kendi görüşlerini oluşturmasına yardımcı olacak yönde ve ürünün özellikleri hakkında bilgilendirici ve kanıta dayalı tıbbi bilgiler içermelidir,
- ürün kullanımını gereksiz yönde teşvik edecek veya beklenmeyen riskli durumlara neden olabilecek yanıltıcı, abartılmış ya da doğruluğu kanıtlanmamış bilgiler vermek suretiyle veya ilgi çekici ve ürünün kendisi ile doğrudan ilgisi olmayan görüntüler kullanılarak yapılamaz.

Tanıtım tıp dergilerinden veya diğer bilimsel çalışmalardan yapılacak alıntılar, tablolar ve diğer görsel materyaller kullanılarak hazırlanan bir dokümantasyonla yapılıyorsa, bu materyaller aslına sadık kalınarak ve kaynakları tam olarak belirtilmek suretiyle kullanılır.

Yukarıdakilere ek olarak; beşeri tıbbi ürünlerin tanıtımı amacıyla düzenlenmiş olmamak kaydıyla, ruhsat sahipleri, kongre ve sempozyum gibi bilimsel faaliyetleri destekleyebilir, katılımcıların ulaşım ve konaklama gibi masraflarını karşılayabilirler. Bu desteğin tabi olduğu kural ve sınırlar aşağıda açıklanacaktır.

(published on the Official Gazette no. 27331) restricts the advertisement of prescription medicines, but does not mention any rule or restriction on the advertisement of non-prescribed medicines.

Article 5/3 of the Pharma Promotion Regulation, on the other hand, prohibits the advertising and promotion of pharmaceutical products to the general public without making any distinction between prescription and non-prescription medicines.

Except for promotion activities during international conferences convened in Turkey, promotion activities can be carried out only for pharmaceutical products that have marketing authorization in Turkey (Article 6/2 of the Pharma Promotion Regulation).

Subject to the above restrictions, pharmaceutical products can be promoted:

- via publications sold/distributed to HCPs or publications in scientific medical or professional magazines; or
- by product promotion, personnel visits to medical doctors, dentists and pharmacists, and by informing other HCPs on the implementation and side effects of the products (Article 5/1 of the Pharma Promotion Regulation).

The promotion activities must:

- conform to the product's brief product information;
- include informative and evidence-based scientific information on the product, and must be in a form to assist HCPs in forming their opinions on the therapeutic value of the product; and
- not include deceptive, exaggerated or unproven information that may lead to an unnecessary use of the product or unexpected risky situations or images that are not directly related to the product.

If the promotion is made by documentation that includes citations from scientific studies, tables or other visual material, such material must conform to the original versions and must include full references to their sources.

Additionally, the marketing authorization holders may financially support scientific activities such as congresses and symposiums, and pay for the participants' costs and expenses such as transportation and accommodation, provided that these activities are not intended to promote a pharmaceutical product. Rules and restrictions applicable to these sponsorships are explained below in more detail.

İzin verilen ve yasaklanan uygulamalar

İlaçlar açısından en sık rastlanan tanıtım faaliyetleriyle ilgili olarak izin verilen ve yasaklanan uygulamalar İlaç Tanıtım Yönetmeliği'nde düzenlenmiştir.

Çekilişler ve kuralar

İlaçların çekiliş ve kura yoluyla tanıtımı yasaktır (İlaç Tanıtım Yönetmeliği, Madde 6/7)

Bağışlar

Ruhsat/izin sahipleri, aşağıdaki şartları sağlamak koşuluyla kamuya ait sağlık kurumlarına ilgili idari kurumun ön onayını alarak bağışta bulunabilirler:

- İlaç ürünlerin kamu ihalelerine ilişkin alınacak kararları etkilememelidir,
- Ürün satışı ile ilişkilendirilebilecek etik dışı bir uygulamaya yol açmamalıdır,
- Spesifik bir ilaç hakkında reçete yazımını teşvik edici olmamalıdır,
- Araştırma, eğitim, sağlık ve hasta bakımını iyileştirmek amaçlarından birini taşımalıdır,
- Sadece bir bireyin kullanımına değil kurum veya kuruluşun genel kullanımına yönelik olmalıdır,
- Bağışlanan malzemede ürünün ismini yazmamalıdır (bağışlanan malzemede ruhsat/izin sahibinin adının bulunabilir),
- Ruhsat/izin sahibi yaptığı bağışı resmî kayıtlarına işlemelidir,
- Klinik araştırmada kullanılması amacıyla yapılacak ilaç, laboratuvar kitleri ve benzeri bağışlar doğrudan sorumlu araştırmacıya yapılmalıdır.

Hediyeler

Beşerî tıbbi ürünlerin hekim, diş hekimi ve eczacıya tanıtımı yapılırken herhangi bir nakdî veya ayni avantaj sağlanamaz, teklif dahi edilemez ve söz verilemez. Bu sağlık meslek mensuplarının da bunları talep etmesi yasaktır. (İlaç Tanıtım Yönetmeliği, Madde 6/8)

Ayrıca 657 sayılı Devlet Memurları Kanunu Madde 29, devlet memurlarının hediye istemelerini ve görevleri sırasında olmasa dahi menfaat sağlama amacı ile hediye kabul etmelerini veya iş sahiplerinden borç para istemelerini ve almalarını yasaklamaktadır. Bu hüküm Kamu Etik Kurulu'nu bu yasağın kapsamını belirlemesi için yetkilendirmektedir.

Permitted and Prohibited Practices

Permitted and prohibited practices relating to the most common promotion activities for medicines are provided under the Pharma Promotion Regulation.

Draws and Lotteries

The promotion of medicines by draws or lotteries is prohibited (Article 6/7 of the Pharma Promotion Regulation).

Donations

Marketing authorization holders may make donations to public health institutions with prior permission from the relevant administrative authority provided that such donation:

- does not influence the decisions relating to public tenders for medicines;
- does not result in unethical behavior which may relate to the sale of the medicines;
- is not made as an incentive for the prescription of a specific medicine;
- has the purpose of research, training or improvement of health, or patient care;
- is intended for general use and not for the use of an individual;
- does not carry the name of the product (the donated material, however, can carry the name of the marketing authorization holder);
- is recorded in the marketing authorization holder's official records; and
- is made directly to the responsible investigator where the donated materials are medicines, laboratory kits or similar materials donated for use in clinical trials.

Gifts

In the context of the promotion of pharmaceutical products to medical doctors, dentists and pharmacists, no monetary or in-kind benefit may be provided, offered or promised. These HCPs are prohibited from asking for such benefits (Article 6/8 of the Pharma Promotion Regulation).

Additionally, Article 29 of the Public Servants Law (Law no. 657) prohibits public servants from receiving or asking for gifts or credits from those for whom they perform their duties with the purpose of taking advantage of their duties. This provision authorizes the Public Ethics Institution to determine

Kamu Görevlileri Etik Davranış İlkeleri İle Başvuru Usul Ve Esasları Hakkında Yönetmelik ("Kamu Görevlileri Etik Yönetmeliği") Madde 15, kamu görevlilerinin hediye kabul etmesi hakkındaki kuralları düzenlemektedir. Kamu görevlisi olan sağlık mensupları da bu hükümlere tabidir.

Kamu görevlileri için temel ilke hediye almamak ve görevinin yerine getirilmesi sonucunda herhangi bir menfaat elde etmemektir. Kamu Görevlileri Etik Yönetmeliği Madde 15 yasak olan hediyelere ve bu yasakların istisnalarına dair örnekleri listelemektedir. Kitap, dergi, makale, kaset, takvim, cd veya buna benzer nitelikte olanlar; tanýtým amacýna yönelik, herkese daðýtýlan ve sembolik deðeri bulunan reklam ve el sanatlarý ürünleri; görev yapýlan kuruma katký anlamýna gelen, kurum hizmetlerinin hukuka uygun yürütülmesini etkilemeyecek olan baðýþlar ve finans kurumlarýndan piyasa koþullarýna göre alýnan krediler bu hüküm altýnda düzenlenen hediye alma yasaðýnýn istisnalarý arasýndadýr.

Seminerler, konaklama ve eğlence

Beşerî tıbbi ürün tanıtımı ile ilgili bilimsel ve eğitsel faaliyetler, var olan tıbbi bilgileri aktarmak ve/veya yeni bilgileri sunmak amacı dışında kullanılamaz. Ruhsat/izin sahipleri, bu faaliyetlere katılan katılımcıların ulaşım ve konaklama masraflarını karşılayamazlar (İlaç Tanıtım Yönetmeliği, Madde 7/1).

Nitekim, İlaç Tanıtım Yönetmeliği Madde 7/2 uyarınca, ruhsat/izin sahipleri; sağlık meslek mensuplarına kongre, (ilaçların tanıtımına yönelik olmayan) sempozyum gibi yurt içi ve yurt dışı bilimsel toplantılara katılımları için aşağıdaki şartlara uymak kaydıyla destek verebilirler:

- Toplantı sağlık meslek mensubunun uzmanlık/görev alanı ile ilgili olmalıdır,
- Bir sağlık meslek mensubu aynı yıl içerisinde toplam beş kez bu destekten yararlanabilir, bu desteğin en fazla ikisini aynı ruhsat/izin sahibi sağlayabilir; ve
- Destek doğrudan sağlık meslek mensubuna değil toplantıyı düzenleyen organizasyona yapılır.

Ruhsat/izin sahipleri, destek verecekleri sağlık meslek mensuplarının bilgilerini, bu konuda yayımlanacak Kılavuzda belirtileceği şekilde Sağlık Bakanlığı'na bildirmek zorundadırlar. Bakanlık bu bilgileri, oluşturacağı veri tabanında toplar (İlaç Tanıtım Yönetmeliği, Madde 7/3).

the scope of this prohibition. Moreover, Article 15 of the Public Servants Ethic Principles and Application Procedures Regulation ("Public Servants Ethics Regulation") sets forth rules on the gifts to be accepted by public servants. Public servant HCPs are also subject to these provisions.

The basic principle for public servants is not to receive gifts and not to derive interest as a result of performing their duty. Article 15 of the Public Servants Ethics Regulation also lists the examples of prohibited gifts and the exceptions to this prohibition. Books, magazines, articles, CDs or similar materials; craftworks and advertising materials distributed to everybody and which have a nominal value; contributions to public institutions that would not hinder the legal performance of their duty; and credit received from the financial institutions at market conditions are among the exceptions to the prohibition of receiving gifts under this provision.

Seminars, Hospitality and Entertainment

Scientific and educational activities for the promotion of pharmaceutical products must be limited to presenting existing/new information. Those holding marketing authorization are prohibited from sponsoring the participants' transportation and accommodation costs for such activities (Article 7/1 of the Pharma Promotion Regulation).

According to Article 7/2 of the Pharma Promotion Regulation, however, marketing authorization holders can sponsor HCPs for their participation in scientific meetings such as congresses and symposiums (that are not intended for the promotion of pharmaceutical products) in Turkey or abroad, provided that:

- the meeting is related to the HCP's area of expertise;
- an HCP may benefit from five sponsorships during a year, with a maximum of two sponsorships from the same marketing authorization holder; and
- the sponsorship is not provided directly to the HCPs, but to the organizations hosting the meeting.

The marketing authorization holders must provide the Ministry of Health with the information of the HCPs they will sponsor. This information will be added to the Ministry of Health's relevant database (Article 7/3 of the Pharma Promotion Regulation).

Ruhsat/izin sahibinin desteklediği ulusal ve uluslararası çok merkezli klinik araştırmaların yurt içi ve yurt dışında yapılacak araştırmacı toplantıları, kongre veya sempozyum katılımı olarak değerlendirilmez. Ancak ruhsat/izin sahipleri söz konusu toplantıyla ilgili olarak Sağlık Bakanlığı'nı bilgilendirmelidir (İlaç Tanıtım Yönetmeliği, Madde 7/4).

Deniz kenarlarındaki tatil beldelerinde ve kayak merkezlerinde aktif sezon döneminde (Aktif sezon dönemleri Bakanlık internet sayfasından duyurulur) ruhsat/izin sahipleri tarafından toplantı organizasyonları düzenlenemez ve desteklenemez. Her defasında başka bir ülkede düzenlenen uluslararası toplantılar için bu hüküm geçerli değildir (İlaç Tanıtım Yönetmeliği, Madde 7/5).

Toplantılara sağlık meslek mensupları dışındaki kişiler davet edilemez ve masrafları karşılanamaz; ancak protokol davetlileri bu hükmün dışındadır. (İlaç Tanıtım Yönetmeliği, Madde 7/6).

Ruhsat/izin sahiplerinin desteklediği toplantılara akılcı ilaç kullanımı konusunda, toplantının konusu ile ilgili bir oturum konulması gereklidir. Bu oturumda yer alacak sunumların içeriği, Sağlık Bakanlığı'nca onaylanmış eğitim materyalleri ve tanı tedavi rehberleri çerçevesinde olur ve izin başvurusu sırasında Sağlık Bakanlığı'na sunulur (İlaç Tanıtım Yönetmeliği, Madde 7/7).

Sağlık Bakanlığı'nca görevlendirilmiş kişiler, denetim amacıyla önceden haber vererek veya haber vermeden bu toplantılara katılabilirler (İlaç Tanıtım Yönetmeliği, Madde 7/8).

Tanıtım Malzemeleri

Tanıtım malzemeleri İlaç Tanıtım Yönetmeliği'ne uygun olmalıdır. Tanıtım malzemelerinin parasal değeri Sağlık Bakanlığı'nca belirlenen miktarı geçemez. Bu miktar Sağlık Bakanlığı'nın internet sayfasında yayımlanır. Tanıtım malzemeleri hastaların göreceği şekilde sergilenemez. (İlaç Tanıtım Yönetmeliği, Madde 8)

Bedelsiz numuneler

İlaç Tanıtım Yönetmeliği Madde 9 uyarınca, bedelsiz ilaç ürünlerinin numuneler, aşağıdaki şartlar yerine getirilmek şartıyla sadece hekim, diş hekimi ve eczacıya dağıtılabilir:

- Ruhsat/izin sahipleri, bedelsiz ürün tanıtım numunelerinin imalat, ithalat ve dağıtımına yönelik olarak bir kayıt ve kontrol sistemini kurar,

The investigator meetings for clinical trials sponsored by the marketing authorization holder are not considered as participation in a congress or symposium. The marketing authorization holders, however, must inform the Ministry of Health of such meetings as well (Article 7/4 of the Pharma Promotion Regulation).

Marketing authorization holders are prohibited from sponsoring scientific meetings at coastal resorts and ski centers during the active season (which is determined by the Ministry of Health). Scientific meetings organized in a different country each year are exempt from this provision (Article 7/5 of the Pharma Promotion Regulation).

Save for distinguished guests (*protokol davetlileri*), persons who are not HCPs cannot be invited to the meetings and their participation cannot be sponsored (Article 7/6 of the Pharma Promotion Regulation).

Meetings sponsored by marketing authorization holders must include a session on rational drug use, related to the subject of the meeting. The content of this session must be within the framework of the educational materials and diagnosis and therapy guidelines approved by the Ministry of Health, and must be submitted to the Ministry of Health during the permission application (Article 7/7 of the Pharma Promotion Regulation).

Persons appointed by the Ministry of Health may participate in the meetings with or without prior notice for clearance (Article 7/8 of the Pharma Promotion Regulation).

Promotional Materials

All promotional materials must comply with the Pharma Promotion Regulation. The value of the promotional materials cannot exceed an amount to be determined by the Ministry of Health. The promotional materials cannot be displayed in a manner visible to patients (Article 8 of the Pharma Promotion Regulation).

Free Samples

According to Article 9 of the Pharma Promotion Regulation, free pharmaceutical product samples can be provided only to medical doctors, dentists and pharmacists under the following circumstances:

- The marketing authorization holder establishes a recording system on the manufacturing, import and distribution of the samples and appoints

sorumlularını belirler. Bu kayıtlar talep edilmesi hâlinde Sağlık Bakanlığı yetkililerine bildirilir.

- Bedelsiz numuneler, azaltılmış miktarlar içerir. Ancak, enteral beslenme ürünlerinde ve teknik nedenlerle azaltılamayan ürünlerin tanıtım numunelerinde bu şart aranmaz.
- Tanıtım numunelerinin dış ambalajları üzerinde "Tanıtım numunesidir, satılamaz" ifadeleri, en az bir yüzeyde ve dikkat çekici nitelikte yer almalıdır. Eğer mümkünse aynı ifadeler iç ambalajda da yer almalıdır.
- Tanıtım numunesi varsa kullanım talimatları ve kısa ürün bilgisi ile sunulmalıdır.
- Psikotrop ve narkotik maddeleri içeren ürünlerin numuneleri dağıtılamaz.
- Sağlık Bakanlığı gerekli görüp izin vermiş olmadıkça ambalajlarında karekod bulunmaması esastır. (Bu hüküm 1 Ocak 2013'te yürürlüğe girecektir)
- Ruhsat/izin sahipleri, bedelsiz numunelerin gereğinde güvenli geri çekilebilmesini sağlamak üzere bir sistem kurarlar. (Bu hüküm 1 Ocak 2013'te yürürlüğe girecektir)
- Numunelerinin yıllık dağıtılan miktarı, ilgili ürünün bir önceki yıla ait satış miktarını geçemez. Bu hükmün uygulanmasına her bir beşerî tıbbi ürün için satış izni alındığı tarihten bir yıl sonra başlanır (Bu hüküm 1 Ocak 2013'te yürürlüğe girecektir).
- Tanıtım numuneleri klinik araştırmalarda araştırma ürünü olarak kullanılamaz

Ürün tanıtım elemanları

Ürün tanıtım elemanlarının faaliyetleri Ürün Tanıtım Yönetmeliği Madde 10'da düzenlenmektedir.

Ürün Tanıtım Yönetmeliği Madde 10/1 uyarınca, ürün tanıtım elemanları;

- Tanıtımını yaptıkları ürünler hakkında tam ve yeterli, gerekli bilimsel veri ve bilgilerle donatılmış olmalıdır (bu hüküm 1 Ekim 2012'de yürürlüğe girecektir).
- Ruhsat/izin sahibi firma tarafından, görülen hizmetin hukuki ve etik çerçevesini de içeren, hizmet eğitimlerine tabi tutulmalıdır. Ruhsat/izin sahibi bu eğitimleri dışardan başka biri tarafından da yaptırabilir. Eğitim programı Sağlık Bakanlığı tarafından sertifikalandırılmış olmalıdır (bu hüküm 1 Ekim 2012'de yürürlüğe girecektir).

responsible persons for this system. These records must be shared with the Ministry of Health upon request.

- The samples include reduced amounts (save for enteral feeding products and products that cannot be reduced for technical reasons).
- The sample packaging bears the statement "promotion sample, cannot be sold" on at least one surface and in a conspicuous manner. If possible, the interior packaging must also bear this statement.
- The instructions for use and brief product information are presented with the sample.
- Samples of psychotropic and narcotic products are not be distributed.
- There are no QR codes on the packaging, unless permitted by the Ministry of Health where necessary. (This provision will enter into force on 1 January 2013.)
- The marketing authorization holder establishes a recall system for the samples, as a measure for cases where recall may be necessary. (This provision will enter into force on 1 January 2013.)
- Distributed samples do not exceed the amount of the same product sold within the previous year. This provision becomes applicable to any product one year after obtaining marketing authorization. (This provision will enter into force on 1 January 2013.)
- Samples are not used in clinical trials.

Product Promotion Personnel

The activities of the product promotion personnel are regulated under Article 10 of the Pharma Promotion Regulation. According to Article 10/1, the product promotion personnel:

- must have the sufficient and necessary scientific data and information on the products that they promote (the provision will enter into force on 1 October 2012);
- must have taken an in-service training from the marketing authorization holder, including, *inter alia*, the legal and ethical framework of the services carried out. The marketing authorization holder may outsource such trainings as well. The training program must be certified by the Ministry of Health (the provision will enter into force on 1 October 2012); and

- Hekim, diş hekimi ve eczacılara bütün olumlu ve olumsuz veriler dahil olmak üzere ürün hakkında tam ve doğru bilgi vermeli ve yardımcı tanıtım malzemelerini temin etmelidir.

Ürün tanıtım elemanları; hekim, diş hekimi ve eczacı haricindeki sağlık meslek mensuplarına herhangi bir ürün ve benzerinin tanıtımını yapamaz; ancak ürünlerin uygulanması ve yan etkileri gibi konularda, ilgili birim yetkilisi veya sorumlu hekimin bilgilendirilmesi ve onayının alınması şartıyla hekim, diş hekimi ve eczacı haricindeki sağlık meslek mensuplarına da bilgilendirmede bulunabilir. Ayrıca ilgili tanıtım malzemelerini hekim, diş hekimi ve eczacı dışındaki kişilere veremezler.

Ürün tanıtımı sırasında ürünle ilgili kendilerine rapor edilen ters etki/olayları firmalarındaki ilgili departmanlarına iletmelidirler.

Ürün tanıtım elemanı birden fazla ruhsat/izin sahibi için çalışabilir.

Kamu hizmeti verilen sağlık kuruluşlarında; ilgili idari amir, ürün tanıtım elemanlarının sağlık meslek mensupları ile yapacakları ürün tanıtımı amaçlı görüşmelerin yapılabilmesini temin etmek üzere, çalışma düzenlerini gözeterek en uygun zamanı tahsis eder. Bu tahsis, eğitim hizmetlerini ve hastalara verilen sağlık hizmetlerini aksatmamalıdır.

Acil servislerde ve hasta kabul saatleri sırasında polikliniklerde ürün tanıtımı yapılamaz.

Kamuya ait sağlık kuruluşlarına, ürün tanıtımı olarak algılanabilecek afiş veya benzeri tanıtım materyalleri konulamaz. Ancak aşılama kampanyaları, salgın hastalıklar, sigara ve obeziteyle mücadele gibi sağlığın teşviki amacıyla Sağlık Bakanlığı'nın gerçekleştirdiği kampanyalarda kullanılacak afiş ve benzeri tanıtım materyalleri bu hükmün dışındadır.

İhlalin Sonuçları

İlaç Tanıtım Yönetmeliği'nin ihlal edilmesinin sonuçları aynı yönetmeliğin 13. maddesinde düzenlenmektedir.

İlaç Tanıtım Yönetmeliği'nin bilim ve eğitim faaliyetlerini düzenleyen 7. maddesinin ihlali halinde, ruhsat/izin sahibi Sağlık Bakanlığı tarafından uyarılır. İhlalin tekrarlanması halinde ruhsat/izin sahibi bir yıl süreyle kongre veya sempozyum faaliyetlerine katılamaz ve katkı sağlayamaz (İlaç Tanıtım Yönetmeliği, Madde 13/2).

- must provide the medical doctors, dentists and pharmacists with complete and accurate information on the product, including all positive and negative data, and with supporting promotional material.

The product promotion personnel cannot promote pharmaceutical products to HCPs other than to medical doctors, dentists and pharmacists; but may inform them of the implementation and side effects of the products provided that the relevant department responsible or the responsible medical doctor is informed and approves such activities. Furthermore, they cannot provide the HCPs other than the medical doctors, dentists and pharmacists with promotional materials.

The product promotion personnel must forward the adverse effects and events reported to them during their promotional meetings to the relevant departments in their company.

Product promotion personnel may work for more than one pharmaceutical company.

The product promotion personnel may visit the HCPs only within the hours determined by the administrative manager of the relevant public health institution. The administrative manager determines these visit hours taking into account the working order, and so as to not hinder studies and health services.

Promotional activities at emergency services departments and during patient admission hours at polyclinics are prohibited.

Placing promotional materials such as posters at public health institutions is prohibited. Posters and other promotional materials to be used for the Ministry of Health campaigns with public health purposes – such as vaccination campaigns, epidemic diseases, fight against smoking or obesity – are exempted from this prohibition.

Consequences of Breach

The consequences of a breach of the Pharma Promotion Regulation are stipulated under Article 13 of the same regulation.

In case of a breach of Article 7 of the Pharma Promotion Regulation which regulates scientific and educational activities, the marketing authorization holder must be warned by the Ministry of Health. In case of a repetition of the breach, the marketing authorization holder is prohibited from

İlacın tanıtımının bu İlaç Tanıtım Yönetmeliği'ne aykırı olarak yapılması durumunda ruhsat/izin sahibi Sağlık Bakanlığı tarafından uyarılır. İhlalin tekrarı hâlinde tanıtım faaliyeti yapamaz. Aynı hususun tekrarı hâlinde ürünün pazarlanması üç ay süreyle, devamında ise bir yıl süreyle askıya alınır (İlaç Tanıtım Yönetmeliği, Madde 13/3).

Ürün tanıtım elemanlarının yaptığı tanıtım ihlallerinde Sağlık Bakanlığı tarafından verilen sertifikalar geçersiz kılınır (ürün tanıtım elemanlarına ilişkin yukardaki bölüme bakınız). Bu durumda olan kişiler, farklı bir firmada olsa dahi bir yıl süreyle yeni bir sertifika programına katılamazlar (İlaç Tanıtım Yönetmeliği, Madde 13/4).

Ürün tanıtım elemanlarının yaptıkları tanıtımdan ruhsat/izin sahibi ile ürün tanıtım elemanı müştereken sorumludur (İlaç Tanıtım Yönetmeliği, Madde 10/2).

Radyo TV Kanunu, bu kanunun ihlal halinde ayrıca medya hizmet sağlayıcılarına uygulanacak yaptırımlar içermektedir. Radyo TV Kanunu Madde 32/2 uyarınca, aynı kanunu ihlal eden medya hizmet sağlayıcıları uyarılır. İhlalin tekrarı halinde medya hizmet sağlayıcıya ihlalin tespit edildiği aydan bir önceki aydaki brüt ticari iletişim gelirinin yüzde birinden üçüne kadar idari para cezası verilir. İdarî para cezası miktarı, radyo kuruluşları için 1.000 Türk Lirası'ndan, televizyon kuruluşları ve isteğe bağlı medya hizmet sağlayıcıları için 10.000 Türk Lirası'ndan az olamaz.

Ayrıca hukuka aykırı tanıtım durumun özelliklerine göre Türk Ceza Kanunu, Tüketicinin Korunması Hakkında Kanun, Türk Rekabet Hukuku açısından sorumluluk doğurabilir. Devlet memuru olan sağlık mesleği mensupları da bu kuralları ihlal etmeleri durumunda disiplin soruşturmasına tabi olabilir.

Mesleki ve sektörel etik kuralları

AİFD

Araştırmacı İlaç Firmaları Derneği ("AİFD") 1 Temmuz 2012'den itibaren geçerli olmak üzere, İyi Tanıtım ve İyi İletişim İlkeleri'ni ("AİFD Tanıtım İlkeleri") İlaç Tanıtım Yönetmeliği doğrultusunda güncellemiştir. AİFD Tanıtım İlkeleri idari bir düzenleme niteliğinde değildir, ancak üyeleri açısından bağlayıcıdır. Dolayısıyla, neredeyse tüm araştırmacı ilaç firmalarının Türkiye iştirakleri için AİFD üyelikleri dolayısıyla bağlayıcı niteliktedir.

participating in and sponsoring congress and symposium activities for a period of one year (Article 13/2 of the Pharma Promotion Regulation).

If the advertising or promotion of a medicine is in violation of the Pharma Promotion Regulation, the marketing authorization holder is warned by the Ministry of Health. In case of repetition of the breach, it is prohibited from promotional activities. If the violation is further repeated, the marketing of the product is suspended for a period of three months, and in case of another repeated breach, for a period of one year (Article 13/3 of the Pharma Promotion Regulation).

In case of violations by the product promotion personnel, the certificates issued by the Ministry of Health are cancelled (please see the above section on the product promotion personnel). These product promotion personnel cannot participate in any other training for a period of one year, even in another company (Article 13/4 of the Pharma Promotion Regulation). The marketing authorization holder is severally liable along with the product promotion personnel for the promotional activities carried out (Article 10/2 of the Pharma Promotion Regulation).

The Broadcasting Law also includes sanctions applicable to media service providers in case of breach of this law. According to Article 32/2 of the Broadcasting Law, media service providers in breach of the same law are warned; in case of repetition of the breach, they must be condemned to a monetary fine of 1 to 3 percent of its gross commercial communication income for the previous month; such penalty, however, may not be less than TRY1,000 for radio establishments, and TRY10,000 for television establishments and optional broadcasting service providers.

Furthermore, illegal promotion may lead to liability under Turkish Criminal Law, Consumer Protection Law and Turkish Competition Law, depending on the case. HCPs who are public officers may also be subject to disciplinary actions in case of breach of these rules.

Professional and Industry Codes of Conduct

Research-Based Pharmaceutical Companies Association ("AIFD")

Research-based Pharmaceutical Companies Association (*Arastırmacı Ilaç Firmaları Dernegi*, "AIFD") updated its Good Promotion and Good Communication Principles ("AIFD Promotion Principles") in line with the Pharma Promotion Regulation, to be applicable as of 1 July 2012. The AIFD Promotion Principles are not state regulations. They are however,

AİFD Tanıtım İlkeleri, İlaç Tanıtım Yönetmeliği ile uyumlu olarak hazırlanmıştır, fakat daha detaylıdır. AİFD Tanıtım İlkeleri, İlaç Tanıtım Yönetmeliği'nde detaylı olarak ele alınmayan üyelerin sağlık meslek mensupları meslek birlikleri ve kongre düzenleyen kuruluşlarıyla olan ilişkileri (Bölüm 17), medya ile ilişkiler (Bölüm 19) ve internet, dijital platformlar ve sosyal medya kullanımı (Bölüm 20) gibi kuralları da düzenlemektedir.

İEİS

İlaç Endüstrisi İşverenler Sendikası ("İEİS") da 2009 yılında İlaç Ürünlerinin Tanıtımı ve Sağlık Meslek Mensupları ile İletişim Hakkında Yönetmelik yayınlamıştır. Ancak bu yönetmelik İlaç Tanıtım Yönetmeliği'nden önce hazırlanmış olduğundan güncel değildir.

Bu yönetmelik de idari bir düzenleme niteliğinde değildir, ve sadece İEİS üyeleri açısından bağlayıcıdır.

TİSD

Türkiye İlaç Sanayi Derneği'nin ("TİSD") de Tıbbi İlaç Tanıtım İlkeleri Kılavuzu (TİSD Tanıtım Kılavuzu) altında ilaçların tanıtımı ve pazarlanması hakkında kendi kuralları vardır. Bu kılavuz da 2006 düzenlenmiş olduğundan güncel değildir. TİSD şu anda TİSD Tanıtım Kılavuzu'nun İlaç Tanıtım Yönetmeliği doğrultusunda güncellenmesi üzerine çalışmaktadır.

TİSD Tanıtım Kılavuzu önceki Beşeri Tıbbi Ürünlerin Tanıtımı Yönetmeliği doğrultusunda hazırlanmış kurallar içermektedir, ancak bunlardan daha detaylıdır. Ayrıca bu kılavuzlarda başka kurallar da, örneğin halka ilişkiler ve medya ilişkileri, ilaçların tanıtımında internet kullanımı ve tanıtım ve satış faaliyetlerinin dışarıdan yaptırılması gibi konular da düzenlenmiştir.

Bu düzenleme de sadece TİSD üyeleri açısından bağlayıcıdır.

TTB

Türk Tabipler Birliği'nin ("TTB") iki kurallar dizisi altında ilaçların tanıtımına ilişkin kendi mesleki ilkeleri mevcuttur: TTB Hekim ve İlaç Tanıtım İlkeleri ve TTB Hekim-Endüstri İlişkisi Bildirgesi.

Bu kurallar altındaki temel ilke; hekimlerin görevini yerine getirmesinde icrasını etkileyebilecek, örneğin reçeteler hakkındaki kararlarını etkileyebilecek hiçbir hediyeyi kabul etmemesidir.

binding on its members who are mostly, if not all, research-based pharmaceutical companies' Turkish subsidiaries.

The AIFD Promotion Principles are prepared in conformity with the Pharma Promotion Regulation, but in a more detailed manner. The AIFD Promotion Principles include rules which are not regulated in detail in the Pharma Promotion Regulation; for instance rules on the members' relationships with HCP associations and congress-hosting entities (Section 17), relationships with the media (Section 19), and the use of internet, digital platforms and social media (Section 20).

Pharmaceutical Industry Employers Syndicate ("IEIS")

Pharmaceutical Industry Employers Syndicate (*Ilaç Endüstrisi Isverenler Sendikası,* "IEIS") also issued its Regulation on the Promotion of the Pharmaceutical Products and Communications with the HCPs in 2009. This regulation, however, was prepared before the Pharma Promotion Regulation and therefore is not up-to-date.

This regulation is also not a state regulation, but is binding only upon its members.

Turkish Pharmaceutical Industry Association ("TISD")

Turkish Pharmaceutical Industry Association (*Turkiye Ilaç Sanayi Dernegi*, "TISD") also has its own rules on the advertising and promotion of medicines, under its Pharmaceutical Products Promotion Guidelines ("TISD Promotion Guidelines"). These guidelines, however, were issued in 2006 and were therefore not up-to-date as well. TISD is currently working on an update of its guidelines in line with the Pharma Promotion Regulation.

The TISD Promotion Guidelines include rules that were prepared in line with the previous Pharmaceutical Products Promotion Regulation, but in more detail. Additionally, these guidelines also set forth some other rules, e.g., rules on public and media relations, use of internet for the promotion of medicines, and outsourced promotion and sale activities.

This regulation is also binding only upon its members.

Turkish Medical Doctors Association ("TTB")

Turkish Medical Doctors Association (*Türk Tabipler Birligi,* "TTB") has its own professional principles related to the promotion of medicines under two sets of rules: TBB Principles on the Medical Doctors and Promotion of

Cezai sorumluluk ve özel hukuk sorumluluğu

Cezai Sorumluluk

İhaleye fesat karıştırma

Ceza Kanunu'nun 235. ve 236. maddeleri kamu ihale sürecine hukuka aykırı her türlü müdahaleyi cezalandırmaktadır. Bir ilaç firması tarafından tanıtım kuralları ihlal edilerek gerçekleştirilen tanıtım faaliyetleri sonucunda kamu ihalelerinde rakiplerine haksız bir şekilde üstünlük sağlaması söz konusuysa bu hükümlerin uygulanması söz konusu olabilir.

Kamu İhale Kanunu'nun 17. maddesi uyarınca, hile, vaat, tehdit, nüfuz kullanma, çıkar sağlama, anlaşma, irtikap, rüşvet suretiyle veya başka yollarla ihaleye ilişkin işlemlere fesat karıştıran veya buna teşebbüs edenler herhangi bir kamu kuruluşu tarafından yürütülecek herhangi bir ihaleye katılmaktan 1 ila 2 yıl süreyle men edilirler.

Rüşvet ve yolsuzluk

Ceza Kanunu'nun 252, 253, 254 ve 255. maddeleri kamu görevlilerini kapsayan rüşvet ve yolsuzluğu yasaklamaktadır. Bu hükümlerin ilaçların sağlık meslek mensuplarına hukuka aykırı tanıtımı açısından da uygulanması söz konusu olabilir.

Türk Ceza Kanunu'nun 6/c maddesi "kamu görevlisi"ni "kamusal faaliyetin yürütülmesine atama veya seçilme yoluyla ya da herhangi bir surette sürekli, süreli veya geçici olarak katılan kişi" olarak tanımlamaktadır. Dolayısıyla, bu kişilerin Türk Ceza Kanunu doğrultusunda "kamu görevlisi" olarak kabul edilmesi, iş ilişkisinin özel bir kurumla mı ya da kamu kurumuyla mı olduğuna bakılmaksızın, bu sağlık meslek mensuplarının kamu yararına (yani kamu sağlığının korunması ve iyileştirilmesine) yönelik görev icra etmelerine bağlıdır.

Kamu sağlık kurumların çalışanı olan veya bunların temsilcisi olarak hareket eden sağlık meslek mensuplarının kamu görevlisi olarak görülmesi gerektiği açıktır. Ayrıca bağımsız çalışan ve kamu sağlık kurumlarının temsilcisi olarak hareket etmeyen veya özel sağlık kurumlarının çalışanı olanlar da kamu menfaati için bazı kanuni görevler yerine getirdiklerinden (örneğin hastalara Sosyal Güvenlik Kurumu'ndan geri ödemesi yapılan ilaçların reçetesini yazmak) Türk Ceza Kanunu anlamında kamu görevlisi olarak kabul edilebilirler.

Pharmaceutical Products, and TBB Declaration on the Medical Doctor-Industry Relationship.

The basic principle under these rules is that medical doctors must not receive gifts that may affect performance of their duty, such as their decisions on prescriptions.

Criminal and Civil Liability

Criminal Law

Bid Rigging

Articles 235 and 236 of the Criminal Code provide for punishment for any unlawful interference with public tender procedures and may apply to the promotion of medicines to HCPs when a promotional scheme is used by a pharma company so that it is unjustifiably favored in a public tender over its competitors. Furthermore, according to Article 17 of the Public Tender Law (Law no. 4734), those who are involved in bid rigging by means of fraudulent and corrupt acts, promises, threats, unlawful influences, undue interest, agreement, defalcation, bribery, or other acts shall be prohibited from participation in any tender carried out by any public body for a period of one to two years.

Bribery and Corruption

Articles 252, 253, 254 and 255 of the Criminal Code prohibit bribery and corruption involving public servants and may apply to the illegal promotion of pharmaceuticals to HCPs.

Article 6/c of the Turkish Criminal Law defines "public servant" as "a person continuously or temporarily appointed or elected or assigned by another manner for a definite or indefinite term to perform public activity." Therefore, irrespective of whether an employment relationship is with a private or a public entity, it is the duties performed by HCPs for the benefit of the public (i.e., the protection and enhancement of public health) that make them regarded as "public servants" for the purposes of the Turkish Criminal Law.

It is clear that HCPs who are employees of public health institutions or who act as agents of these must be viewed as public servants. Additionally, even HCPs who are self-employed and not acting as agents of public health institutions or who are employed by private health institutions may be regarded as public servants for the purposes of the Turkish Criminal Code

Rüşvet; "görevinin ifasıyla ilgili bir işi yapması veya yapmaması için, doğrudan veya aracılar vasıtasıyla, bir kamu görevlisine veya göstereceği bir başka kişiye menfaat sağlanması (veya bir kamu görevlisi tararından böyle bir menfaatin elde edilmesi)" olarak tanımlanmaktadır.

Türk Ceza Kanunu'nda "menfaat"in kapsamı açıkça belirtilmemiştir. Dolayısıyla "menfaat"in kapsamı her olaya özgü olarak belirlenecektir. Türk hukuk doktrinindeki genel yaklaşım uyarınca; sağlanan her türlü maddi, manevi veya cinsel fayda menfaat niteliğindedir. Dolayısıyla, herhangi bir hediye verilmesi değerine veya cinsine bakılmaksızın bir ihlal oluşturabilir.

Türk Ceza Kanunu uyarınca hem rüşvet alan kamu görevlisi (eğer varsa kamu görevlisi tarafından menfaati almak üzere gösterilen üçüncü kişi) hem de kamu görevlisine rüşvet veren kişi cezalandırılmaktadır.

Haksız menfaat rüşvet yoluyla bir tüzel kişiye sağlanmışsa, tüzel kişi de tüzel kişilere özgü güvenlik tedbirlerine tabi olacaktır.

Türk Ceza Kanunu Madde 60 uyarınca, tüzel kişilere özgü güvenlik tedbirleri aşağıdaki şekildedir:

- İznin/ruhsatın iptali: a) Eğer bir kamu kurumunun verdiği izne dayalı olarak faaliyette bulunan özel hukuk tüzel kişisinin organ veya temsilcilerinin iştirakiyle ve b) bu iznin verdiği yetkinin kötüye kullanılması suretiyle tüzel kişi yararına suç işlenmişse, mahkeme iznin iptaline karar verebilir.
- Mülkiyetin veya maddi menfaatin müsaderesi: Mahkeme suç/tecavüz ile bağlantısı olan malları veya maddi menfaatleri müsadere edebilir.

Ek olarak, özel hukuk tüzel kişisinin müdürleri, çalışanları veya yöneticileri (örneğin yönetim kurulu üyeleri veya şirketin temsil ve ilzamından sorumlu olanlar) suç teşkil eden fiilin işlenmesine kasıtlı olarak iştirak etmişlerse ceza hukuku anlamında sorumlu tutulabilirler. Suçun işlenmesine iştirak etmek buna karar vermek, bunu uygulamak veya suçun işlenmesini önlememek şeklinde olabilir.

due to certain statutory duties they perform for the benefit of the general public (e.g., prescribing medicines to patients that are reimbursable by the Social Security Institution).

Bribery is defined as providing benefit to (or receiving of a benefit from) a public servant or a third person determined by the public servant for the performance or non-performance of an act in violation of his/her duties.

The scope of the term "benefit" in the Turkish Criminal Code is not explicitly determined. The scope of the "benefit" is, therefore, determined on a case by case basis. According to the general approach in Turkish legal doctrine, it is any and all material, moral or sexual advantage gained. Potentially, therefore, the provision of any gift, regardless of its value or type, may constitute an offense.

The Turkish Criminal Code punishes both the public servant who receives the bribe (and the third person, if any, determined by the public servant and who receives the benefit) and the person who provides the bribe to the public servant.

If the unfair advantage is provided to a legal entity as a result of bribery, the legal entity will also be subject to the security precautions specific to legal entities.

According to Article 60 of the Turkish Criminal Code, the security precautions specific to legal entities are as follows:

- Revocation of license/permit: If a private legal entity abuses the authority arising out of a license/permit granted to it by a public entity; and the governing bodies or representatives of the legal entity have participated in the actions of such entity, the court may revoke the license/permit of the legal entity.
- Confiscation of property or material interests: The court may decide to confiscate the property or material interests which have a connection to the offense/crime.

Additionally, the managers, officers or directors of the private legal entity (e.g., members of the board of directors or those responsible for the representation and management of the company) may be held criminally liable if they intentionally participate in the commission of the criminal act. This participation in the commission of the act, for instance, may be in the form of deciding on, implementing or not preventing the commission of the criminal acts.

Reklam ve pazarlama faaliyetlerine ilişkin genel kurallar beşeri tıbbi ürünlerin tanıtımına da uygulanır. Dolayısıyla; aldatıcı, örtülü veya karşılaştırmalı reklamlar ve tanıtım faaliyetleri haksız rekabet niteliğindedir ve beşeri tıbbi ürünlere ilişkin olarak da yasaklanmıştır.

Türk Ticaret Kanunu'nun haksız rekabete ilişkin hükümleri (m. 55 ve devamı) *başkalarının mallarını, faaliyetlerini, ürünlerini ve ticari işlerini yanlış, yanıltıcı veya gereksiz yere incitici açıklamalarla kötülemeyi* yasaklamaktadır. Ayrıca 4077 sayılı Tüketicinin Korunması Hakkında Kanun'un 16. maddesi aldatıcı reklamları yasaklamaktadır.

İlaç Tanıtım Yönetmeliği'nin 6. maddesi de beşerî tıbbi ürün kullanımını gereksiz yönde teşvik edecek veya beklenmeyen riskli durumlara neden olabilecek yanıltıcı, abartılmış ya da doğruluğu kanıtlanmamış bilgiler vermek suretiyle veya ürün ile ilgisi olmayan görüntüler kullanılarak tanıtım yapılmasını yasaklamaktadır.

Haksız rekabet doğuran bir olay olduğunda, hakkı tecavüze uğrayan mahkemeden şu taleplerde bulunabilir:

(a) Fiilin haksız olup olmadığının tespitini;
(b) Haksız rekabetin men'i;
(c) Haksız rekabetin sonucu olan maddi durumun ortadan kaldırılmasını, haksız rekabet yanlış veya yanıltıcı beyanlarla yapılmışsa bu beyanların düzeltilmesi;
(d) Zararın tazmini;
(e) Manevi zararın tazmini.

(d) bendi hükmünce zararların tazmini olarak mahkeme, haksız rekabet yoluyla davalının elde etmiş olduğu menfaatin karşılığının da davacıya ödenmesine karar verebilir.

Bazı haksız rekabet fiilleri aynı zamanda cezai sorumluluk da doğurur. Bu tür eylemler için öngörülen ceza, bir aydan bir yıla kadar hapis ve/veya 500 Türk Lirası'ndan 10.000 Türk Lirası'na kadar adli para cezasıdır. Tecavüz mahkeme kararına rağmen devam ettiği takdirde, saldırgan taraf altı aydan az olmayacak şekilde hapis cezasına ve 5.000 TL'den 10.000 TL'ye kadar para cezasına mahkum edilebilir.

Civil Law

The general rules on advertisement and promotional activities are applicable also to the promotion of pharmaceutical products. Therefore, misleading, implicit and comparative advertisements and promotional activities are regarded as acts of unfair competition and thus prohibited with regard to pharmaceutical products as well.

The Turkish Commercial Code provisions on the acts of unfair competition (Articles 55 *et seq*.) prohibit discrediting others' goods, activities, products or commercial affairs by means of wrong, deceitful or unnecessarily offensive statements. Additionally, Article 16 of the Turkish Consumer Protection Law (Law no. 4077) prohibit misleading advertisements.

Article 6/6 of the Pharma Promotion Regulation also prohibits the promotion of medicines by deceptive, exaggerated or unproven information that may lead to unnecessary use of the product, or unexpected risky situations or images that are not directly related to the product.

In case of any act of unfair competition, the victim may demand from the courts:

- the establishment of the existence of unfair competition;
- the prevention of unfair competition;
- the suppression of the material conditions resulting from unfair competition and, if unfair competition is manifested in untrue or deceitful statements, the rectification of these statements;
- compensation for damages; and
- the payment of moral damages.

With regards to compensation for damages, the court may also order the payment to the plaintiff of the value of the advantages which the offender may secure through the relevant unfair competition acts.

Some acts of unfair competition may also result in criminal liability. The sanction for such acts is imprisonment of one month up to one year and/or a monetary fine of TRY500 to TRY10,000. If the offending acts continue in spite of a final judgment, the offending parties may be subject to imprisonment of not less than six months and a monetary fine of TRY5,000 to TRY10,000.

Sağlık meslek mensupları ve sağlık kurumları ile yapılacak sözleşmeler

Sağlık meslek mensupları ve sağlık kurumları ile yapılacak sözleşmeler Türk Medeni Kanunu, Türk Borçlar Kanunu ve Türk Ticaret Kanunu'nda belirtilen Türk Sözleşmeler Hukuku genel ilkelerine tabidir.

Kamu görevlisi olan sağlık meslek mensupları ile sözleşme yapılmasında bunlara ek olarak özel kurallar uygulanmaktadır: Kural olarak hekimler ve diş hekimleri dışındaki kamu görevlisi sağlık meslek mensupları başka ticari faaliyetler yürütemezler (Devlet Memurları Kanunu, Madde 28). Nitekim, kamu görevlisi olan hekimlerin ve diş doktorları ticari faaliyette bulunabilirler (1219 sayılı Tababet ve Şuabatı San´atlarının Tarzı İcrasına Dair Kanun) ("1219 sayılı Kanun"). Son zamanlarda hem Devlet Memurları Kanunu'nda hem de 1219 sayılı Kanun'da kamu görevlisi olan hekimlerin ve diş doktorlarının ticari faaliyet sürdürmesini yasaklayan değişiklikler yapılmıştır. Ancak Anayasa Mahkemesi 2011/112 E. saylı kararıyla bu değişiklikleri iptal etmiştir. Sonuç olarak, şu anda kamu görevlisi olan hekimlerin ve diş doktorlarının ticari faaliyet sürdürüp sürdüremeyeceğine ilişkin hükümlerde bir kanun boşluğu vardır. Dolayısıyla, mevcut durumda kamu görevlisi olan hekimlerin ve diş doktorlarının üçüncü kişilerle özel bir sözleşme ilişkisine girip giremeyeceği konusunda net bir görüş belirtmek mümkün değildir.

Kamu görevlisi olmayan sağlık meslek mensuplarıyla sözleşme ilişkisine girmek mümkündür, fakat eğer varsa sağlık meslek mensubunun sağlık kurumları ile aralarındaki iş sözleşmelerinden kaynaklanan kısıtlamalar söz konusu olabilir.

Sağlık meslek mensuplarına veya sağlık kurumlarına sözleşme ilişkisi altında menfaat sağlamak onların görevlerini icrası sırasında ilaç şirketi veya ürünüyle ilgili kararlarını etkilemeye yönelik olmamalıdır.

Tavsiyeler

Aşağıdaki tavsiyeler Türkiye'de tanıtım faaliyetlerinde bulunan ilaç şirketlerine rehberlik etme amacı taşımaktadır. Aşağıdaki tavsiyeler örnek niteliğinde olup, bunların dışındaki faaliyetlerin hukuka aykırı veya uygun olduğu anlamına gelmez.

Contracts with Healthcare Professionals and Medical Institutions

Contracts between HCPs and medical institutions are governed by the general principles of Turkish contract law set out in the Turkish Civil Law, the Turkish Code of Obligations and Turkish Commercial Law.

Special additional rules apply to executing contracts with HCPs who are public servants. In principle, public servant HCPs other than medical doctors and dentists cannot conduct any other commercial activity (Article 28 of the Public Servants Law). Medical doctors and dentists who are public servants, however, are permitted to carry out commercial activities (Law no. 1219 on the Conduct of Medical Professions). There have been recent amendments to both the Public Servants Law and the Law on the Conduct of Medical Professions, which prohibit medical doctors and dentists who are public servants from carrying out other commercial activities. The Turkish Constitutional Court, however, cancelled these amendments with its decision no. E. 2011/113. As a result, there is currently a gap in the legal provisions on whether public servant medical doctors and dentists can carry out other commercial activities or not. Therefore, it is currently not possible to give a clear opinion on whether public servant medical doctors and dentists can enter into private contractual relationships with third parties.

Entering into contractual relations with HCPs who are not public servants is possible, but may be subject to restrictions on the side of these HCPs as a result of their employment contracts, if any, with the medical institutions.

Providing benefits to HCPs or health institutions under the contractual relations must not aim to affect their decisions with regard to a pharmaceutical company or product when performing their duties.

Hediyeler

Kural olarak sağlık meslek mensuplarına hediye verilmemelidir. Sağlık meslek mensuplarına verilen tanıtım malzemeleri pahalı olmamalıdır.

Numuneler

Numunelerin dağıtımı ilaçların reçeteye yazılmasını veya satışını artırma amacıyla yapılmamalıdır.

Dağıtım ve Tanıtım Malzemeleri

Alıcının iletişim bilgilerinin ayrıntıları tanıtım malzemelerinin ilgisiz kişilere ulaşmasını engellemek adına güncel olmalıdır. Ayrıca bu iletişim bilgileri kişisel veri niteliğindedir ve bu yüzden gizlilik esaslarına uygun hareket edilmeli ve bunların korunması için gerekli koruma önlemler alınmalıdır.

Konaklama

İlaç ürünlerinin tanıtımı ile ilgili organizasyonlar veya sağlık meslek mensuplarının bu tür organizasyonlara katılımı desteklenmemelidir.

Verilen destek makul bir seviyede olmalıdır.

Bir sağlık mensubunun bir kongre veya sempozyuma katılımının desteklenmesinin ilaçların geçmişteki veya gelecekteki reçetelendirilmesi ile hiçbir bağlantısı olmamalıdır. Destek, belli bir sayıda ilacın reçeteye yazılmasına bağlı olma şartıyla veya bu amaçla verilmemelidir.

Destek verilen kongre veya sempozyum gibi bilimsel faaliyetler aşırı gösterişli veya lüks yerlerde yapılmamalıdır.

Sağlık meslek mensupları ve sağlık kurumları ile yapılacak sözleşmeler

Sağlık meslek mensuplarına ve sağlık kurumlarına yapılan ödemeler piyasa şartlarına uygun bir seviyede olmalıdır.

Recommendations

The following recommendations are intended to offer guidance to pharmaceutical companies with regard to their promotional activities in Turkey. These are exemplary recommendations only, and must not be construed as an exhaustive list.

- Gifts: In principle, no gifts must be provided to HCPs. Promotional materials provided to HCPs must be inexpensive.
- Samples: The distribution of samples must not aim to increase the prescription or sale of the medicines.
- Distribution of Promotional Materials: The contact details of the recipients must be up-to-date in order to prevent inappropriate persons from receiving the promotional materials. Additionally, these contact details are personal information and hence must be treated as confidential, and necessary protective measures must be taken for their protection.
- Hospitality:
    - Events aimed at the promotion of pharmaceutical products, or participation of HCPs in such events must not be sponsored.
    - Sponsoring the participation of an HCP in a congress/symposium must not be linked in any manner to the past or future prescription of medicines. The sponsorship must not be provided for or with the condition of a certain number of prescription of medicines.
    - The sponsorship must be at a reasonable level.
    - Sponsored scientific meetings such as congresses or symposiums must not be held in too lavish or luxurious locations.
- Contracts with HCPs and health institutions: Payments to HCPs and health institutions must be at the market level.

Ukraine

Olga Shenk

Introduction

The Ukrainian pharma market is growing constantly and offers to both health professionals and consumers larger scope of medications each year. At the same time, the regulation of activities in the Ukrainian pharma market, including such a sensitive matter as promotion of medical products, is sometimes ambiguous and has specifics to be considered. Thus, below is a summary covering basic concepts of the regulatory framework, the allowed and the prohibited practices related to promotion of the medical products, the attached risks and the possible negative consequences, as foreseen by the applicable Ukrainian legislation.

The Regulatory Framework

The principal legislative acts governing the promotion of medications in Ukraine are the Law of Ukraine On Medicines of 4 April 1996 ("Law on Medicines") and the Law of Ukraine On Advertising of 3 July 1996 ("Advertising Law").

The Law on Medicines regulates research and development activities with respect to medications. In particular, it regulates carrying out of clinical trials, registration, production and sale of medicines in Ukraine. The Law on Medicines provides, however, that the promotion of medications in Ukraine is governed by the Advertising Law.

The Advertising Law provides for both general advertising rules and rules specific for promotion of medical products. All types of medications, medical devices, preventive measures and any methods of diagnosis, treatment and rehabilitation, which are authorized in Ukraine, fall under the scope of the Advertising Law. The provisions of the Advertising Law also apply to promotion of cosmetics, food, vitamins and other types of food additives which have certified medical effect.

The Law of Ukraine On Protection from Unfair Competition of 7 June 1996 ("Unfair Competition Law") together with the Advertising Law specifies general requirements to comparative advertising.

The promotion of medications to medical institutions and health professionals is also regulated by Order No. 177 of the Ministry of Health of

Ukraine On Approval of Legislative Acts Governing Promotion of Medical Products of 10 June 1997 ("Order No. 177").

Permitted and Prohibited Practices

The abovementioned legislative acts define the scope of permitted and prohibited practices relating to the promotion of medical products in Ukraine. At the same time, the recently amended Law of Ukraine On Fundamentals of Legislation of Ukraine on Health Protection ("Law on Health Protection") provides for some restrictions, although rather unclear, which can apply with regard to the provision of gifts, seminars, hospitality and entertainment to health professionals. In addition, the general provisions of Ukrainian law, as well as provisions of Ukrainian legislation aimed at combating corruption in Ukraine, will be applicable.

Gifts, Seminars, Hospitality and Entertainment

Ukrainian law specifically addresses the issue of providing gifts to public servants or officials of public legal entities[1] in Ukraine, including health professionals. In addition, the Law on Health Protection prohibits health professionals and pharmacists from receiving unlawful benefits while performing their professional duties; however, such unlawful benefits are not clearly determined in law.

In particular, Ukrainian law restricts the value of provided gifts, as well as other gratuitous benefits, to those health professionals who qualify as public servants or officials of public legal entities. Pursuant to the Law of Ukraine On Public Service, any and all employees of Ukrainian public authorities (including the highest public authorities such as the Verkhovna Rada (Parliament) of Ukraine, the Secretariat of the President of Ukraine, the Cabinet of Ministers of Ukraine, the Ministry of Health of Ukraine, as well as other Ukrainian ministries and state administrations of the national and various local levels qualify as public servants.

The new Law of Ukraine On Prevention of and Counteraction Against Corrupt Practices of 7 April 2011("Anti-Corruption Law") further determines

[1] Part 2 of Article 81 Civil Code of Ukraine foresees that the public legal entity is a legal entity established by the administrative act of the President of Ukraine, of the state authority, of the authority of the Autonomous Republic of Crimea or by the local self-government authority, which means that, generally, medical institutions are considered public legal entities.

persons who can be found liable for the corrupt actions. In particular, such persons are: Ukrainian public servants and officials of the public legal entities; foreign public servants; and officials of international organizations, among others.

Note that officials of public legal entities became a new subject of liability for corruption actions in Ukraine.

According to the rules of the Anti-Corruption Law, public servants and officials of public legal entities are explicitly prohibited: to receive gifts (donations) from legal entities or individuals in exchange for decisions, actions or inactivity, performed directly or by other officials in the interests of the presenter; and to receive such gifts from any subordinated person.

Gifts and donations, which meet the generally accepted criteria of hospitality, are allowed, but the value of such gifts and donations is limited. In particular, such value cannot exceed half of the statutory minimum monthly salary effective as of the date of the acceptance of such gift (donation), and the aggregate value of such gifts (donations) accepted from a single source during one year cannot exceed one minimum monthly salary, set as of 1 January of the respective year.

As of July 2012, the value of a single gift cannot exceed approximately USD71, and the total value of gifts during one year cannot exceed approximately USD134 (i.e., one minimum monthly salary as of 1 January 2012).

Therefore, those health professionals who have the status of public servants or officials of public legal entities under the applicable Ukrainian legislation can receive gifts or donations, bearing in mind the abovementioned restrictions regarding value of such gifts (donations).

As to participation in scientific seminars, as well as receiving relevant payments for such participation, health professionals who qualify as public servants or officials of public legal entities in Ukraine may lawfully participate in scientific seminars only if their participation is paid for either by themselves or by their employer.

In turn, health professionals who do not have the status of public servants or officials of public legal entities under the applicable Ukrainian legislation are authorized to take part in scientific seminars or conferences, and to be paid for such participation.

Ukrainian legislation fails to provide for any specific rules governing hospitality or entertainment to health professionals. Therefore, one may conclude that any such hospitality or entertainment may be extended to those health professionals who do not qualify as public servants or officials of public legal entities, bearing in mind, however, the restriction regarding obtaining unlawful benefit under the Law on Health Protection.

At the same time, under the Anti-Corruption Law, the value of hospitality or entertainment offers should be taken into account by health professionals holding positions of public servants or officials of public legal entities. If the hospitality or entertainment offer is extended to and/or accepted by a public servant or official of a public legal entity, those mere facts may qualify as corrupt practice if the value of such hospitality or entertainment exceeds the allowed gifts value according to the applicable legislation, and/or the purpose of such hospitality is to receive competitive advantage or other benefit.

Promotional Activities

Under the Advertising Law, the promotion of medical products qualifies as 'advertising,' which is defined as "information about a person or a product disseminated in any form and by any method, which purports to form or to maintain the awareness of the consumers and their interest in such person or products."

An advertisement should be designated for an indefinite number of persons. The Advertising Law lists advertising practices which are prohibited in Ukraine.

Under the general rules, applicable to advertising of any products in Ukraine, including medications, such advertising should:

- be lawful, accurate, true, and harmless to its consumers;
- comply with the principles of fair competition;
- not include information or images which contradict the principles of morality and humanity; and
- consider particular sensitiveness of children and avoid inflicting damage.

The Advertising Law makes precise distinction between promoting medications to the general public and to health professionals. Such distinction primarily concerns the promotion of prescription and non-prescription medications in Ukraine. Only non-prescription medications, not

entered into the special list of medications prohibited for advertising, may be advertised to the general public in Ukraine.

The following information cannot be included into advertisements of medications, medical devices, etc.:

- Information regarding the guaranteed curative effect of the advertised product
- References to actual cases of the successful application of the advertised product
- Comparisons to other products intended to increase the impact of the advertised product
- Information stipulating that use of the advertised medications or medical technologies does not require consultation with a doctor
- Images of the effect of illness or injury to the human body or its parts
- Statements provoking fear of illness or deterioration of one's health condition as a result of failure to use the advertised products
- Statements supporting self-diagnosis and self-treatment with the use of the advertised products
- References to medications, medical equipment, methods of prevention, diagnostics, treatment and rehabilitation as the most effective, most secure and exclusive because of lack of side effects
- References to separate cases of successful use of medications, medical equipment, methods of prevention, diagnostics, treatment and rehabilitation
- Recommendations or references to recommendations of the advertised product or service by medical professionals, scientists, medical institutions and organizations
- Special expressions of gratitude, the letters or extracts therefrom with recommendations, stories about the use of the advertised goods or services and the results of such use
- Images and references to celebrities, film characters or reputable organizations
- Information, which may mislead the consumer on composition, origin, production, effectiveness or patent protection of product
- References to the therapeutic effect of advertised products on incurable illnesses or illnesses which are uneasily responding to treatment

Advertisements of medications and medical devices must include the following:

- True information on the advertised product with the clear statement of such information being an advertisement and the advertised product being a medical product
- Requirement of the mandatory consultation with a doctor before use of the product
- Recommendation on the mandatory review of the instruction on use of the advertised product
- The warning: "Self-treatment can damage your health" which must take up at least 15 percent of the advertisement's area.

Participation of doctors or other health professionals or persons, whose appearance imitates appearance of doctors, is prohibited while advertising medical products. In addition, it is prohibited for health professionals to use prescription forms bearing any information of advertising nature. The advertisement of medications cannot contain statements suggesting that the medication is food, a cosmetic product or any other consumer product, or that the effectiveness of such product is caused by its natural origin.

The Advertising Law also prohibits promotion, *inter alia*, of prescription-only medications, doping and methods of its use in sport, etc.

As regards the promotion of medications to health professionals, both prescription and non-prescription medications may be lawfully advertised, provided, however, that advertisements of prescription medications published in specialized editions for medical institutions and health professionals, or be disseminated during scientific medical conferences, and further provided that only authorized medical products are promoted to health professionals in Ukraine.

According to Order No. 177, information in promotional materials of any kind intended to health professionals must be based on scientific evidence, and must include full, precise and clear information which may not exceed, however, the scope of information specified in the instructions for the use of the advertised medical products.

The Ukrainian law also defines the scope of permitted and restricted practices with regard to comparative advertising of medications and medical devices. Further to the explicit prohibition in the Advertising Law, comparative advertising is governed by the Unfair Competition Law.

The Unfair Competition Law defines comparative advertising as advertising containing comparison between particular products, works, services or activities of one business entity to another. It establishes that such comparison is not unlawful as long as it provides information which is based on fact, is accurate, objective and useful for consumers.

Notwithstanding the above general rule, no advertising of a medical product may contain comparison to another medical product, if such comparison is intended to increase the impact of the advertisement.

The Antimonopoly Committee of Ukraine is the Ukrainian authority responsible for determining whether a particular comparative advertisementis accurate, objective and useful for consumers.

Samples

The Law on Health Protection prohibits health professionals and pharmaceutists from obtaining samples of medications or medical devices for their use while performing professional duties, except for such samples being used in the respective clinical trials.

Consequences of Breach of Legislation

In accordance with Article 27 of the Advertising Law, violations of Ukrainian legislation on advertising are subject to civil, criminal and disciplinary liability. In addition, the applicable legislation provides for the imposition of administrative economic sanctions for violations of advertising of medical products' rules.

Civil Liability

Civil liability, which may be imposed for violation of the applicable rules on promoting medical products in Ukraine, generally amounts to the compensation of damages by the liable party.

Civil liability may be imposed if the promotion of medical products inflicted damages on any legal entity and/or individual.

In particular, damages can be inflicted by violating the provisions of the Advertising Law regulating both the general procedures of advertising and the special legal requirements on advertising medical products. Damages can also be awarded as a result of the violation of the Unfair Competition Law.

Under the Civil Code of Ukraine, damages may be awarded if the competent court establishes:

- the fact that the damage had been caused;
- the fact of the unlawful activities of the infringer; and
- the link between the unlawful activities and the damage caused.

Economic Sanctions

According to the applicable Ukrainian legislation, economic sanctions can also be imposed on individuals and/or legal entities performing promotional activities contravening the applicable Ukrainian advertising legislation.

In particular, economic liability can be imposed for advertising medical products, which are prohibited for advertising in Ukraine (e.g., advertising of unauthorized medications, advertising of prescription-only medications, etc.).

Penalties may also be imposed for failure to comply with the legal requirements on the content of advertising (e.g., the name of the producer of the medical product in the advertising; thank-you letters with regard to the curative effect of the advertised product; if advertising supports the idea that the involvement of a health professional is not and/or will not be required if the advertised product is consumed; that the advertised medical product is a food or cosmetic product, or any other consumable product not having curative effect, etc.).

The economic liability for violation of Ukrainian legislation on advertising is imposed in accordance with Resolution of the Cabinet of Ministers of Ukraine No. 693 On Adoption of Order on Imposing of Penalties for Violation of Legislation on Advertising of 26 May 2004.

A fine in the amount of five times the value of the placed advertisement may be imposed for the violation of the applicable Ukrainian advertising rules.

Also, publication of the information clarifying or supplementing the non-compliant advertising may be required.

The responsibility for enforcing the applicable advertising legislation and the right to impose the respective penalties are vested with the State Inspection for Consumer Rights Protection of Ukraine.

The Antimonopoly Committee of Ukraine is also authorized to impose penalties for violations of the applicable competition legislation rules with

regard to the pharmaceutical advertising, in particular, in case of the comparative advertising and the achievement of unfair advantage in competition.

Criminal Liability

Under the applicable Ukrainian criminal legislation, only individuals may be subject to criminal liability. Thus, individuals unlawfully proposing or providing gifts, hospitality offers, etc., exceeding the determined value (as discussed earlier) in exchange for receiving competitive advantage, as well as health professionals receiving such gifts or hospitality offers, if such persons qualify as public servants or officials of public legal entities in Ukraine, may be subject to criminal liability.

In particular, there is a risk that any such benefit, gift or hospitality offer to public servants or officials of public legal entities in Ukraine, with the value exceeding the established one, can be considered a bribe, if it was provided in exchange for receiving competitive advantage.

In such case, the provisions of Article 368 "Acceptance of Bribe" and Article 369 "Proposal or Giving of Bribe" of the Criminal Code of Ukraine ("Criminal Code") will apply.

In particular, the liability of the public servants or officials of public legal entities for acceptance of a bribe involves a fine in the amount between 500 and 750 non-taxable minimal incomes (i.e., approximately from USD1,063 to USD1,595), or by corrective labor for up to one year, or imprisonment for up to six months with the prohibition to hold certain positions for a term of up to three years.

However, the amount of such penalties and liabilities may be seriously increased, including imprisonment for a term of up to 12 years, subject to occurrence of aggravating circumstances (e.g., depending on the amount of a bribe, or if the bribery was committed upon previous collusion by a group of persons, etc.).

Proposal of a bribe is punished by imposition of a fine amounting from 100 to 250 non-taxable minimal incomes (i.e., approximately from USD213 to USD532), or the limitation of freedom for up to two years.

Giving of a bribe is punishable by imposition of a fine in the amount from 250 up to 750 non-taxable minimal incomes (i.e., approximately from USD532 to USD1,595) or imprisonment for a term between two and five

years. The Criminal Code also provides for imprisonment of an individual for a term between three and six years, with or without confiscation of property if bribing is committed by such individual repeatedly. The sanctions (i.e., both the amount of fine and the term of imprisonment) for proposal or giving of a bribe can also be increased subject to occurrence of aggravating circumstances.

Disciplinary Liability

According to the applicable Ukrainian legislation, disciplinary liability can be imposed by the employer on the employee for his/her failure to fulfill or to properly fulfill his/her professional duties. The disciplinary liability can be applied by issuance of a reprimand or dismissal of the employee. Thus, the disciplinary liability for the violation of the applicable Ukrainian legislation on promotion of medication and medical devices can be imposed by the employer on the employee in the course of the latter's performance of his/her labor duties.

Professional Codes of Conduct

In 1999, a group of companies established the European Business Association ("EBA") in Ukraine. EBA is the premier organization of foreign businesses in Ukraine, currently representing the interests of 900 European (both national and international) companies operating in Ukraine.

Due to the efforts of its Medical Committee, EBA adopted the Code of the Marketing Practice of Manufacturers of Medical Products and Their Representative Offices ("Code").

The Code was developed for purposes of assisting the respective EBA member-companies in their development and application of standards based on fair and responsible marketing practices. The Code expressly provides that Ukrainian laws shall at all times have the highest priority, and that all EBA member-companies shall undertake not to publish any advertising materials which contradict the principles established by Ukrainian laws as well as those set out in the Code.

The Code establishes the standards of advertising of prescription as well as non-prescription medical products. With respect to prescription medical products, the Code provides that "advertising materials pertaining to medical products should be precise, comprehensible, objective and set out in the form which complies both with the requirements of applicable laws and ethical standards. Claims contained in the advertising materials, pertaining to effect

of the treatment based on the specific medical products should not exceed the respective effect confirmed by scientific evidence. Companies should undertake maximum efforts aimed at avoiding any misunderstandings in providing information about medical products."

As regards the provision of samples of medical products to health professionals, the Code establishes that "samples of medical products which are expressly determined as such (they should necessarily be marked in order to prevent any abuse) may be provided to health professionals who were granted the right to prescribe respective medical product, for the purpose of finding out more about such medical product and gaining practical experience."

With regard to the organization of symposia and congresses of health professionals, the Code establishes that "symposia, congresses and similar events are to be held in order to disseminate knowledge and experience. Objectives for holding such events should be associated with science. Entertainment and exercise of hospitality should not go against such scientific objective."

The Code also establishes the following rules as to offering of gifts and hospitality to health professionals:

- "No gifts, remuneration or incentives whatsoever shall be offered or promised to be granted to health professionals, except for the instances when such gifts are inexpensive and comply with the practice acceptable in the fields of medicine and pharmacology."
- "Hospitality should be offered at the professional and scientific events within reasonable limits and be of auxiliary/supplementary nature in comparison with the main objective of such event."

Contracts with Healthcare Professionals and Medical Institutions

The general rules of Ukrainian contractual law are applicable for entering into agreements with health professionals and medical institutions. However, the principles and limitations in respect of the health professionals having the status of public servants should be considered with regard to such contracts.

The main types of contracts entered into by health professionals and medical institutions are clinical trials contracts and contracts regarding the provision of expert services (consulting contracts).

Clinical trials contracts are usually entered into by the companies (mainly pharmaceutical research and development ("R&D") companies or their authorized representatives) and Ukrainian specialized medical institutions. However, a company may also enter into a separate contract with a health professional (an individual) who heads a group of health professionals conducting clinical trials in Ukraine. The essential provisions of such contracts are provided for by Ukrainian legislation on conducting clinical trials.

Generally, no restrictions apply to consulting contracts with health professionals under the applicable Ukrainian legislation. At the same time, the restrictions imposed by Ukrainian law on health professionals qualifying as public servants, as outlined above, should be considered when concluding consulting contracts with such health professionals.

Medical institutions and health professionals may also be involved in market research contracts. Neither partly is subject to any restrictions other than those generally applied to public servants and those relating to unfair advantage rules, which are described above.

Recommendations

While promoting medical products in Ukraine, including by way of providing gifts (donations), hospitality and entertainment to health professionals, the limitations established by the applicable law must be considered to avoid allegations of corrupt practices, which may involve criminal liability. The same limitations must be taken into account while entering into clinical trial contracts with the respective health professionals.

It is also important to strictly follow the requirement of the Advertising Law, especially in terms of distinguishing advertising of non-prescription and prescription-only medications. The limitations in respect of the advertising content, established by the Advertising Law, must be considered and complied with as well.

Finally, further to the mandatory compliance with the applicable Ukrainian legal rules, in order to promote medical products in Ukraine, it is also recommended to follow the EBA's Code of the Marketing Practice of Manufacturers of Medical Products and their Representative Offices, as the Code specifically developed standards for EBA member-companies in advertising of their medical products.

United Kingdom

John Leadley, Richard Davies

Introduction

The promotion of medicinal products in the United Kingdom is regulated by a combination of statute, government, industry and professional voluntary codes of conduct, together with professional rules and guidance introduced by the bodies regulating the prescribers themselves.

The regulation is not always consistent, but the recurring themes running through the various sources are proportionality and relevance as regards promotional effort.

The ultimate goals are the protection of patients and upholding confidence in the healthcare industry, and the overriding principle is that pharmaceutical companies must not bring discredit upon or reduce confidence in manufacturers and distributors of medical products, for example, by promoting certain products directly to patients, on the one hand, or by using or being perceived to use inappropriate pressure or inducements to encourage doctors to prescribe their products, on the other.

The Regulatory Framework

A distinction is drawn in English law between medicinal products and medical devices. A "medicinal product" is any substance or article used for a medicinal purpose, such as diagnosing, treating and preventing disease that is not "an instrument, apparatus, or appliance". This includes both proprietary and generic pharmaceuticals. A "medical device" is defined as "an instrument, apparatus, appliance or other article" used for a medicinal purpose.

The Medicines Act 1968 ("the Act") as amended by the Medicines (Advertising) Regulations 1994[1] , as further amended by the Medicines (Advertising Amendments) Regulations 2005[2] ("Advertising Regulations"), which implements European Community law[3], imposes restrictions and

[1] SI 1994/1932.
[2] S1 2005/2787.
[3] Directive 2001/83/EC (as amended by Directive 2004/27/EC).

requirements that must be followed in all forms of advertising and promotion of medicinal products, and in the provision of free samples.[4]

By contrast, the Medical Devices Regulations 2002[5] do not contain any provisions or restrictions on the advertising and promotion of medical devices. It should be noted, however, that the Advertising Regulations do cover the supply of devices in some circumstances, namely, where the supply of devices is used as an inducement to purchase medicinal products.

The promotion of pharmaceutical products is also regulated by the legislation generally applicable to product promotion, including the Trade Descriptions Act 1968, the Consumer Protection from Unfair Trading Regulations 2008 and the Business Protection from Misleading Marketing Regulations 2008.

Under the Act and the Advertising Regulations, it is the Health Minister that has responsibility for ensuring compliance. In the UK, this responsibility is devolved to the Medicines and Healthcare products Regulatory Agency ("MHRA"). In accordance with its regulatory role, the MHRA issues the Blue Guide which contains detailed guidance on the advertising and promotion of medicines in the UK. The Guide is available on the MHRA website.[6]

The Regulations are supplemented by a number of voluntary standards applicable to the healthcare industry.

With regard to prescription medicines, the Association of the British Pharmaceutical Industry ("ABPI") has set guidelines that are embodied in the

[4] The Medicines and Healthcare Regulatory Authority has announced that the existing legislative regime will be consolidated and replaced by the Human Medicines Regulations 2012 ("2012 Regulations"), which will come into force in 2012 and will replace most of the Medicines Act 1968 and consolidate around 160 statutory instruments as well as bringing the UK into compliance with other European Directives related to the licensing, manufacture, supply and monitoring of pharmaceuticals. The 2012 Regulations are intended to simplify and bring clarity to the regulatory regime. Directive 2001/83/EC remains in force and therefore, the process of consolidation is not anticipated to bring about significant changes to the regulation of medicinal advertising and promotional activities. At the time of writing, the Regulations are available in draft form only.

[5] SI 2002/618

[6] www.mhra.gov.uk.

Code of Practice for the Pharmaceutical Industry ("ABPI Code").[7] The ABPI Code deals, amongst other things, with promotional activity relating to the prescription, supply, sale and administration of medicines. According to the ABPI, virtually all pharmaceutical companies operating in the UK have agreed to abide by the conditions of the ABPI Code, whether or not they are members of the ABPI. Companies must now appoint a senior employee to be responsible for ensuring that the company meets the requirements of the Code. There is an assumption that the responsible person will be the managing director or chief executive.[8]

With regard to over-the-counter ("OTC") medicines, the Proprietary Association of Great Britain Codes of Practice for Advertising OTC Medicines (incorporating the Consumer Code and Professional Code) 2004 ("PAGB Code") is applicable. The PAGB Code is very similar to the ABPI Code, detailing guidelines on general duties, acceptable information in advertising, hospitality and free goods and samples. Since OTC medicines may be promoted to both consumers and medical practitioners, the PAGB Code makes separate provision for each. As OTC medicines may be advertised to the public, the PAGB Code supplements the more general codes which govern advertising: the UK Code of Non-Broadcast Advertising, Sales Promotion and Direct Advertising ("CAP Code") and the UK Code of Broadcast Advertising ("BCAP Code"), both of which are administered and breaches investigated by the Advertising Standards Agency.

Lastly, with regard to medical devices, the Association of British Healthcare Industries ("ABHI") has set down the Association of British Healthcare Industries' Code of Business Conduct ("ABHI Code of Conduct"), which includes Guidelines on interactions with healthcare professionals ("ABHI Interaction Guidelines") that are largely consistent with the ABPI Code. The

[7] The ABPI Code incorporates the principles set out in the EC Directive on the Community Code relating to medicinal products for human use (2001/83/EEC), as amended by Directive 2004/27/EC and the Codes and Criteria of several international and regional bodies, including the International Federation of Pharmaceutical Manufacturers and Associations, the World Health Organisation and the European Federation of Pharmaceutical Industries' Associations. The draft in force at the time of writing came into operation on 1 January 2012. The ABPI has announced that a new Code will be published and become effective from November 2012. The changes are not fundamental, but there are some amendments to the rules and definitions surrounding promotions to healthcare professionals. These developments continue the trend toward limiting promotion more fully.

[8] ABPI Code, Clause 1.8 and Supplementary Information to Clause 1.8.

ABHI has also recently published the ABHI Guidelines on Advertisements & Promotions addressed solely or primarily to Healthcare Professionals ("ABHI Advert Guidelines").

While membership of these industry bodies and compliance with the relevant codes of practice are generally voluntary, such industry codes are likely to be highly relevant to any assessment of whether a company had in place measures to prevent bribery, so as to avoid criminal liability under the Bribery Act 2010 (discussed further below).

In addition to the codes of practice detailed above, there are further codes and guidance that will be applicable to purchasers; for example, the General Medical Council ("GMC") issues guidance to the doctors it regulates on how to conduct dealings with industry, and the General Pharmaceutical Council ("GPC") has published and enforces standards of conduct, ethics and performance for pharmacists ("the GPC Standards"). Similarly, prescribers and those involved in procurement for the National Health Service ("NHS") will be subject to specific internal rules and guidance on procurement and business ethics. For example, the Department of Health has published a guide entitled Commercial Sponsorship: Ethical Standards for the NHS ("NHS Code").

Permitted and Prohibited Practices

Gifts, Seminars, Hospitality and Entertainment

Regulation 21 of the Advertising Regulations provides that where medicinal products are being promoted to persons qualified to prescribe or supply such products, it is an offence to supply, offer or promise such persons any gifts, pecuniary advantage or benefit in kind, unless it is inexpensive and relevant to the practice of medicine or pharmacy.

Regulation 21 does permit the offering of hospitality (including the payment of travelling and accommodation expenses) to such persons at events for purely professional or scientific purposes, or at meetings or events for the promotion of medicinal products, provided such hospitality is: strictly limited to the main scientific objective of the event and offered only to health professionals.

Lastly, Regulation 21 makes it an offence for any person qualified to prescribe or supply medicinal products to accept any gift, pecuniary advantage, benefit in kind, hospitality or sponsorship which is prohibited by Regulation 21.

In addition to the legal restrictions, the industry codes of practice described above seek to ensure that the promotion of medicines to healthcare professionals and administrative staff (and also the public in the case of the PAGB Code) is carried out in a transparent, responsible, ethical and professional manner. This aim recognises the reality of an environment in which seminars, and goods and services, are necessary for educational purposes, whilst professional independence and integrity are fundamental.

The ABPI, PAGB and ABHI Codes provide for a number of restrictions.

All of these codes concur that interactions with healthcare professionals, including gifts and inducements should not be used to induce a healthcare professional to use or recommend a company's products.

Under the PAGB Code, it is permissible to provide inexpensive gifts (costing no more than GBP6, excluding VAT) which are relevant to the recipient's work and the PAGB Code gives examples of acceptable gifts which include pens, notepads, diaries and calculators.[9] The Code also permits prizes up to GBP130 excluding VAT, and sets out some acceptable prizes, including relevant books and journal subscriptions, training courses, briefcases and electronic organisers, among others. However, the prizes must not be of the sort likely to be taken home, for example, microwave ovens.

Similarly, the ABHI Code permits inexpensive branded or non-branded gifts (but not cash or cash equivalents), which relate to the healthcare professional's practice, benefit patients or serve a genuine educational function.[10]

The approach under the ABPI Code is more strict, prohibiting the provision of all promotional aids, and allowing healthcare professionals to be provided only with inexpensive notebooks, pens and pencils for use at scientific meetings and conferences. These items must not state the name of the medicine but may bear the name of the company providing them.[11] It is not permissible to give any items for the personal benefit of healthcare professionals or administrative staff.[12] It is possible to provide "patient support items" which are inexpensive (under GBP6, excluding VAT),

[9] PAGB Code Rule 4.5.9.32.
[10] ABHI Interaction Guidelines – "Gifts".
[11] ABPI Code Clause 18.3.
[12] ABPI Code Clause 18.1 (Commentary).

provided they are supplied to directly benefit patient care.[13] The example given is of peak flow meters or pedometers to support wider campaigns around obesity.[14]

The provisions of the codes in connection with hospitality and meetings generally agree that, provided the hospitality offered is reasonable in level and limited to the main purpose or scientific objective of the meeting or event, it is permissible to offer hospitality to healthcare professionals.[15] Any hospitality offered must be at a subsistence level only (including reasonable travel) and any hospitality of a social or sporting nature is not acceptable.[16] A general theme across the codes is that sponsorship of meetings is permissible provided that the meetings have a clear educational content, focus on improving care and/or are aimed at medical advancement. The codes are also consistent in providing that for any meetings sponsored by pharmaceutical companies, the content of the meetings should be controlled. For example, the ABPI Code requires the fact of sponsorship to be disclosed in all of the papers relating to the meetings and in any published proceeding.[17] The ABPI Code confirms that the declaration must be sufficiently prominent to ensure that readers are aware of it at the outset.[18] Where attendance of healthcare professionals at a conference organised by a third party is sponsored by a company, that sponsorship must be declared in full, including details of all registration fees, costs of accommodation and any travel expenses.[19] Where a meeting itself is sponsored by a company, all materials used in the meeting must be checked for compliance with the ABPI Code. Similarly, the ABHI Code provides that the sponsor of a meeting should have no input into the content of the meeting.[20]

Note that meetings held at venues outside the UK may be permissible but there must be valid and cogent reasons for them to be held at the venue in question. For example, if most of the invitees are from outside the UK and, given their countries of origin, it makes greater logistical sense to hold the

[13] ABPI Code Clause 18.2.
[14] ABPI Code Supplementary information to Clause 18.2.
[15] PAGB Code Rule 4.5.10.33; ABPI Code Clause 19.1; ABHI Interaction Guidelines – "Supporting Third-Party Educational Conferences", "Member-Sponsored Product Training and Education" and "Sales and Promotional Meetings".
[16] ABPI Code Clause 19.1.
[17] PAGB Code Rule 4.5.10.33.
[18] ABPI Code Clause 19.3.
[19] ABPI Code Clause 19.4.
[20] ABHI Interaction Guidelines "Conference Support".

meeting outside the UK or, given the location of the relevant resource or expertise that is the object or subject matter of the meeting, it makes greater logistical sense to hold the meeting outside the UK. Consideration should be given to the educational programme, cost, venue facilities, nature of the audience and hospitality involved. In essence, the delegates must be attracted by the programme, not the associated hospitality or venue.

Under Clause 1.7 of the ABPI Code, pharmaceutical companies must ensure they comply with all applicable codes, laws and regulations to which they are subject. This is particularly relevant when materials and activities involve more than one country or when a pharmaceutical company based in one country is involved in activities in another.

The ABPI Code recognises that where "international" meetings are held in the UK, difficulties may arise with the promotion at such meetings of medicines not having a UK marketing authorisation at the time. Provided certain specified conditions are met, such promotion is permitted.[21]

Entertainment is permitted, but the same restrictions apply as to hospitality. Company-sponsored events are seen as designed for the promotion of the company's products and as such are only acceptable if such hospitality is reasonable and subordinate to the main purpose of the event, which must be medical or scientific and offered to healthcare professionals only. Thus, a half-hour presentation on a product, followed by a skiing trip or a meal in an expensive restaurant, for instance, would be an unacceptable form of entertainment.

Other Promotional Activities

There are a number of limits imposed by the Advertising Regulations on promoting medicinal products. Among a number of restrictions on advertising, the Advertising Regulations include offences for advertising unlicensed medicinal products[22] and for issuing an advert to the general public that is likely to lead to the use of prescription-only medicines.[23]

Medicinal products, including those that are prescription only, may be promoted to medical practitioners subject to certain limits imposed by the Act. Part VI of the Act defines "advertisement" widely as including every

[21] ABPI Code Clause 3.
[22] Medicines (Advertising) Regulations 1994, Regulation 3(1).
[23] Ibid, Regulation 7.

form of advertising whether in a publication, notice, catalogue, price list, letter or other document or by means of a photograph, film, signed recording, broadcast or cable programme.[24] Subject to one exception, no advertisement relating to medicinal products may be sent or delivered to a medical practitioner by a commercially interested party and no representation likely to promote the use of medicinal products may be made. An advertisement may be made only if a data sheet relating to the medicinal products in question is delivered with the advertisement or representation, and such advertisement or representation is not inconsistent with the particulars contained in the data sheet. The information contained in the data sheet should be presented clearly and legibly and be positioned for ease of reference. It is not acceptable for the information to be presented in such a way that the reader has to turn the material around to read the text, for example, diagonally or around the borders of a page.

The Act prohibits false or misleading advertisements. In particular, it is an offence (which may be punishable by a limited fine and/or imprisonment for up to two years) to: provide a false or misleading advertisement relating to the medicinal product; make a false or misleading representation in connection with a sale or offer for sale or in order to induce a prescription or supply; or include in any advertisement an unauthorized recommendation.[25] It is a defence under this section if the party providing the advertisement or making the representation did not know that the advertisement or representation was false and misleading or that the recommendation was unauthorised and could not have found that out through reasonable diligence.

The Advertising Regulations prohibit certain activities when advertising to the public, which is relevant for OTC medicines. By way of example, the limits include not targeting advertisements directly, exclusively or principally at children,[26] not including medical or celebrity endorsements that may encourage consumption of medicinal products,[27] and not presenting the medicinal product as a foodstuff or cosmetic.[28]

The UK Licensing Authority, the Medicines and Healthcare products Regulatory Agency ("MHRA"), may further require the commercially interested party to provide it with copies of the advertisement and data sheet

[24] Medicines Act 1968, Section 92.
[25] Medicines Act 1968, Section 93.
[26] Medicines (Advertising) Regulations 1994, Regulation 9(1)(e).
[27] Medicines (Advertising) Regulations 1994, Regulation 9(1)(f).
[28] Medicines (Advertising) Regulations 1994, Regulation 9(1)(g).

for prescription medicines. For OTC medicines, it is a condition of membership in PAGB that all advertisements are submitted to PAGB for approval before they are released into the public domain.

In addition to the legal obligations detailed above, it is a requirement of the ABPI Code that promotional materials and activities are not disguised.[29] Specific examples of activities not to be used as disguised promotion are market research, post-marketing surveillance studies, clinical assessments and similar activities.[30] This said, promotional material should in any event only be sent or distributed to those categories of persons whose need for, or interest in, the particular information can reasonably be assumed.[31] Importantly, while any joint working between health professionals and commercial organisations is permitted in accordance with the code, care must be taken to ensure that such working does not constitute disguised promotional activity but is carried out in a transparent and open manner. The ABPI Code has specific rules on joint working with health providers, setting out requirements to ensure it is done appropriately, for example, the joint work be in the best interests of the patient and any agreements between the parties must be clearly recorded in writing.[32]

In the first six months following the launch of a new medicinal product, a health professional may be sent an initial mailing giving detailed information about its use, including, for example, the summary of product characteristics, the public assessment report, the package leaflet and the product monograph, and no more than three other mailings about the medicinal product. Furthermore, no more than eight mailings for a particular medicinal product may be sent to a health professional in a year.[33] Mailings concerned solely with safety issues are exempt from these restrictions.

It should be noted that all the provisions and considerations mentioned above still apply where a pharmaceutical company is promoting its image only, and not a specific product. Such activity could still be an inducement to prefer that company, and hence its products.

In addition, all materials relating to medicines and their uses, whether or not promotional in nature, but which are sponsored by a pharmaceutical

[29] ABPI Code Clause 12.1.
[30] ABPI Code Clause 12.2.
[31] ABPI Code Clause 11.1.
[32] ABPI Code Clause 18.5.
[33] ABPI Code supplementary information to Clause 11.2.

company, must clearly indicate the sponsorship. Even where companies are involved in the distribution of reports on meetings, such reports may constitute promotional material, and thus be fully subject to the ABPI Code.

An important requirement of the ABPI Code is that all promotional material, other than promotional aids, must include prominent information about adverse event reporting mechanisms. This could be satisfied by the inclusion of a statement such as "Information about adverse event reporting can be found at www.yellowcard.gov.uk" and "Adverse events should also be reported to [the relevant pharmaceutical company.]"[34]

The PAGB Code is largely similar to the ABPI Code, although there are certain differences, which may reflect the difference between prescription only medicines and OTC medicines. For example, there is no requirement to include information on adverse event reporting under the PAGB Code (although it is stated that it may be helpful).[35] The provisions of the PAGB are generally more focused on the content of advertisements directed to consumers. The PAGB Code therefore, reflects and provides further information on elements of the Advertising Regulations such as those relating to advertising to children and to celebrity or medical endorsements.[36]

The ABHI Advert Guidelines apply to promotion aimed at healthcare professionals. Advertisements aimed at the public are covered by the general law on advertisements. The ABHI Advert Guidelines have similar provisions to the other Codes, and require that advertisements be immediately recognisable as such and the commercial intent should be made clear,[37] as well as requirements of balance, fairness and lack of ambiguity.[38]

Samples

Samples are defined as a small supply of a medicinal product provided to members of the healthcare profession in order that they may familiarise themselves with it and acquire experience in dealing with it. The definition does not include titration packs, free goods, bonus stock or starter packs.

[34] ABPI Code, Clause 4.10 and Supplementary Information to Clause 4.10.
[35] PAGB Code Clause 4.5.14.
[36] For example, see PAGB Code Clauses 3.5.8-3.5.10.
[37] ABHI Advertisement Guidelines Clause 1.5.
[38] ABHI Advertisement Guidelines Clause 2.1.

The Advertising Regulations, discussed above, apply to samples and specifically to labelling and packaging. In addition, the ABPI and PAGB Codes both include guidance on what constitutes a sample and how and to whom samples should be distributed.

The PAGB Code states that a limited number of samples may be provided to persons qualified to prescribe for the purpose of becoming familiar with the product (and not for promotional purposes), upon a written, signed and dated request.[39] The samples must be labelled "free medical sample - not for resale" and must be no larger than the smallest marketed pack. A Summary of Product Characteristics (in accordance with the Advertising Regulations) must be included. The pharmaceutical company must maintain an adequate system of control and accountability.

In addition to the above, the ABPI Code requires that no more than 10 samples per year of any one medicinal product should be given to an individual health professional.[40] The health professional must be qualified to prescribe the product concerned. It is expressly forbidden to supply samples to administrative staff.[41]

The ABHI Code expressly states that the section on gifts does not apply to providing appropriate samples for product evaluation. Provided the intention behind supplying the samples is not promotional, then the ABHI Code should not apply.

Consequences of Breach

Whilst the ABPI, ABHI and PAGB Codes are voluntary, they are intended to be the primary means of regulating the sector, with the law providing a more general legislative framework. Under each code there is a complaints committee to consider any alleged breaches.[42]

The MHRA, which is an agency of the Department of Health, is accountable to government ministers to consider breaches of the Act and the Advertising Regulations, including in relation to the promotion of medicines. The key

[39] PAGB Code Clause 4.5.12.
[40] ABPI Code Clause 17.2.
[41] ABPI Code Clause 17.1.
[42] The ABPI Code is administered by the Prescription Medicines Code of Practice Authority. The PAGB Code is administered by the PAGB Secretariat. Complaints under the ABHI Code go before an adjudication committee.

function of the MHRA is to protect public health by promoting the safe use of medicines, ensuring that they are honestly promoted as to their benefits, uses and effects, in compliance with current legislation. The MHRA in its guidelines encourages complainants to use the self-regulatory system in the first instance, as complaints can often be dealt with more easily in this way. As such, healthcare companies and professionals should be mindful of the consequences, other than the purely legal, of ignoring the industry codes.

Anyone, whether a consumer, a competitor company or a healthcare professional, is free to make a complaint about a member company under the codes.[43]

If a breach of the relevant Code is found, and the offending company has not already taken appropriate corrective action, the company will be asked to comply and the decision will be published. In more serious cases, the result can be advertised in the medical and pharmaceutical press or a public reprimand issued, and material can be recovered from those to whom it has been given. Furthermore, an audit of the company's procedures to comply with the Code can be carried out with the possible imposition of a requirement for the pre-vetting of all future material. In certain cases, companies may be expelled from the membership of the industry bodies.

A potentially more significant consideration arising from any breach of industry codes as they relate to interactions with healthcare professionals may be their relevance to any allegations of bribery and, in particular, to any defence against a charge of the corporate offence of failing to prevent bribery, as discussed below.

In relation to violations of the Act, on summary conviction, a party could face a fine not exceeding the statutory maximum (currently GBP5,000[44]). On conviction on indictment, a party could face a fine, up to two years imprisonment, or both.

[43] If the company that is the subject of a complaint is not a member, the complaint may be reported to the trade association representing that company or, failing this, to the MHRA.

[44] Under the Legal Aid Sentencing & Punishment of Offenders Act 2012, the cap on fines will be removed such that unlimited fines may be imposed for breaches of primary and secondary legislation. The legal changes associated with the Act will be implemented throughout 2012 and 2013.

Professional Codes of Conduct

Paragraph 74 of the GMC Code of Good Medical Practice imposes an obligation on doctors that they "must not ask for or accept any inducement, gift or hospitality which may affect or be seen to affect the way [they] prescribe for, treat or refer patients".

The GPC Standards make similar provision for pharmacists, requiring that they "Do not ask for or accept gifts, rewards or hospitality that may affect, or be seen to affect, [their] professional judgement".[45]

The guidance to the GMC Code of Good Medical Practice refers directly to the MHRA Blue Guide and the ABPI Code, for doctors to inform themselves on requirements in relation to the limits of acceptable behaviour in relation to inducements, hospitality and other issues.

The NHS is a significant purchaser in the UK market. The NHS Code directs NHS staff at all levels within the organisation to refuse gifts, benefits, hospitality or sponsorship of any kind so as to ensure that they remain impartial. NHS staff must use local arrangements to declare publicly any commercial sponsorship (which is defined in the NHS Code as including any funding from an external source including funding of all or part of the costs of a member of staff, NHS research, staff, training, pharmaceuticals, equipment, meeting rooms, costs associated with meetings, meals, gifts, hospitality, hotel and transport costs [including trips abroad], provision of free services [speakers], buildings or premises) linked to the supply of goods or services and be prepared to be held to accountable for it. It is suggested that a simple ledger will suffice to avoid any unnecessary paperwork.

These arrangements do not apply to personal gifts of less than GBP25 per gift (e.g., gifts of post-it pads, pens). However, gifts should be declared if several small gifts worth a total of over GBP100 are received from the same or closely-related source over a 12-month period.

The NHS Code provides that industry representatives organising meetings are permitted to provide appropriate hospitality and/or meet any reasonable, actual costs, which may have been incurred. If no hospitality is required, there is no obligation or right to provide any such hospitality, or indeed any benefit of equivalent value.

[45] GPC Standards para.6.3.

Liability Under Criminal (and Civil) Law

The Regulatory Framework

Criminal Law

The Bribery Act 2010 was introduced to overhaul the very complex legal framework on bribery and corruption that had developed over time. Existing offences were clarified and new offences were introduced.

The Act has extra-territorial effect, covering all activities by the company whether the bribery occurs in the UK or outside the UK. Any company which carries on all or part of its business in the UK is caught by the Bribery Act. Companies may also incur liability for the actions of third parties who carry out business on behalf of the company, if the company receives a benefit from the provision of those services.

Civil Law

While the Bribery Act governs criminal liability for bribery and corruption, it should be noted that a company engaging in corrupt practices with employees of another may incur civil liability under express statutory provisions, with liability being imposed on both the individual as well as the organization involved in the corrupt conduct.

Permitted and Prohibited Practices

The Bribery Act sets out four offences, namely: bribing;[46] being bribed;[47] bribing a foreign public official;[48] and a specific corporate offence of failing to prevent bribery.[49]

The definition of a bribe is very wide and includes the offer, promise or provision of any advantage (whether financial or not), where the offeror's intention is to induce the recipient to perform a function improperly or where the offeror knows that acceptance of the advantage is, in itself, an improper performance of the function.

[46] Bribery Act 2010, Section 1.
[47] Bribery Act 2010, Section 2.
[48] Bribery Act 2010, Section 6.
[49] Bribery Act 2010, Section 7.

This has the potential to capture many types of promotional expenditure, including, for example, corporate hospitality and sponsorship of practitioners. If the advantage given is lavish and disproportionate to common practice, there will be a greater inference that it was intended to induce improper behaviour from the recipient.

In assessing whether the provision of any corporate hospitality to healthcare professionals in the UK was improper, the normal practices of the relevant industry (including in this case the provisions of the ABPI Code, the ABHI Code and the PAGB Code) would be highly relevant. Similarly, since the industry codes are incorporated into the professional obligations of the healthcare professionals, non compliance by the healthcare professionals would, in itself, be evidence of an improper performance of their functions, which may constitute bribery.

In relation to the bribery of foreign officials, the Bribery Act prohibits any financial or other advantage being offered, promised or given to a foreign official. To fall within the prohibition, the offeror's intention must be to obtain or retain business or a competitive advantage. Any local industry practices are irrelevant for the purposes of the Bribery Act, unless they are specifically permitted or required by local law.[50] As such, even if it is commonplace in a certain country to make facilitation payments, the company making such payments would be in breach of the Bribery Act.

Under the previous regime, it was generally quite difficult to impose criminal liability on a corporate entity, as it was necessary to attribute the criminal intent to the guiding mind of the company. However, under the Bribery Act 2010, there is now an offence for commercial organisations that fail to prevent bribery by their employees and/or third party representatives.

It is a defence to this corporate offence for a company to show that it had adequate procedures in place in order to prevent bribery.[51] In March 2011, guidance was issued by the Ministry of Justice setting out six principles around which the adequacy of procedures would be decided. These six principles are: proportionate procedures; top-level commitment; risk assessment; due diligence; communication; and monitoring and review. Again, industry practices such as those set out in the industry codes will be relevant to an assessment of whether procedures are proportionate, and full

[50] Bribery Act 2010, Section 5.
[51] Bribery Act 2010, Section 7(2).

compliance with those codes is likely to help avoid a charge of bribery from being made out.

On a related note it is important to note that NHS employees are employees and representatives of the State in the UK. Interactions with them may be relevant for other corruption legislation with extra-territorial effect, such as the US Foreign Corrupt Practices Act.

Sanctions

Criminal Law

Any individual found to have committed the offence of bribery, accepting a bribe or bribery of a foreign official is liable on summary conviction to imprisonment for a term not exceeding 12 months, and/or a fine not exceeding the statutory maximum (currently GBP5,000); and on indictment, to imprisonment for a term not exceeding 10 years and/or to an unlimited fine.[52]

Companies guilty of an offence, including failing to prevent bribery, may be subject to an unlimited amount.[53] Any senior officers with a close connection with the UK, who committed or consented to the commission of the offence, may also be prosecuted individually.

If a company is found guilty of an offence under the Bribery Act, that company may also be blacklisted from future government procurement activity.

Civil Law

Any contract which has been induced corruptly will be deemed illegal and therefore, unenforceable pursuant to common law rules which provide that a contract made for the purpose of committing a fraud on a third person or the public cannot be enforced and is deemed void from the outset.

Equitable principles allow the court to set aside a contract that has been entered into as a result of conduct which is contrary to good conscience, which would include the procurement of a gift or other benefit by the exertion of undue influence.

[52] Bribery Act 2010, Sections 1.
[53] Bribery Act 2010, Sections 11(2) and 11(3).

A company that can show that its employee has been bribed may have claims against the company making the bribe for the dishonest assistance given to the employee in the conduct of his/her duties, and that company would be required to account for any profits made from entering into the arrangement.

Contracts with Healthcare Professionals and Medical Institutions

The formation and performance of all contracts between healthcare companies and professionals or medical institutions will be governed by normal principles of English contract law, discussion of which is beyond the scope of this chapter. It is also not the purpose of this chapter to review the regulations and principles of good medical practice that may be applicable to clinical trials and other research-related contracts. However, any contractual relationship between a healthcare company and a professional in the UK, the essential purpose of which is to promote the company and its products, will be subject to the same regulatory framework of statute and industry and professional codes that are described above.

The offering by a pharmaceutical company of contracts for the sponsorship or other financial support of a healthcare professional is not a prohibited practice under pharmaceutical advertising law, the codes of conduct or the criminal (and civil) law. There is no requirement in the UK to obtain approval, nor any specific legal regime, but, as for all promotional activities, a sponsorship or other contract should not amount to an inducement. For example, if a healthcare company requires the sponsored healthcare professional to purchase certain products, or the technique on which training is given is one in which only the company's products can be used (assuming it is not the only technique available for a particular treatment), this might be seen as an inducement for the purposes of the ABPI, ABHI and PAGB codes.[54]

Although not directly applicable to the healthcare company that is seeking to sponsor a healthcare professional or provide some other form of financial support, the impact of the professional codes of conduct on any contract should not be ignored.

[54] For the consequence of a breach of the ABPI and PAGB Codes, see Section 1.3 above.

In view of the potentially serious consequences of a member of the healthcare profession failing to meet the applicable professional standards set by the GMC, whilst not a strict requirement, many healthcare professionals may prefer interested healthcare companies to contract with the employing medical institution for purposes of sponsorship or other financial support (whether a grant for specific scientific research or otherwise), or at least to seek the institution's approval before contracting with the individual professional. If a healthcare company does find itself contracting directly with the healthcare professional, it would be advisable in any event to confirm that the terms of any employment or other contract between the professional and a medical institution permit external contracts with independent pharmaceutical companies.

In any event, healthcare companies should aim to be as transparent as possible in all contractual dealings with healthcare professionals and medical institutions. The industry codes may require publication of promotional material for healthcare professionals, institutions or patient organizations. By way of example, the ABPI Code requires the company to have in place a self-certification system for confirming that such material complies with the ABPI Code (carried out by appropriately qualified and senior employees or officers of the company),[55] and requires that details of donations and sponsorship and of agreements with healthcare professionals that may be construed as promotional, or executive summaries of such agreements be published on the company's website.[56]

Recommendations

In all promotional activities in the UK, pharmaceutical companies selling prescription-only medicines should be guided by the overriding principle, as enshrined in the ABPI Code, that such activities must not bring discredit upon, or reduce confidence in the pharmaceutical industry. In dealing with healthcare professionals, companies would be expected to observe the increasingly restrictive limits on their interactions, and there may be serious results from failing to do so, including potential allegations of bribery.

[55] ABPI Code Clause 14.

[56] For example, details of donations to institutions, organisations or associations comprised of healthcare professionals, must be published, ABPI Code Clause 18.6 and executive summaries of joint working agreements between industry and healthcare institutions must also be published, ABPI Code Clause 18.5.

Companies selling OTC medicines and medical devices may be able to carry out more promotional activity under the details of their relevant rules (while always respecting the principle of not discrediting or undermining confidence in their industry), but should be aware that the tendency in all areas appears to be toward more restrictive regulation and this should be monitored.

In all cases, companies selling medical products should have comprehensive policies in place for staff interacting with healthcare professionals, which should be enforced effectively and on which full training should be provided. In this way, if an employee does behave inappropriately, the company will improve its chances of having a defence against charges of the corporate offence of failing to prevent bribery.

Where a company sells a mixture of OTC medicines, prescription medicines and/or medical devices, the risk of mistakes being made by employees as to the applicable rules would likely increase. In such circumstances, it would be advisable either to set one policy for all areas at the highest level (i.e., the ABPI Code) or, if practicable, to divide the business in such a way as to ensure representatives are only dealing with one type of product.

The following recommendations offer some guidance for best practice in the UK at the highest standard set by relevant regulations.

Do not make or offer gifts to individuals in the medical profession:

Inexpensive stationery labelled with the company name (and not with any names of medical products) may be provided at meetings, but other than this, no items should be given for the personal benefit of healthcare professionals.

Certain patient support items and promotional aids may be supplied for the benefit of patients, provided that these are also inexpensive and do not bear the name of any medical products (the name of the company is permitted).

If giving free samples, be sure to comply with the Advertising Regulations and industry codes of practice, particularly in terms of the recipients and the number and content of the samples.

When providing hospitality, consider whether it is:

- reasonable;
- strictly limited to the primary, medical or scientific purpose of the meeting or event; and
- offered only to healthcare professionals.

When sending promotional material to healthcare professionals, ensure that:

- the product is of a type that may be advertised (i.e., not an unlicensed product);
- the promotional material is not false or misleading and that any comments are verified; and
- a data sheet accompanies the promotional material, which complies with the requirements of the Advertising Regulations and the industry codes, and the limits on how many times material may be sent, and to whom, set down in the industry codes are observed.

Further recommendations:

- Ensure any charitable donations made are modest and used for the practice of medicine.
- Volume rebates and discounts are probably acceptable, but they should not be dependant on purchases by certain individuals and should be part of normal commercial trade.
- Be transparent in all dealings with healthcare professionals and medical institutions.

In conclusion, whilst the degree to which individual healthcare professionals may be influenced by the promotion of healthcare products is uncertain, some forms of promotion are acceptable. Healthcare companies are advised to keep activities transparent, to record properly and account for all expenditures and, where possible, to deal with institutions rather than on a personal level.

North America

Canada

Kanta Wadhwan, Lisa Douglas, Jonathan Tam

The Regulatory Framework

Introduction

The relationship between medical product manufacturers, healthcare professionals and members of the public depends on a legal and ethical framework that prioritizes the promotion of health and principled decision-making. In Canada, this legal and ethical framework consists of various statutes and regulations that define the standards of permissible medical product promotion, as well as professional and industry codes that guide the interactions between medical product manufacturers and healthcare professionals.

This chapter surveys the applicable laws and the relevant professional and industry codes and ethical standards that govern healthcare professionals and medical product manufacturers and suppliers in relation to the promotion of drugs, natural health products and medical devices to healthcare professionals in Canada.[1]

Government

Canada operates as a federal state with governmental powers divided between the federal government and 13 provincial/territorial governments. Government at all levels is involved in health protection and promotion, including the regulation and delivery of healthcare services. The federal government has responsibility for matters of national health and welfare, while the provinces and territories have constitutional authority for health within their jurisdictions, including the regulation of healthcare professionals.

[1] The information presented reflects applicable federal law and national policy, as well as the law and policy of the province of Ontario. Although the same may generally be true for other provinces and territories, Ontario will stand as a representative example, without addressing the complex web of applicable statutes, regulations and codes of conduct covering all 10 provinces and three territories of Canada.

Public Healthcare

The marketing and promotion of medical products, including pharmaceuticals, takes place within the context of Canada's public healthcare system. The universal public healthcare system established under the Canada Health Act,[2] known to Canadians as "Medicare," is public in that universal access to medically necessary physician and hospital services is publicly funded for all Canadians. Various levels of government are involved in the healthcare system and provide funding, but do not own, administer or directly provide healthcare services (with minor exceptions discussed below). Access to medical products is separately regulated, with both public and private insurance plans providing coverage to most Canadians.

It is important to recognize the nexus between commercial interest and public policy interest in order to understand the rules with respect to promoting medical products in Canada.

Healthcare Professionals and Medical Product Manufacturers

Independent professional healthcare providers and medical product manufacturers and suppliers are important partners in the healthcare system. The Canadian healthcare system relies on private industry not only to conduct research and development necessary to manufacture new medical products, but also to inform and educate healthcare professionals about the availability and appropriate use of their products. Because direct to public advertising of all prescription pharmaceuticals with the exception of certain contraceptives is highly restricted in Canada under the federal Food and Drugs Act,[3] the relationship between manufacturers and healthcare professionals is particularly important.

As previously noted, in Canada there are no specific statutes that govern the promotion and marketing practices of medical product companies in terms of their interaction with healthcare institutions and professionals. While various civil and criminal statutes capture clearly egregious behavior, the appropriate relationship between medical product companies and healthcare professionals is typically established through various professional and industry codes, guidelines and ethical standards. The legitimacy of any marketing and promotion scenario that may arise is often fact-specific and context-sensitive. Regulators must balance the competing interests underlying the relationship

[2] R.S.C. 1985, c. C-6.
[3] R.S.C. 1985, c. F-27, s. 3(1).

between commercially motivated medical product manufacturers and healthcare professionals who must make treatment decisions based on objective scientific data free of commercial influence.

There is, however, a significant degree of similarity between ethical standards across all provinces and territories and among the various healthcare professional bodies. This is also true within the medical products industry in Canada. Clear common themes tend to emerge as to the proper conduct expected of healthcare professionals and medical product manufacturers and suppliers. The purpose of this chapter is to extract from the maze of statutes, regulations, codes and guidelines those core concepts and key examples that define acceptable practices. This overview will provide the basis for a general understanding of the law and policy sufficient to guide prudent decision-making.

Restrictions Under Pharmaceutical Advertising Law

Federal Law

Health Canada is the federal department responsible for national public health in Canada. The Therapeutic Products Directorate is the agency of Health Canada responsible for regulating drugs and medical devices. The Natural Health Products Directorate is the agency of Health Canada responsible for regulating natural health products. The Food and Drugs Act defines "drug" and "device" as follows:

- "Drug" includes any substance or mixture of substances manufactured, sold or represented for use in:
    - the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals;
    - restoring, correcting or modifying organic functions in human beings or animals; or
    - disinfection in premises in which food is manufactured, prepared or kept.
- "Device" means any article, instrument, apparatus or contrivance, including any component, part or accessory thereof, manufactured, sold or represented for use in:
    - the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals;

- restoring, correcting or modifying a body function or the body structure of human beings or animals;
- the diagnosis of pregnancy in human beings or animals; or
- the care of human beings or animals during pregnancy and at and after birth of the offspring, including care of the offspring, and includes a contraceptive device but does not include a drug.[4]

The Natural Health Products Regulations,[5] under the Food and Drugs Act, define "natural health product" as follows:

- "Natural health product" means a substance set out in Schedule 1 or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, a homeopathic medicine or a traditional medicine, that is manufactured, sold or represented for use in:
  - the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
  - restoring or correcting organic functions in humans; or
  - modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.[6]

Schedule 1 of the Natural Health Products Regulations includes vitamins, minerals, amino acids, essential fatty acids, probiotics and certain organic materials and their synthetic duplicates.

Before a drug or device can be sold or advertised in Canada, it must be approved by the Therapeutic Products Directorate.[7] Before a natural health product can be sold or advertised in Canada, it must be approved by Natural Health Products Directorate.[8]

The Food and Drugs Act defines an advertisement broadly as "any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any food, drug, cosmetic or device."[9] Health Canada has published a document entitled "The Distinction Between

[4] *Ibid.*, s. 2.
[5] S.O.R./2003-196.
[6] *Ibid.* at s. 1(1).
[7] "Therapeutic Products Directorate," Health Canada, 5 August 2011: http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/tpd-dpt/index-eng.php.
[8] Natural Health Products Regulations, *supra* at note 5, s. 4(1).
[9] Food and Drugs Act, *supra* at note 3, s. 2.

Advertising and Other Activities,"[10] which provides guidance on the distinction between an advertisement and non-promotional information.

The Food and Drugs Act strictly regulates the labeling and advertising of all medical products and prohibits misleading or deceptive practices.[11] It is the responsibility of all advertisers to ensure that medical product advertisements comply with the requirements of the Food and Drugs Act and the related Food and Drug Regulations,[12] Medical Devices Regulations[13] and Natural Health Products Regulations.

The requirements under the various regulations differ depending on the type of medical product being sold, labeled or advertised. For instance, with respect to drugs, the promotion of prescription drugs to the general public is limited to name, price and quantity,[14] and no drug may be advertised to the general public for the treatment, prevention or cure of diseases identified in Schedule A of the Food and Drugs Act.[15] With respect to medical devices, Class II, Class III and Class IV medical devices must be licensed by the Therapeutic Products Directorate before they can be advertised[16] (Class I devices are those that present the lowest levels of risk).[17] Finally, licensed natural health products may be advertised as a preventative to the diseases identified in Schedule A of the Food and Drugs Act, but may not be advertised as a treatment or cure to any of the Schedule A diseases.[18]

The Food and Drug Regulations prohibit a manufacturer from selling or advertising a drug for a use other than for indications that have been approved by Health Canada (i.e., off-label use).[19] Medical professionals are not prevented from prescribing drugs for uses other than indications for which the drug is approved. Manufacturers receiving unsolicited queries regarding a product's off-label use must be careful to ensure that their

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[10] Ottawa, Health Canada, issued 12 January 1996; updated August 2005: http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/advert-publicit/actv_promo_vs_info-eng.pdf.
[11] Food and Drugs Act, *supra* at note 3, ss. 9 and 20.
[12] C.R.C, c. 870, s. C.01.044.
[13] S.O.R. 98/282.
[14] Food and Drug Regulations, *supra* at note 12, s. C.01.044.
[15] Food and Drugs Act, *supra* at note 3, s. 3(1).
[16] Medical Devices Regulations, *supra* at note 13, s. 27.
[17] *Ibid.*, s. 6 and Schedule 1.
[18] Natural Health Products Regulation, *supra* at note 5, s. 103.2.
[19] Food and Drugs Regulations, *supra* at note 12, s. C.08.002.

response is not interpreted by Health Canada as being for the purpose of sale or promotion of the drug for the off-label use. Health Canada does not condone or authorize off-label use of drugs, primarily due to the risks associated with there having been no formal clinical trials conducted to determine how the off-label use will affect the patient's condition.[20] If a manufacturer wishes to promote a drug for off-label use, it must make a separate regulatory submission to Health Canada for approval.

The Food and Drugs Act, the Food and Drug Regulations and the Medical Devices Regulations do not specifically address the promotion of medical products to healthcare professionals.

Health Canada publishes instructive policy documents in relation to the advertising of drug and health products, a list of which can be found on the Health Canada website.[21]

In addition to the Food and Drugs Act and its related regulations, there are certain federal commercial and criminal laws that must be observed. For example, the Competition Act[22] prohibits misleading, deceiving or otherwise exploiting consumers, with both civil and criminal sanctions available to deter offenders.[23]

Provincial Law

For purposes of this chapter, the province of Ontario is used as a representative example of the provincial regulatory structure across the 10 provinces and three territories of Canada. Occupations falling the category of 'healthcare professional' are defined by statute. In Ontario, the Regulated Health Professions Act[24] regulates the scope of practice of 26 statutorily-created councils of self-governing healthcare professionals, from audiologists and traditional Chinese medicine practitioners.[25]

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[20] "Response to Recommendations to Health Canada of the Coroner's Jury into the Death of Ashley Marie Atkinson," Health Products and Food Branch, Health Canada, 29 July 2003, http://www.hc-sc.gc.ca/ahc-asc/pubs/hpfb-dgpsa/death-deces_atkinson-eng.php.
[21] http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/pol/index-eng.php.
[22] R.S.C. 1985, c. C-34.
[23] *Ibid.*, ss. 52 and 74.01.
[24] 1991, S.O. 1991, c. 18.
[25] *Ibid.*, Schedule 1.

The Health Professions Procedural Code in Schedule 2 of the Regulated Health Professions Act delegates to each council's governing body the authority to prescribe binding codes of professional conduct and to enforce them. These codes of conduct provide most of the specific practical guidance to healthcare professionals in their interactions with the medical products industry. The Professional Misconduct Regulation[26] under the Medicine Act,[27] for instance, generally prohibits physicians from having a conflict of interest.[28] In conjunction with certain voluntary industry and professional codes, these regulatory codes of conduct for healthcare professionals serve to define the scope of acceptable and unacceptable marketing and promotional practices.

Restrictions Under Professional Codes of Conduct

Physicians

The Canadian Medical Association ("CMA") is the largest association of physicians in Canada. It has established certain standards of ethical behavior expected of Canadian physicians. As a voluntary organization, the CMA has no authority to enforce these standards; however, as a national association representing the interests of physicians, various CMA codes and standards of conduct have been used as models or adopted by the regulatory authorities for physicians within the provinces.

The CMA has developed a Code of Ethics[29] as a guide for Canadian physicians, which includes the following statement: "Avoid promoting, as a member of the medical profession, any service (except your own) or product for personal gain."[30]

The CMA has also adopted the "Guidelines for Physicians in Interactions with Industry"[31] (the "CMA Guidelines"). The CMA Guidelines establish the principles underlying appropriate interactions between physicians and the pharmaceutical and health supply industries. The goal of the CMA

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[26] O. Reg. 856/93.
[27] Medicine Act, 1991, S.O. 1991, Chapter 30.
[28] Professional Misconduct Regulation, *supra* at note 26, s. 1(1).
[29] "CMA Code of Ethics," Canadian Medical Association, updated 2004, available at: http://www.cma.ca/index.php?ci_id=53556&la_id=1
[30] *Ibid.*, at page 4
[31] Canadian Medical Association, 2007, available at: http://www.cma.ca/index.php?ci_id=10041931&la_id=1

Guidelines is to ensure that both sides of the relationship maintain autonomy and that their patients' interests come before personal consideration or profit-making. The CMA Guidelines cover a variety of areas, such as industry-sponsored research, continuing medical education and conflicts of interest. The document applies to residents and medical students as well.

The governing body for medical doctors in the province of Ontario is the College of Physicians and Surgeons of Ontario. The College has developed a practice guide that articulates the Ontario health profession's values and principles.[32] The practice guide contains a general section on the avoidance of conflicts of interests. The College has also adopted the CMA Guidelines as its own conflict of interests policy, although the College's council has yet to formally approve this policy.[33] Finally, the College has a conflict of interest policy on the recruitment of subjects for research studies.[34]

The CMA has worked with other Canadian stakeholders to resolve discrepancies between the CMA Guidelines and pharmaceutical industry codes of conduct, especially with respect to industry sponsors paying the travel or lodging costs, or other personal expenses, of physicians attending a continuing medical education ("CME") event. The CMA continues to explore strategies for making physicians and medical students more aware of the CMA policy with respect to physicians and the medical products industry, and the reasons underlying its policy.

Pharmacists

The Canadian Pharmacists Association ("CPhA") is a national association of pharmacists. It maintains several policy and position statements, such as the "CPhA Position Statement on Pharmacist Prescribing,"[35] which underscores the principle that all decisions related to medication management must be collaborative, patient-centered and focused on addressing the healthcare

[32] "The Practice Guide: Medical Professionalism and College Policies," the College of Physicians and Surgeons of Ontario, September 2007, available at: http://www.cpso.on.ca/policies/guide/default.aspx?id=1696
[33] "MD Relations with Drug Companies," the College of Physicians and Surgeons of Ontario, available at: http://www.cpso.on.ca/policies/policies/default.aspx?ID=1832
[34] "Conflict of Interest: Recruitment of Subjects for Research Studies," the College of Physicians and Surgeons of Ontario, December 2006, available at: http://www.cpso.on.ca/policies/policies/default.aspx?ID=1536
[35] Canadian Pharmacists Association, October 2011, available at: http://www.pharmacists.ca/cpha-ca/assets/File/cpha-on-the-issues/PPPharmacistPrescribing.pdf.

needs of the patient. The CPhA has also formally articulated its opposition to direct-to-consumer advertising.[36]

The Canadian Society of Hospital Pharmacists ("CSHP") is another national association of pharmacists. Like the CPhA, the CSHP provides policy documents on the subject of proper pharmaceutical practices, such as the "Guidelines for the Relationship Between Healthcare Facility Pharmacists and the Pharmaceutical Industry."[37] Unlike the CPhA, the CSHP's policy documents are private to members of the society.

On a provincial level, councils of pharmacists maintain codes of ethics. For instance, the Ontario College of Pharmacists has adopted the "Code of Ethics for Members of the Ontario College of Pharmacists,"[38] which establishes fundamental principles of ethical behavior for its members.

Pharmaceutical Companies

There are two components to the pharmaceutical industry. The first comprises research-driven pharmaceutical companies, which share the common purpose of discovering new drugs. Canada's Research-Based Pharmaceutical Companies ("Rx&D") is a voluntary national association of research- and development-based pharmaceutical companies of all sizes. As a member of the International Federation of Pharmaceutical Manufacturers & Associations ("IFPMA"), Rx&D supports the principles of the IFPMA's "Code of Pharmaceutical Marketing Practices."[39] This code lays out rules and principles relating to a broad range of pharmaceutical company activities, from interacting with healthcare professionals to the contents of pharmaceutical advertisements. The code emphasizes that the healthcare and well-being of patients must be the priority for pharmaceutical companies.

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[36] "CPhA Position Statement on Direct-to-Consumer Advertising," September 2009, available at: http://www.pharmacists.ca/cpha-ca/assets/File/cpha-on-the-issues/PPDirectToConsumerAdvertising.pdf.
[37] Canadian Society of Hospital Pharmacists, 2001.
[38] Ontario College of Pharmacists, December 2006, available here: http://www.ocpinfo.com/Client/ocp/OCPHome.nsf/web/OCP+Bylaw+-+Schedules+A-B#A.
[39] International Federation of Pharmaceutical Manufacturers & Associations, 2012, available at: http://www.ifpma.org/fileadmin/content/Publication/2012/IFPMA_Code_of_Practice_2012_new_logo.pdf.

Rx&D also publishes its own "Code of Ethical Practices"[40] (the Rx&D Code), which sets out numerous principles and practices for the promotion of pharmaceutical brand products dispensed under a medical prescription for human consumption. An agreement to comply with the rules of the "Code of Ethical Practices" is a condition of Rx&D membership.[41]

The second segment of the pharmaceutical industry is not research-driven but instead manufactures established pharmaceutical formulations on a non-branded basis. The Canadian Generic Pharmaceutical Association ("CGPA") is a voluntary industry association that represents manufacturers and distributors of generic pharmaceutical products. The CGPA has adopted the "Code of Marketing Conduct Governing the Sale of Generic Pharmaceutical Products in Canada,"[42] which describes the association's rules and principles of promoting generic medicines in Canada.

Pharmaceutical Advertising Advisory Board

The Pharmaceutical Advertising Advisory Board ("PAAB") is an independent review agency whose primary role is to ensure that advertising of prescription drugs is accurate, balanced, and evidence-based. It is an autonomous, multi-disciplinary body that provides a mechanism for the independent review and clearance of drug advertising and promotional materials submitted by manufacturers on a voluntary basis prior to exposure to healthcare professionals. The PAAB reviewed 6,901 new submissions in 2011.[43]

The PAAB maintains a "Code of Advertising Acceptance"[44] (the "PAAB Code") which conforms with the relevant requirements of the Food and Drugs Act, as well as various applicable guidelines and policies issued by Health Canada. The code has also been approved by PAAB's member

[40] Canada's Research-Based Pharmaceutical Companies, 2012, available at: https://www.canadapharma.org/en/commitment/healthcare/documents/2012_CodeofEthicalPractices_ENFinal.pdf.
[41] *Ibid.* at page 7.
[42] Canadian Generic Pharmaceutical Association, February 2010, available at: http://www.canadiangenerics.ca/en/conduct/docs/CGPACodeofMarketing_February5_2010.pdf
[43] "PAAB Views." PAAB newsletter, January 2012, page 3: http://www.paab.ca/local/files/en/newsletter//PAAB%20Views%20January%202012%20E.pdf.
[44] Pharmaceutical Advertising Advisory Board, April 2009, available at: http://www.paab.ca/local/files/PAAB%20Code%20Eng%20April%2017%202009.pdf

organizations.[45] The code covers the promotion of prescription, non-prescription, biological and natural health products to healthcare professionals in all media. The code provides standards with respect to promotional claims, comparative claims, the disclosure and presentation of scientific and statistical data, and the prescription of products.

As noted above, the PAAB operates a self-financing program that pre-clears advertising prior to publication to ensure that the advertising meets the standards of the code. Although it is not mandatory for drug advertisers to take advantage of the PAAB pre-approval mechanism, Health Canada strongly encourages all sponsors to comply with the voluntary pre-clearance review. Health Canada's "Guidance Document – Health Canada and Advertising Preclearance Agencies' Roles Related to Health Product Advertising"[46] provides information about the PAAB pre-approval process and Health Canada's relationship to PAAB.

The PAAB regularly reviews journals, the internet, and direct-mail/detail aid materials collected by healthcare professionals as part of its monitoring program.[47] When code violations are identified, PAAB sends a letter to the advertiser seeking its cooperation to meet the requirements of the code. When appropriate, the PAAB will notify the advertiser's trade association and/or Health Canada for their assessment of additional penalties.[48]

While the PAAB reviews and clears advertising material and administers a complaints and appeals procedure, the Therapeutic Products Directorate of Health Canada remains responsible for establishing the minimum standards to be met in drug advertising by developing appropriate regulations, guidelines and policies, and by bringing these standards to the attention of the PAAB. Health Canada will intervene when advertising that contravenes the Act and Regulations may present an imminent and/or significant health hazard,[49] or when contravening advertising arises from failure of the PAAB

[45] Member organizations include the Canadian Generic Pharmaceutical Association, the Canadian Medical Association, the Canadian Pharmacists Association, and Canada's Research-Based Pharmaceutical Companies.
[46] Health Canada, November 2010, available at: http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/pol/role_apa-pca-eng.php.
[47] "[PAAB] Code of Advertising Acceptance," *supra* at note 44, s. 10.1.
[48] "PAAB Views." PAAB newsletter, April 2012, page 4: http://www.paab.ca/local/files/en/newsletter//PAAB%20Views%20April%202012%20E.pdf.
[49] "[PAAB] Code of Advertising Acceptance," *supra* at note 44, s. 9.9.5.

process through wilful non-participation of the drug advertiser.[50] The Therapeutic Products Directorate of Health Canada is an ex-officio observer and advisor to the PAAB's Board of Directors.[51]

Medical Technology Industry

Canada's Medical Technology Companies ("MEDEC") is the national association that was created by and for the Canadian medical technology industry. MEDEC has adopted the "MEDEC Code of Conduct on Interactions with Healthcare Professionals"[52] (the "MEDEC Code of Conduct"), which is intended to promote ethical business practices and socially responsible conduct in the context of interactions between healthcare professionals and the Canadian medical technology industry. The MEDEC Code of Conduct addresses numerous types of interactions, such as gifts, grants, arrangements with consultants, company-sponsored product training and "value added" items in conjunction with requests for proposals.

Permitted and Prohibited Practices

Gifts, Hospitality and Entertainment

The CMA Guidelines provide that physicians should not accept personal gifts from the medical products industry.[53] However, they may accept patient teaching aids appropriate to their area of practice provided these aids carry only the logo of the donor company and do not refer to "specific therapeutic agents, services, or other products."[54]

As mentioned above, regulations under the Medicine Act, 1991 (Ontario) deem an act of professional misconduct to be a conflict of interest.[55] Under these Regulations, it is a conflict of interest for a member of the College of Physicians and Surgeons of Ontario to, among other things, receive any "benefit" directly or indirectly, from a supplier who sells or otherwise supplies "medical goods or services" to the patients of the member; or sells

[50] "Guidance Document – Health Canada and Advertising Preclearance Agencies' Roles Related to Health Product Advertising," *supra* at note 46, 3.5.2.4.
[51] "[PAAB] Code of Advertising Acceptance," *supra* at note 44, at page 2.
[52] MEDEC, adopted 1 January 2005, revised/restated 5 August 2010, available at: http://www.medec.org/webfm_send/899.
[53] "[CMA] Guidelines for Physicians in Interactions with Industry," *supra* at note 31, at para. 44.
[54] *Ibid*. at para. 50.
[55] Professional Misconduct Regulation, *supra* at note 26, s. 1(1).

or otherwise supplies any drug, medical appliance, medical product or biological preparation to a patient at a profit except under exceptional circumstances, such as medical emergency or immediate treatment need.[56] "Benefit" is defined as any benefit, gift, advantage or emolument of any kind, whether direct or indirect. "Medical goods or services" includes medical goods, appliances, materials, services and equipment, and drugs and laboratory services. Note that the prohibition placed on the member includes a member of his or her family, or a corporation wholly, substantially, or actually owned or controlled by the member or a member of his or her family.[57]

The College of Physicians and Surgeons of Ontario explains the fundamental principle of its conflict of interest policies as follows: "A physician must always act in the patient's best interests. A physician's interests should not be in conflict with the patient's. Any conflicts of interest must be properly managed so as not to compromise the patient's best interests, or be avoided."[58]

The "Code of Ethics for Members of the Ontario College of Pharmacists" provides that members of the council must not accept gifts or other benefits for services related to their profession, although they are allowed "reasonable customary hospitality" so long as they are reported to the council.[59]

On the industry side, the Rx&D Code provides that member companies must not offer to any healthcare professional, or to any member of a healthcare professional's clinical or administrative staff, any gift or any promotional aid, prize, reward, or any other item which is intended for personal or family benefit or pecuniary advantage. Members must ensure that the distribution of service-oriented items is not carried out for product promotional purposes.[60]

The Rx&D Code provides that member companies may distribute acceptable service-oriented items, defined as items having the primary goal of enhancing the healthcare practitioner's or patient's understanding of a condition or its

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[56] O. Reg. *114/94*, s. 16.
[57] *Ibid*., s. 16.
[58] "Duties: To the Patient," the College of Physicians and Surgeons of Ontario, last accessed 3 June 2012, http://www.cpso.on.ca/policies/guide/default.aspx?id=2018&terms=conflict
[59] "Code of Ethics for Members of the Ontario College of Pharmacists," *supra* at note 38, at 1.2.10.
[60] "[Rx&D] Code of Ethical Practices," *supra* at note 40, at 15.1.3 and 15.1.4.

treatment. Such items may bear the corporate name and logo of the donor, but must not bear the name of any brand or medicine.[61]

The Rx&D Code also provides that during business interactions with healthcare professionals or other stakeholders,[62] members may only provide reasonable refreshments and meals that are ancillary to the associated activity. Under no circumstances can refreshments or meals be extended to spouses or companions of healthcare professionals unless the spouse or companion is also a healthcare professional. No other form of hospitality or entertainment is to be provided, including tickets, vouchers or defraying the cost of any event. The number of attendees is limited to an amount that is reasonable and justifiable.[63]

The MEDEC Code of Conduct provides that companies occasionally may provide gifts to healthcare professionals. However, gifts should have a fair market value of less than CAD100, unless they are medical textbooks or anatomical models used for educational purposes. Companies may also occasionally provide healthcare professionals with branded promotional items of minimal value related to the healthcare professional's work or for the benefit of patients. No gifts of cash or cash equivalents may be given.[64]

Seminars, Conferences and Continuing Health Education

The Rx&D Code acknowledges that symposia, congresses and other continuing health education ("CHE") programs are important ways for companies to dispense knowledge and for healthcare practitioners to share their experience with each other.[65] The guidelines in the various professional codes of conduct distinguish between payments on behalf of those who attend the congresses and those who participate as speakers and moderators.

Member companies may provide grants and honoraria to healthcare practitioners who speak at or moderate CHE programs. Such grants and honoraria cannot be extended to other healthcare practitioners who attend the program or to the spouses or family members of those in attendance.

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[61] *Ibid*. at 15.1.1.
[62] "Other stakeholder" is defined to include any individual or organization impacted by the activities of a member company, *ibid*. at page 8.
[63] *Ibid*. at 6.3.1 and 6.3.2.
[64] "MEDEC Code of Conduct on Interactions with Healthcare Professionals," *supra* at note 52, at page I.
[65] "[Rx&D] Code of Ethical Practices," *supra* at note 40, at 9.1.1.

Therefore, generally speaking, travel and accommodation expenses can only be paid to speakers and moderators, not to attendees. In no cases may such expenses be subsidized for the spouse and family members of any professional conference participant. Member companies should not be involved in the development of or payment for social functions conducted in conjunction with any CHE event.[66]

With respect to CHE events held outside Canada, both the supporting company and the recipient(s) of the financial support should proceed on the understanding that the ultimate objective in exposing Canadian healthcare practitioners to international CHE events is improved healthcare for Canadians. In considering such requests, Rx&D members must adhere to the following parameters:

- The request must be made in writing and include all details of the program, as well as the proposed educational program(s) to be delivered by the returning participant, and indicate whether support has been requested from any other company for the same event.
- The member providing the support must respond to the request in writing, and explain the conditions for financial support.
- The returning participant will be required to share with Canadians the benefit of knowledge gained through a written report to the supporting company and to the relevant speciality society or academic institution, or through an oral presentation to healthcare professionals (such reports and presentations must acknowledge the financial support received and the company providing it).
- Support may be provided by members to a maximum of 10 healthcare professionals to any one international CHE event.[67]

The CMA Guidelines also set out principles of appropriate conduct with regards to continuing medical education ("CME") and continuing professional development ("CPD"). The CMA Guidelines provide that the primary purpose of CME/CPD activities should be to address the educational needs of healthcare professionals in order to improve the health care of patients.[68] Travel, accommodation, hospitality and social events for industry-sponsored CME/CPD activities should align with those that would normally

[66] *Ibid*. at 9.2.5 and 9.2.7.
[67] *Ibid*. at 10.2.
[68] "[CMA] Guidelines for Physicians in Interactions with Industry," *supra* at note 31, at para. 22.

be made without industry sponsorship. Hence, the industry sponsor should not pay for travel, lodging costs or other personal expenses of physicians.[69] The CMA also prohibits peer selling. Peer selling is the process by which a pharmaceutical or medical device manufacturer, service provider or third-party representative engages a physician to conduct a seminar that focuses on its own products and is designed to enhance the sale of those products.[70] All principles in the CMA Guidelines apply to medical students and residents as well.[71]

The MEDEC Code of Conduct provides that education and training must be given in a way that ensures the independence of healthcare professionals. Companies are required to ensure that:

- the main focus of an event is educational;
- hospitality is modest;
- social and non-professional activities do not overshadow educational events;
- programs and events are conducted in appropriate locations, such as clinics, laboratories or educational facilities;
- training is completed by qualified staff; and
- guests of healthcare professionals are not subsidized.[72]

Additionally, MEDEC companies may provide educational grants to CHE conference sponsors if the grant is focused on scientific or educational activities and the conference sponsor selects the program content, the participating faculty, the educational methods, the materials to be used, and the healthcare professionals who will attend. Funding may be provided to conference faculty for travel, lodging, meals and honoraria. Companies may purchase advertisements and lease booths for CHE conference displays.[73]

Samples

The federal Food and Drugs Act prohibits the distribution of any drug as a sample, unless it is done under prescribed conditions to physicians, dentists,

[69] *Ibid*. at para. 32.
[70] *Ibid*. at para. 29.
[71] *Ibid*. at para. 51.
[72] "MEDEC Code of Conduct on Interactions with Healthcare Professionals," *supra* at note 52, at page 4.
[73] *Ibid*. at pages 4-5.

veterinary surgeons or pharmacists.[74] Under the Food and Drug Regulations, where one of the foregoing healthcare professionals provides a signed order to a pharmaceutical company/representative specifying the brand name, proper name or common name and quantity of a drug (other than a narcotic, a controlled drug or a new drug for which a notice of compliance has not been issued), the company or representative may distribute the drug to the healthcare professional as a sample if the drug is labeled in accordance with the regulations.[75]

The Food and Drug Regulations also mandate record-keeping requirements. Any company distributing a drug as a sample must maintain records showing:

- the name, address and description of each person to whom the drug is distributed;
- the brand name, quantity and form of the drug distributed; and
- the date upon which each such distribution was made.

These records and all orders received for samples must be kept for a period of at least two years from the date when the sample was provided.[76]

The CMA Guidelines provide that the distribution of samples (often referred to as "clinical evaluation packages" in the industry and professional codes) should not involve any form of material gain for the physician or for the practice with which he or she is associated. Physicians who accept samples and other healthcare products are responsible for ensuring their age-related quality and security. They are also responsible for the proper disposal of unused samples.[77]

The Canadian Society of Hospital Pharmacists advises that samples be received and distributed according to hospital policy and the Rx&D Code. The hospital policy will describe the particular procedures for handling samples for inpatients and outpatients. All samples should be listed on an invoice and authorized for acceptance by the director of pharmacy, in order to allow the monitoring of expiry dates and lot numbers. Samples are to be delivered directly to the pharmacy department from the company or company

[74] Food and Drugs Act, *supra* at note 3, s. 14.
[75] Food and Drug Regulations, *supra* at note 12, s. C.01.048.
[76] *Ibid*., s. C.01.049.
[77] "[CMA] Guidelines for Physicians in Interactions with Industry," *supra* at note 31, at paras. 42-43.

representative to ensure product integrity. Any current or previous use of samples must not influence formulary decisions.

The Rx&D Code provides that only healthcare professionals may dispense samples.[78] In addition to the legal requirements in the Food and Drugs Act and associated Food and Drug Regulations, the Rx&D Code indicates that the following rules also apply to members:

- Distribution[79]

Samples shall only be given to authorized healthcare professionals who have filled out a request form for the sample. The request form must be fully completed by the healthcare practitioner before being passed on to authorized company personnel (such as the company representative or another designated employee) for signature.

An essential part of the sample service involves providing the healthcare professional with prescribing information. This information is to be shared with his/her patient.

The company should also provide full prescribing information on the sample for a minimum of two years following the introduction of a product to the Canadian market. A shorter version of the disclosure may be provided two years after the product is first introduced.

All free goods given to a healthcare practitioner as part of an order must be included on the invoice. If no order is made when the free goods are supplied, the goods must be documented on a separate 'no charge' invoice.

Members should implement a policy to comply with all applicable requirements set out in the Food and Drugs Act and Regulations, and measures to prevent the theft, sale or inappropriate distribution of samples.

It is not appropriate to give out samples at conventions.

[78] "[Rx&D] Code of Ethical Practices," *supra* at note 40, at 16.1.2.
[79] *Ibid*. at 16.3.

- Storage[80]

All samples must be stored in locked cabinets, storage areas, or rooms which are only accessible to company representatives or other authorized people.

Companies must direct their employees to store samples in conditions where the stability, integrity and effectiveness of the samples will be maintained.

- Disposal[81]

Companies are responsible for making sure that all excess and/or expired samples of their own manufacture are returned to the company's storehouse or head office, or an authorized third party, for appropriate disposal.

- Inventory[82]

Companies must make sure that a complete and accurate inventory of all samples held by company representatives be conducted at least once a year. Inventory will be taken by an independent agent hired by the company, not by the representative who holds the samples.

Sanctions and Liability

Liability Under the Food and Drugs Act

A manufacturer or supplier of medical products that contravenes any provision of the Food and Drugs Act or its regulations, including those provisions relating to advertising and labeling, may be found guilty of an offense and liable on conviction to a fine of up to CAD5,000, and to imprisonment for a term of up to three years.[83]

Health Canada administers the Food and Drugs Act and its regulations, establishes certain minimum standards to be met in advertising, and may intervene in relation to contraventions.[84]

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[80] *Ibid*. at 16.4.
[81] *Ibid*.at 16.5.
[82] *Ibid*. at 16.6.
[83] Food and Drugs Act, *supra* at note 3, s. 31(b).
[84] *Ibid*. at ss. 22, 23 and 30(1)(p).

Professional and Industry Codes

If a member of a regulated health profession under the Regulated Health Professions Act, 1991 (Ontario) is found to have committed an act of professional misconduct (which includes conflict of interest), one or more of the following orders may be made:[85]

- Revocation of the member's certificate of registration
- Suspension of the member's certificate of registration for a specified period of time
- Imposition of specified terms, conditions and limitations on the member's certificate of registration for a specified or indefinite period of time
- Requiring the member to appear for reprimand
- Requiring the member to pay a fine of not more than CAD35,000

Despite the existence of the CMA Guidelines and similar codes of conduct for healthcare professionals, it is widely known that some Canadian physicians frequently do take advantage of a variety of offers and benefits provided by medical product manufacturers and suppliers, occasionally with negative publicity when the personal benefit appears to be excessive in relation to the medical education provided, or when a conflict of interest is obvious. That said and having investigated the question to the extent possible, it would appear to be highly unusual for a physician to be disciplined by the College for contravening the CMA Guidelines.

Although Rx&D is a voluntary association, it requires its members to uphold the Code of Marketing Practices, and also urges all companies that market or sell pharmaceuticals but who are not members of Rx&D, to follow the code as well. The principles set out in this code must be adhered to as a condition of membership in Rx&D. Complaints received by the Rx&D Industry Practices Committee in Ottawa (usually from physicians) will be investigated. A list of the complaints filed since 2006 is available online, along with the committee's decision in each case.[86] The committee's written decision is delivered to all parties involved in the matter.

[85] Regulated Health Professions Act, 1991, *supra* at note 24, s. 51.
[86] "Complaints 2008-2011," Rx&D, last updated 20 October 2011, https://www.canadapharma.org/en/commitment/healthcare/complaints.aspx.

The following penalties apply to companies that violate the code during any 12-month period:[87]

- First violation: Publication of infraction in the *Rx&D Update* and a fine of CAD25,000.
- Second violation: Same, and a fine of CAD50,000.
- Third violation: Same, a fine of CAD75,000, and the CEO of the company must appear before its board of directors in order to provide a detailed explanation of the violations and a comprehensive written action plan to ensure remediation.
- Additional violation: Publication of the infraction on the Rx&D website and a fine of CAD100,000.

There are also provisions in the Rx&D Code that deal with repeat offenders and deliberate contraventions.[88]

Any party involved in the complaint has recourse to an appeal process. If no appeal is filed in the time provided, the Committee's decision will be considered final and the company must adhere to the decision as a condition of continued membership in Rx&D.[89]

Liability Under Criminal Law

Professional misconduct and breach of the applicable codes of conduct for healthcare professionals and for members of Rx&D are not grounds for criminal sanction. Only where corruption, surreptitious distribution, fraud, secret commissions in agency relationships, or acceptance of illicit inducements is involved would criminal liability be possible.

Public Corruption and Bribery

No level of government in Canada is generally in the business of buying or selling medical products. As mentioned above, the majority of hospitals in Canada are public hospitals in the sense that they are government-funded, but they are neither owned nor controlled by the government. Furthermore, the activities of hospital professionals and staff are regulated but not controlled by government. Most physicians in Canada are in private practice and serve patients in hospitals on the basis of accreditation and 'hospital privilege'

[87] "[Rx&D] Code of Ethical Practices," *supra* at note 40, at 19.7
[88] *Ibid*. at 19.9 and 19.10.
[89] *Ibid*. at 19.13.

access to the facilities. Hence, most physicians employed in hospitals are essentially independent contractors and those staff physicians directly employed by these hospitals would not be considered "government employees." On this basis, Canadian anti-bribery and anti-corruption laws would have no application.

However, there are some psychiatric facilities and military hospitals that are government-owned, and physicians employed by these facilities may be considered public officials for purposes of Canadian anti-bribery and anti-corruption statutes. As well, physicians employed by federal or Ontario government entities, such as the Ontario Ministry of Health and Long-Term Care would be considered government employees. In relative proportions, there are only a small number of healthcare institutions and professionals that would be included in this category. To the extent that Canada's public anti-bribery and anti-corruption laws may apply to this group of healthcare institutions and professionals, the following elements should be noted in passing:

- Federal government procurement policy prohibits the payment of business and sales representatives on a commission basis for being instrumental in the obtaining of a government contract.
- The federal government also has various codes of ethics pertaining to government procurement, which include policies with respect to gifts and entertainment that appear to be consistent with those referenced in the industry codes identified above. In this regard, Canadian law is also expressed in the Criminal Code bribery provisions ("frauds upon the government"), as well as certain government codes and guidelines that restrict the giving of payments, gifts, hospitality, and other benefits to Canadian government officials.
- Individuals who lobby the federal government, or who lobby provincial government officials in the provinces of British Columbia, Alberta, Manitoba, Ontario, Quebec, Nova Scotia, or Newfoundland and Labrador must register under the Lobbying Act (Canada) and/or the applicable provincial lobbyists registration acts, as appropriate. In this regard, by way of example, "public office holder" is broadly defined in the Ontario statute[90] to include virtually everyone working

[90] Ontario's *Lobbyists Registration Act, 1998*, S.O. 1998, c. 27, Schedule ("LRA") came into effect on 15 January 1999. The LRA is very similar to Canada's federal lobbyists registration legislation that was enacted in 1989. The stated intention of the Ontario government is to create a public record of paid lobbyists to ensure that the

within the Ontario government, whether elected, appointed or employed, although it does not include Crown corporation employees (unless appointed by the provincial Cabinet), judges, justices of the peace, officers of the Legislative Assembly (e.g., Ombudsman, Information & Privacy Commissioner), or broader public sector entities such as hospitals, universities and local government institutions. Failure to register could result in a fine of up to CAD25,000.

- The Canadian Criminal Code[91] contains a number of offenses dealing with bribery under the title "Corruption and Disobedience" in sections 119 to 130, including "frauds on the government," which is aimed, in part, at what is known as influence peddling.[92] These anti-bribery provisions are rather broad and make it an offense for anyone dealing with the government to confer any advantage or benefit of any kind on an employee or official of the government with respect to those dealings. If a company representative were to commit bribery, the Criminal Code provisions with respect to "aiding and abetting" means it is conceivable that the firm involved could also be found guilty under these broad anti-bribery provisions. The US federal Foreign Corruption Practices Act[93] (the "FCPA") may apply to corrupt practices that involve government-employed healthcare professionals. The FCPA prohibits US and foreign issuers from bribing public officials outside the US and applies to any person pursuing a bribery arrangement with a foreign official while in American territory.

Private Bribery

There are no specific recourses available to a person who has been a victim of corruption, but Canadian courts have had to consider the tort of unlawful interference with economic interests. With regard to existing contracts, there is some case law supporting the proposition that a party, such as a business competitor, who induces a breach of a rival's contract by convincing a third party to do an unlawful act, may be liable for the loss or damage that the rival

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process of lobbying government is kept open and transparent, and that the public interest is protected from undue influence. Any individual or organization that lobbies a "public office holder" is required to register with the Office of the Integrity Commissioner.

[91] R.S.C. 1985, c. C-34.

[92] Section 121.

[93] 15 USC § 78dd-1 *et seq.*

sustains. Tort liability could also arise in a case of interference short of a breach. With regard to new contracts, the law is less clear.

The tort of unlawful interference is discussed in the Ontario case of *Future Health Inc. v. Cividino,*[94] where the court dismissed a motion to strike a statement of claim for failure to disclose a reasonable cause of action. In Quebec, there are no cases where corruption has been recognized as a fault giving rights to damages. However, the Civil Code contains provisions that could be invoked to claim damages. In conclusion, in both the common law provinces and in Quebec, possible remedies exist for those "whose rights and interests are affected by corruption."[95]

Contracts with Healthcare Professionals and Medical Institutions

It would be a conflict of interest and professional misconduct for a Canadian healthcare professional to receive a commission or referral fee from a medical products manufacturer or supplier for the referral of patients, or to sell or otherwise supply any medical product to a patient at a profit.

In addition to their altruistic public welfare value, continuing medical education programs and research sponsorship clearly constitute promotional activities. Educational grants and sponsorships are a fact of life in an environment of increasing financial strain on the Canadian public healthcare system. The specific by-laws and policies of each individual hospital or educational institution must be considered in terms of the acceptable standards of conduct. Each such institution can be expected to have a policy in place with respect to sponsorship and external funding. Such policies may indicate that there is to be no real or implied obligation to promote or purchase a product manufactured by the company providing funding, and that the grant must not influence therapeutic decision making.

Although the regulatory and ethical environment applicable to clinical trials is beyond the scope of this chapter, many of the principles in the various codes of conduct reviewed in relation to advertising and promotion are repeated with respect to clinical trials and, in fact, clinical trials may be considered a preliminary form of promoting medical products to the healthcare profession.

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[94] (1999), 41 O.R. (3d) 275 (Ont. Gen. Div.)

[95] All provinces and territories in Canada are common law jurisdictions, with the exception of Quebec which is a civil law jurisdiction.

Relevant to this consideration is a certain heightened sensitivity over conflict of interest concerns involving the nexus between Canadian hospitals and medical product manufacturers following a well-publicized case involving an Ontario hospital, one of its physicians involved in clinical research, and the pharmaceutical company responsible for the drug research in question. In 1996, the drug company threatened the physician with legal action if she published research findings unfavorable to the company's product which she had been studying. The case involved important issues of research ethics and academic freedom that attracted national and international attention. The Report of the Committee of Inquiry into this case, initially published in 2001, found that the company should not have attempted to impede the physician from informing patients, regulators and the scientific community of the risks that she had identified regarding the drug in question. The committee recommended that companies should not attempt to suppress or control results, and that all research hospitals should have in place a policy - and measures to ensure its implementation - that prohibits agreements, contracts, or protocols that have clauses that restrict communication of risks identified in research projects, particularly clinical trials. Research hospitals were advised to react strongly in support of their clinical researchers if any sponsor threatens the researchers' independence or academic freedom, in order to fulfil their responsibility to protect the safety of their patients.

The fall-out from this case has resulted in Canadian publicly funded institutions (hospitals and universities in particular) addressing and containing, in their own policies, the "demand-side" problems and risks associated with increasing reliance on outside resources of financial support.

Conclusions and Recommendations

As with many jurisdictions, the healthcare system in Canada is facing review and reform in the face of growing financial strain and public concern. In an era of decreased government funding and the corresponding opportunity for private participation, commercial concerns are therefore very much part of the social welfare debate and in the public view. With heightened sensitivities, bad behavior can garner significant public attention. Ultimately, significant incidents can generate intensification of regulatory oversight with increased administrative costs to enterprise. The damage to brand value and reputation can be much more immediate. Public perception is therefore the principal forum of accountability to keep in mind when interpreting the various laws and guidelines surveyed in this chapter.

United States of America

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Introduction

The promotion of pharmaceutical and medical device products in the United States is regulated at the federal level by a number of different agencies according to various statutory requirements governing not only traditional advertising mediums, but also promotional efforts intended to influence prescribing, dispensing and purchasing decisions.

Regulatory Framework

Food and Drug Administration ("FDA")

Overview

The FDA is the principal agency with oversight authority over pharmaceutical and medical device labeling, promotion and advertising. The FDA is responsible for protecting the public health by assuring the safety, effectiveness and security of human and veterinary drugs, vaccines and other biological products, medical devices, foods, cosmetics, dietary supplements, tobacco products and products that give off radiation. The FDA's authority primarily flows from the Federal Food, Drug, and Cosmetic Act ("FDCA" or "the Act")[1]. The FDCA, along with the regulations and guidance issued by the FDA to implement and interpret the Act, governs the labeling and advertising of pharmaceutical drug and medical device products, which include prescription drugs and devices, over-the-counter ("OTC") drugs and devices, vaccines, blood products and other biological drug products.

[1] 21 U.S.C. §§ 301 et seq. The US Congress has amended the federal drug law many times since the passage of the Food and Drugs Act of 1906, including the federal Food, Drug, and Cosmetic Act of 1938, the Kefauver-Harris Amendments of 1962, the Medical Device Amendments of 1976, the Food and Drug Administration Modernization Act of 1997, and the Food and Drug Administration Amendments Act of 2007 ("FDAAA"). Most recently, the US Congress enacted and the President signed the Food and Drug Administration Safety and Innovation Act of 2012 (Pub. L. 112-144).

i. Scope of Authority over Pharmaceutical Products

The scope of FDA's regulatory authority over pharmaceutical drug products includes any information that a manufacturer sponsors or creates about its product that is disseminated externally, including to consumers, patients, healthcare professionals, pharmacies, healthcare plans, systems and other payors, wholesale distributors and formularies.

FDA's authority to regulate drug promotion primarily stems from its authority over drug manufacturers — it can dictate the content and form of drug promotion because it has authority over drugs in the United States and the manufacturers who market them. In contrast, the FDA does not regulate communications about a drug that are created and disseminated by a pharmacy, physician, hospital, or health plan or other entity. However, if the manufacturer sponsors the communication in some way, e.g., provides the content to a pharmacy, health plan or other entity, the communication is subject to FDA regulation. FDA's authority over manufacturer-disseminated information is very broad and includes the following:

- Drug product labels and accompanying labeling
- Print and broadcast advertising
- Content on websites, in electronic mail, sponsored internet search engine links, social media and public sites to which the manufacturer or its representative posts content, such as YouTube, Tumblr, Pinterest and Facebook
- Educational materials provided to patients, consumers and healthcare professionals
- Reprints of scientific and medical articles
- Product samples
- Consumer and healthcare professional products, such as magnets, t-shirts, mugs, prescription pads and coloring books
- Speeches, presentations, posters and convention booths
- Oral representations made by company representatives
- "Homemade" materials
- Any other dissemination of any manufacturer-sponsored drug product-related information

Other entities with enforcement authority over manufacturer-sponsored pharmaceutical product promotion arising under other laws include: the Department of Health and Human Services ("HHS"); the Office of Inspector

General ("OIG"); Centers for Medicare and Medicaid Services; the Federal Trade Commission ("FTC"); and the individual states. Entities with significant authority, such as OIG, are discussed further below.

This chapter focuses on the FDA and human prescription drugs promotion. FDA's Office of Prescription Drug Promotion ("OPDP") within FDA's Center for Drug Evaluation and Research ("CDER") regulates human prescription drug promotion.[2] The Advertising and Promotional Labeling Branch ("APLB") within the Center for Biologics Evaluation and Research ("CBER"), regulates the promotion of biological products, including vaccines, blood-related products, and cellular and gene therapies.[3]

ii. Scope of Authority over Medical Devices

The FDCA also governs the labeling of medical devices in the United States, as well as advertisements for restricted medical devices.[4] The relevant definitions found in the FDCA, and subsequent court interpretations thereof, directly bear upon FDA's authority to regulate the labeling and advertising of medical devices. Specifically, court and agency treatment of the term "labeling" has given FDA authority over a broad spectrum of materials that might otherwise be viewed by the layman as advertising as opposed to labeling.

Medical devices sold in the US are generally regulated by two FDA centers: the Center for Devices and Radiological Health ("CDRH") and the Center for Biologics Evaluation and Research ("CBER"). CDRH is responsible for regulating firms that, among other things, manufacture, repackage, relabel, sterilize, distribute, import and/or export medical devices. Examples of medical devices include surgical instruments, implantable devices, diagnostic equipment, clinical laboratory tests and medical radiation emitting products

[2] Regulation of over-the-counter drug promotion by the FTC is discussed below.
[3] FDA's Office of Surveillance and Compliance in the Center for Veterinary Medicine ("CVM") is responsible for oversight of promotion of animal drugs. The nuances of CVM requirements are beyond the scope of this chapter. However, the basics of compliance described here are applicable to most promotion of FDA-regulated human and animal drugs and biologics and medical device products.
[4] Restricted devices are those that are restricted to sale, distribution, or use (1) only upon the written or oral authorization of a practitioner licensed by law to administer or use such device, or (2) upon such other conditions as FDA may prescribe in such regulation, if, because of its potentiality for harmful effect or the collateral measures necessary to its use, FDA determines that there cannot otherwise be reasonable assurance of its safety and effectiveness. FDCA § 520(e) (21 U.S.C. 360j(e)).

(e.g., lasers, x-ray systems, and ultrasound equipment). CBER regulates some medical devices used in the collection of whole blood and other blood products. Examples of such medical devices include cell separation devices, blood collection containers and HIV screening tests that are used to prepare blood products or to ensure the safety of the blood supply.

Important Definitions

"Drug" means:

(A) articles recognized in the official United States Pharmacopoeia, the official Homoeopathic Pharmacopoeia of the United States or the official National Formulary, or any supplement to any of them;
(B) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals;
(C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and
(D) articles intended for use as a component of any article specified in clause (A), (B) or (C).[5]

For purposes of this discussion, it should be assumed that biological drugs are included in the general definition of "drug" and that the standards are, insofar as promotional requirements are concerned, the same.

"Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which:

- is recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them;
- is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease in man or other animals; or
- is intended to affect the structure or any function of the body of man or other animals; and
- which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.[6]

[5] 21 U.S.C. § 321(g)(1).
[6] FDCA § 301(h); 21 U.S.C. § 321(h).

"Label" and "labeling": The FDCA defines "label" as "a display of written, printed, or graphic matter upon the immediate container of any article . . . ."[7] Therefore, "label" applies only to what is affixed to the container that holds the actual product. "Labeling," however, has a broader definition and includes "all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article."[8] The term "labeling" has been interpreted in a very broad way and has come to include any written, printed or graphic material that supplements or explains the product; is disseminated by the manufacturer in the commercial context as part of the selling process; and reaches the customer, doctor, or patient, either before, with or after the product.[9]

It is important to distinguish between two types of "labeling" for prescription drugs. The first, the drug's approved product labeling, is also referred to as the "prescribing information," the "full product labeling" or the "package insert" ("PI"). The PI is negotiated between the manufacturer and the FDA, intended for the healthcare professional, as a document that sets forth the "adequate directions for use," conditional for safe use of the product.[10] By regulation, the PI must contain certain information, such as indications, warnings, precautions, contraindications, summary of clinical data supporting the FDA approval, pharmacokinetic information, information on special populations and other information.[11] Labeling which is not the PI is considered promotional labeling, akin to advertising, and is subject to additional requirements when the manufacturer disseminates it.

"Promotional Labeling": As to prescription drugs, the FDA has created a subcategory of labeling materials to account for those materials that can be viewed as labeling but which also contain promotional or advertising qualities. This category has been termed "promotional labeling."

Pursuant to regulation, advertisements are limited to: published journals, magazines, other periodicals and newspapers, and advertisements broadcast through media such as radio, television and telephone communication systems.

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[7] FDCA § 301(k); 21 U.S.C. § 321(k).
[8] FDCA § 301(m); 21 U.S.C. § 321(m).
[9] See, e.g., Kordel v. United States, 335 U.S. 345 (1948).
[10] FDCA § 502 (f)(i); 21 U.S.C. § 352(f)I; 21 C.F.R. § 201.5.
[11] 21 C.F.R. § 201.56.

As discussed above, true drug labeling — the PI — is an FDA-approved document that always accompanies a prescription drug and contains the "adequate directions for use" of the product.[12] For prescription drugs, all labeling other than the PI is "promotional labeling" which is much broader in scope than advertising and includes:

- brochures, booklets, mailing pieces, calendars, price lists, catalogs, letters, films, sound recordings, exhibits, literature, reprints and other printed, audio or visual matter
- which are descriptive of a drug supplied by the manufacturer, packer or distributor of the drug
- which are disseminated by or on behalf of its manufacturer, packer or distributor[13]

Although the concept of "promotional labeling" has not been formally adopted by CDRH, the Center has applied similar principles to medical device promotional labeling materials. Device labeling includes more than the package insert and the label for a device; it may include brochures, billboards, promotional mailings, posters, "Dear Doctor" letters, trade show display materials, many website materials and scientific journal articles. For example, reprints of medical articles distributed with a device are categorized as promotional labeling where the articles supplement or explain the device. As a result, virtually all promotional materials regarding a device are viewed by the FDA as "labeling" or "promotional labeling." However, a subset of promotional materials are not written, printed or graphic, and use oral, audio and/or video representations to promote the subject medical device. As such, they arguably fall outside the scope of "labeling." This subset of materials is considered "advertising" or "promotion."

"Advertising": The terms "promotion" and "advertising," although used synonymously, are not defined in the FDCA, nor has the FDA issued any definitions of the terms. This situation can be confounding for companies because they assume that educational materials, treatment communications and other materials that are not "selling" or "marketing" the drug or device are not promotional and so therefore are not subject to FDA's promotional requirements. This is not always correct. For example, if a communication regarding a drug product, in whatever form, is sponsored (financially or otherwise) by the manufacturer, it is "promotional" unless it is the FDA-

[12] FDCA § 301(k); 21 U.S.C. § 321(k); and 21 C.F.R. § 201.5.
[13] 21 C.F.R. §§ 202.1(1) and (2).

approved PI. Even a PI becomes promotional and subject to FDA requirements if it has been altered in some way, e.g., parts of it have been highlighted.

For the most part, the few promotional materials that fall outside of the enormously broad scope of "labeling" are generally regulated by the FTC as advertising/promotion, including OTC drug advertising.[14] Pursuant to a Memorandum of Understanding between FDA and FTC, the FTC in the first instance asserts primary authority over the advertising of foods, dietary supplements, OTC drugs, and non-restricted medical devices, while the FDA asserts primary authority over the labeling of those products. The FDA retains authority over all prescription product promotion. In practice, the agencies frequently act in concert and each agency's statutory authority is broad enough to permit it to look to all promotional materials when bringing enforcement actions. The FTC's authority also broadly extends to healthcare professionals and their promotional activities and so it has investigated whether pharmacies participating in manufacturer-sponsored patient education programs had been paid to provide false or misleading representations regarding the safety or efficacy of drug products or failed to make adequate disclosures of sponsorship.[15]

With regard to medical devices, the FTC is charged with regulating the advertising (as opposed to the labeling) of many medical devices under sections 12-15 of the FTC Act, which prohibit false or misleading advertising of certain products that the FDA regulates.[16] Still, the FDA has statutory authority to regulate "advertising" of "restricted" devices (including prescription-only devices), and there are "misbranding" provisions related to "restricted" devices.[17] Neither the FDA nor the FTC requires the submission of medical device advertisements for pre-approval.

[14] FTC has authority to bring enforcement actions for false advertising and other unfair or deceptive acts or practices affecting commerce, including some drug and device advertising. 15 U.S.C. §§ 45(a) and 52(a).
[15] The FTC closed its investigation of three pharmaceutical chains in January 2003. See Letters from M. Engle to J. Davis, D. Balto, P. Proger dated January 13, 2003.
[16] 15 U.S.C. §§ 52-55.
[17] See, e.g., Sections 502(q) and 502(r) of the FDCA.

"Misbranding" – Prohibited Acts and Violations of the FDCA

Section 301 of the FDCA[18] sets forth a number of "prohibited acts" against which the FDA (and in certain cases, the Department of Justice on behalf of the FDA) can exercise its enforcement authority. For example, the "introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or "misbranded" is a prohibited act.[19] There are approximately 39 prohibited acts in § 301, and many of these prohibited acts concern regulated products considered to be "misbranded" by virtue of their associated labeling or advertising materials. The application of the term "misbranded" as it applies to pharmaceutical products and medical devices is discussed in more detail below.

"Misbranded" Pharmaceutical Products

Violations of the FDCA involving labeling and advertising of drugs are tied to "misbranding." The following, among others, are all prohibited under the FDCA:

- The introduction or delivery for introduction into interstate commerce of any misbranded drug
- The misbranding of any drug in interstate commerce
- The receipt or delivery in interstate commerce of any misbranded drug
- Misbranding a drug that is held for sale (whether or not the first sale) after shipment in interstate commerce[20]

A drug is misbranded if its labeling or advertising is false or misleading.[21] Furthermore, to avoid being misbranded, a drug must comply with the following:

- In package form, the drug must bear a label containing: the name and place of business of the manufacturer, packer or distributor; and an accurate statement of the quantity of the contents in terms of weight, measure or numerical count.
- Any word, statement or other information required under the FDCA to appear on the label or labeling must be prominent and conspicuous.

[18] 21 U.S.C. § 331.
[19] FDCA § 301(a); 21 U.S.C. § 331(a).
[20] 21 U.S.C. § 331(a)-(c).
[21] 21 U.S.C. § 352(a); 21 C.F.R. § 202.1(e)(5)(i).

- The label must bear:
  - the established name (the official, chemical generic as opposed to "brand" or proprietary name);
  - the established name and quantity of each active ingredient; and
  - the established name of each inactive ingredient listed in alphabetical order on the outside container of the retail package.
- The established name must be printed prominently and in type at least half as large as any proprietary name.
- The labeling must bear adequate directions for use, that is, the FDA-approved PI.
- The manufacturer, packer or distributor must include in all advertisements and other descriptive printed matter a true statement of: the drug's established name, printed prominently and in type at least half as large as that used for any trade or brand name; the formula showing quantitatively each ingredient; and a brief summary of information relating to side effects, contraindications and effectiveness as required by regulation.
- Printed direct-to-consumer ("DTC") advertisements must include the following statement printed in conspicuous text: "You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088."
- Television and radio advertisements for prescription drugs presented directly to consumers must state the name of the drug, its conditions of use, and include a majority of the drug's side effects and contraindications in a clear, conspicuous and neutral manner.[22]

"Misbranded" Medical Devices

Labeling and advertising materials that are not in compliance with FDA's requirements can "misbrand" (or even "adulterate") the subject device under the FDCA.[23] Some examples of misbranding under § 502 include circumstances where:

- the labeling is false or misleading in any particular way;[24]
- the device packaging label does not contain:
  - the name and place of business of the manufacturer, packer or distributor; and

[22] See generally, 21 U.S.C. § 352.
[23] 21 U.S.C. §§ 351 and 352; FDCA §§ 501 and 502.
[24] 21 U.S.C. § 352(a); FDCA § 502(a).

- an accurate statement of the quantity of the contents;[25]
- information required to be on the device labeling or label is not conspicuous or is not clear;[26]
- OTC device labeling does not contain "adequate directions for use" or "such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner or form, as are necessary for the protection of users";[27] and
- the device is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended or suggested in its labeling.[28]

In determining whether a drug or device is misbranded due to false or misleading labeling or advertising, the FDA considers not only representations made or suggested about the drug or device, but also the extent to which the labeling or advertising fails to reveal facts material to the representations made or consequences that may result from the use of the product. Specifically, the FDCA provides that:

> . . . in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.[29]

With regard to labeling and advertising, what qualifies as false or misleading information is determined by the effect the label and labeling will have on prospective purchasers to whom the claims are addressed. Therefore, a manufacturer should ensure that information about the use, benefits and risks stated in labeling or advertising is consistent with the product's approved or

[25] 21 U.S.C. § 352(b); FDCA § 502(b).
[26] 21 U.S.C. § 352(c); FDCA § 502(c).
[27] 21 U.S.C. § 352(f); FDCA § 502(f).
[28] 21 U.S.C. § 352(j); FDCA § 502(j).
[29] 21 U.S.C. § 321(n); FDCA § 201(n).

cleared labeling. Labeling and advertising must present a fair balance of information relating to the side effects, safety and effectiveness of the product. As a general rule, product claims should be based on reliable scientific data, which may require the use of well-controlled clinical trials.

"Intended Use" and "Off-Label" Promotion

As a general rule, manufacturers and distributors of FDA-regulated medical products may not promote their products for "off-label" uses and may not disseminate materials that discuss "off-label" uses (either directly or impliedly). An "off-label" claim is a claim or statement about an FDA-regulated product that represents or implies that the product is useful in ways that are not approved or cleared by the FDA.[30] Although the FDA recognizes that physicians often use pharmaceutical products and medical devices for "off-label" uses and that such uses have an important place in the practice of medicine, it is the agency's view that allowing manufacturers to promote their products for these kinds of uses "can have negative public health consequences -- including the exposure of patients to unnecessary risks and destroying the incentive for companies to conduct the necessary research to demonstrate that products are safe and effective for these uses."[31]

Whether a claim is "off-label" can be a function of how the FDA perceives the promoted "intended use" of the device. "Intended use" refers to the "objective intent of the persons legally responsible for the labeling of devices."[32] Intent is determined by "such persons' expressions" or "by the circumstances surrounding the distribution of the article."[33] The FDA explains that "objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives."[34] Likewise, intended use may also be shown if the manufacturer or its representatives are aware that the product is being "offered and used for a purpose for which it is neither labeled nor advertised."[35] It is a "totality of circumstances" analysis.

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[30] 21 U.S.C. §§ 351-52.
[31] See Testimony of Then-FDA Deputy Commissioner for Policy William Schultz, Before the Committee on Labor and Human Resources of the United States Senate (22 February 1996).
[32] 21 C.F.R. § 201.128 and 801.4.
[33] Id.
[34] Id.
[35] Id.

The FDA approves or clears a prescription drug or medical device for particular indications under certain conditions of use. Any statements, written, oral or broadcast (express or implied) by the manufacturer or its representatives suggesting a different use than that which the FDA approved or cleared is unlawful and misbrands the product.

The Elements of Lawful Prescription Pharmaceutical Promotion

The elements of a lawful pharmaceutical product promotion are:

- Fair balance and presentation of risk information
- Accompanying information
- Submission to the FDA
- Prominence of proprietary and established name of product

Fair Balance and Presentation of Risk

A drug promotion item misbrands the drug and is unlawful unless it presents a "fair balance between information relating to side effects and contraindications and information relating to effectiveness."[36] The FDA has extensive regulations regarding what constitutes fair balance.[37] A promotion is lacking in fair balance, if, among other things, it:

- contains a representation not approved by the FDA in the PI (e.g., that the drug is better, more effective or useful in a broader range of conditions than those FDA approved, and has fewer side effects than has been demonstrated);
- represents that the drug is safer or more effective than another drug, though not demonstrated by substantial evidence or substantial clinical experience;
- contains favorable information, opinions or cites to authorities that have since been rendered invalid by more credible recent information, or uses literature or quotations that are significantly more favorable to the drug than has been demonstrated;

[36] 21 C.F.R. § 202.1(e)(5)(ii). While the fair balance requirement stems from FDA's regulations governing the advertising of prescription drugs, the agency has extended the fair balance requirement to promotional labeling as well. Any advertising or promotional labeling lacking in fair balance will misbrand the product in violation of the FDCA.
[37] 21 C.F.R. § 202.1(e)(6).

- selectively presents information in order to suggest the drug is safer than has been demonstrated by substantial evidence or substantial clinical experience;
- misrepresents the effectiveness of the drug by referencing literature or studies and not disclosing that claimed results may be due to other factors, such as concomitant therapy or placebo effect;
- presents nonclinical studies of a drug, such as in laboratory animals or in vitro, to suggest they have clinical significance when clinical significance has not been demonstrated;
- uses a quote, paraphrases, citations to literature or references out of context or to make them appear they support a claim when they do not;
- uses "statistics" on numbers of patients, or counts of favorable results or side effects in a way that suggests either that such "statistics" are valid when they are not;
- uses erroneously a statistical finding of "no significant difference" to claim clinical equivalence or to deny or conceal the potential existence of a real clinical difference; or
- uses headlines, pictorial or other graphic matter in a way that is misleading.[38]

A promotion may be lacking in fair balance, if, among other things, it:

- contains favorable information or conclusions from an inadequate study;
- uses the concept of "statistical significance" to support a claim that has not been demonstrated to have clinical significance;
- uses statistical analyses on a retrospective basis not supported by the study or to suggest validity and rigor not present;
- uses tables or graphs to distort or misrepresent results;
- uses statistical information that violates established principles of statistical theory, or that is derived from clinical studies which substantially invalidate the application of statistical analyses;
- contains claims concerning the mechanism or site of drug action that are not established;
- fails to provide sufficient emphasis for the risk information or with a prominence and readability comparable to benefit information;

[38] 21 C.F.R. § 202.1(e)(6).

- fails to provide adequate emphasis for the fact that two facing pages of a print advertisement, one with benefit information and one with risk information are part of the same advertisement for the same drug; or
- fails to include on each page or spread of an advertisement the risk information or a prominent reference to its presence and location when it is presented as a distinct part of an advertisement.[39]

A critical component of fair balance is assuring that risk information is adequately presented. If insufficient prominence is given to risk information, promotion of an FDA-regulated product is not fairly balanced and misbrands the drug in violation of the FDCA. In May 2009, CDER, CBER, CVM, and CDRH jointly issued a draft Guidance for Industry: Presenting Risk Information in Prescription Drug and Medical Device Promotion ("Risk Information Draft Guidance").[40] While not final, the Risk Information Draft Guidance provides important insight for manufacturers seeking to promote their products in the US.

The Risk Information Draft Guidance extensively discusses how to present risk information in promotional material directed to patients, consumers, and healthcare professionals. The FDA states: "This draft guidance describes how FDA reviews prescription drug and medical device promotional pieces to determine whether they adequately present risk information. … The draft guidance then describes factors FDA considers when reviewing risk communication in promotional materials."[41]

The FDA provides numerous examples of the types of risk presentation issues the Risk Information Draft Guidance addresses:

> Example 1: A broadcast television ad for a cholesterol-lowering drug contains a factually accurate audio risk statement that discloses the drug's major side effects and contraindications. This audio presentation is accompanied by quick scene changes showing comforting visual images of patients benefiting from the drug. It is also accompanied by loud, upbeat music.

[39] 21 C.F.R. § 202.1(e)(7).
[40] Draft Guidance for Industry: Presenting Risk Information in Prescription Drug and Medical Device Promotion (May 2009), http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM155480.pdf.
[41] Risk Information Draft Guidance at lines 71-77.

In this case, the audio disclosure may not adequately communicate risks because of the accompanying discordant visuals and distracting music.

Example 2: A one-page prescription drug ad for an arthritis drug, run in a medical journal, prominently presents the following headline claims in large bolded font and with abundant surrounding white space:

- ***Benefits!*** **DrugX is proven safe and effective for the relief of arthritis pain and stiffness**
- ***Difference!*** **DrugX's unique gel formulation is convenient and easy to use**
- ***Reason to Believe!*** **Drug X is the most frequently prescribed arthritis drug in the United States**

The bottom of the page contains an inconspicuous statement in small, non-bolded font and without surrounding white space: "Like all arthritis medications, Drug X has been associated with a risk of serious infection." The emphasis on benefit information in this piece — in terms of the way the information is formatted and framed — overwhelms the risk information and may cause readers to receive an erroneous impression that the drug is safer than it has proven to be, even though the statements themselves may be factually accurate.[42]

Furthermore, the FDA also identifies various factors and considerations in determining the adequacy of risk information presentation. Under General Considerations, the FDA states:

- Consistent Use Of Language Appropriate For Target Audience – Promotional materials directed to professionals can use medical language, but promotional materials directed to consumers should convey benefits and risks in language understandable to consumers.
- Use Of Signals – Signals are used to highlight certain information, such as through headlines in print and broadcast promotions. The FDA looks to see if the use of signals is consistent across benefit and risk information.
- Framing Risk Information – Framing refers to how a particular piece of information is stated or conveyed, such as by emphasizing either the

[42] Id. at lines 130-150.

positive or negative aspects of the information or by presenting the information in vague versus specific terms. The FDA evaluates how risk information is framed because framing can affect the presentation of risks and benefits in a promotional piece.

- Hierarchy of Risk Information – The FDA considers the ordering of risks within a presentation in determining whether the risks are adequately disclosed.[43]

Under Content Considerations, the FDA identifies the following factors that may influence whether risk information is adequately presented:

- Quantity – The FDA considers the amount or quantity of information conveyed by a promotional piece, recognizing, for instance, that a 30-second broadcast ad is likely to present less information than a 60-second broadcast ad. Importantly, as the amount of benefit information conveyed increases, the amount of risk information conveyed should similarly increase.
- Materiality and Comprehensiveness – A promotional piece that omits material information about a product's risks could be considered misleading. In determining the materiality of the risks associated with a drug or device, the FDA refers to the product's PI.[44]

The formatting of the risk information, particularly relative to the benefit information, is important to determining whether a promotion is misleading. FDA's Format Considerations include the following:

- For print promotions:
  - Overall Location of Risk Information – For a piece to be accurate and non-misleading, risk information should be included in the main part of the piece.
  - Location of Risk Information within a Part of the Promotional Piece – In addition to appearing with or near benefit presentations, risk information should be integrated into the piece, just as benefit information is.
  - Font Size and Style, Contrast, and White Space – The FDA looks to the visual presentation of the piece — if, in comparison to benefit information, risk information is presented in small,

[43] Id. at lines 202-337.
[44] Id. at lines 344-512.

difficult-to-read font, with poor contrast and insufficient white space, the piece is likely misleading.

- For broadcast promotions:
  - Textual Elements – Broadcast promotions must present major product risks in the audio or audio and visual parts of the promotion. When presenting risk information in text in a broadcast promotion, care must be taken to assure, among other things, that it is readable, legible and not minimized by other competing elements in the ad. There must also be adequate contrast.
  - Dual Mode Considerations – Distracting elements, such as visuals, should not be used to distract from the risk information appearing at the same time in the promotion.
  - Audio Considerations – Voiceovers, recordings, and other audio elements should be properly paced, clear and articulate to present risk information in the same manner as the benefit information.[45]

Accompanying Information

In addition to the requirement that a prescription drug promotion should be fairly balanced in its presentation of risk information, it must also be accompanied by other certain information. Promotional labeling must be accompanied by "adequate directions for use," that is, the full PI.[46]

In contrast, prescription drug advertisements must include "information in brief summary relating to side effects, contraindications, and effectiveness."[47] For many years, drug manufacturers/sponsors reprinted all or most of the PI in conjunction with print advertisements for their drugs in order to satisfy FDA's "brief summary" requirement.[48] In the 2004 Draft Guidance for Industry: Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements (January 2004)[49], the FDA stated that it would exercise

[45] Id. at lines 516-713.
[46] 21 U.S.C. § 352(f); 70 Fed. Reg. 54,054, 54,055 (September 13, 2005).
[47] 21 U.S.C. 352(n); 21 C.F.R. § 202.1(e).
[48] The "brief summary" requirement is not feasible for the typical broadcast advertisement. By regulation and guidance, FDA has provided other means to satisfy these accompanying information requirements which are discussed in more detail below.
[49] Brief Summary Draft Guidance: Disclosing Risk Information in Consumer-Directed Print Advertisements (January 2004),

enforcement discretion and not take action against a manufacturer/sponsor of a prescription drug solely because it failed to reprint the PI to satisfy the brief summary requirement if, in lieu of the PI, the manufacturer/sponsor provided:

- the drug's FDA-approved patient package insert ("PPI"); or
- a consumer-friendly version of the "Highlights" of the PI that is included with newly-approved prescription drugs and supplements.[50]

All or most of the PI is still commonly reprinted in print advertisements directed to healthcare professionals.

Submission to FDA

Prior to approval of its new drug, manufacturers frequently submit their "launch" materials to OPDP for review. Drugs and biologics subject to accelerated approval must submit copies of all promotional materials, including promotional labeling and advertisements, intended for dissemination or publication within 120 days following marketing approval prior to FDA approval or licensing.[51] Post-approval, all advertisements and promotional labeling for prescription drugs must be submitted at the time of dissemination or publication.[52]

Prominence of Proprietary and Established Name of Product

Generally, each time the proprietary name of a drug appears, the established name must also appear. The FDA issued detailed draft guidance on how to accomplish the appropriate placement and prominence of a drug's trade/proprietary and established names in product promotions.[53]

Lawful Medical Device Promotion

Lawful promotion is that which is conducted in compliance with applicable FDA regulations and guidance. To implement the various provisions of the

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http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM069984.pdf.

[50] Brief Summary Draft Guidance, lines 65-73.

[51] 21 CFR § 314.550 and § 601.45.

[52] 21 CFR § 314.81(b)(3)(i).

[53] 21 C.F.R. § 202.1(a)-(c); Guidance for Industry, Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling (January 2012), http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ ucm070076.pdf.

FDCA affecting medical device labeling, the FDA has promulgated numerous regulations setting forth various device labeling requirements, including: general device labeling;[54] requirements specific to *in vitro* diagnostic products;[55] labeling requirements associated with Investigational Device Exemptions ("IDE");[56] and requirements for labeling control associated with the good manufacturing practices found in the Quality System Regulation ("QSR").[57] Moreover, other regulations prohibit labeling or other claims that represent or leave an impression of FDA's approval of a facility or device by reference to an establishment registration or medical device listing number or to a premarket notification ("510(k)") clearance.[58]

Pursuant to FDA's general device labeling requirements, the labels of all medical devices are required to contain the name and place of business of the manufacturer, packager or distributor.[59] OTC devices are required to have the common name of the device, a statement of the net quantity of the product, adequate directions for use that can be understood by a lay person, a statement of the intended purpose for the device may be used, and warnings and precautions, among other things. Prescription devices are devices deemed not safe for use except under the supervision of a healthcare practitioner licensed by law to direct the use of the device. Prescription devices are exempt from the requirement for "adequate directions for use" provided the conditions enumerated on the FDA's general device labeling requirements are met.[60]

Legal Dissemination of Off-Label Information Versus Illegal Off-Label Promotion

Legal Background

As discussed, the FDCA and FDA's implementing regulations prohibit manufacturers of new drugs or medical devices from distributing products in interstate commerce for any intended use that FDA has not previously sanctioned.[61] FDA and the US Department of Justice, on the agency's behalf, have aggressively pursued companies who have marketed their products for

[54] 21 C.F.R. Part 801.
[55] 21 C.F.R. Part 809.
[56] 21 C.F.R. Part 812.
[57] 21 C.F.R. Part 820.
[58] 21 C.F.R. §§ 808.39 and 807.97.
[59] 21 C.F.R. Part 801.
[60] Id.
[61] FDCA § 301(a) (21 U.S.C. § 331(a)); FDCA § 505(a) (21 U.S.C. § 355(a)).

unapproved uses. Failure to comply with the FDCA can have grave repercussions for a company.

In July 2012, GlaxoSmithKline LLC ("GSK") pled guilty and agreed to pay USD3 billion to resolve its criminal and civil liability arising from, among other things, the company's unlawful promotion of certain prescription drugs.[62] GSK agreed to plead guilty to a three-count criminal information that included introducing the misbranded drugs Paxil and Wellbutrin into interstate commerce. GSK will pay a total of USD1 billion, including a criminal fine of USD956,814,400 and forfeiture in the amount of USD43,185,600. The settlement included a Corporate Integrity Agreement and other compliance commitments and certifications by GSK's US president and board of directors.

In the unlawful promotion of unapproved drugs part of the GSK settlement, the government alleged that GSK promoted Paxil and Wellbutrin for numerous off-label uses. GSK allegedly paid millions of dollars to doctors to speak at and attend meetings and spas at which the off-label uses for these drugs were promoted. GSK was also alleged to have used sales representatives, sham advisory boards, and independent Continuing Medical Education ("CME") programs to promote their drugs for unapproved uses. For the Paxil and Wellbutrin misbranding offenses, GSK agreed to pay a criminal fine and forfeiture of USD757,387,200.[63]

An important component of this, and similar recent drug cases, includes liability and settlements under the federal Anti-Kickback Statute and the False Claims Act ("FCA"). These are matters separate from violations of the FDCA but can arise as a result of the same off-label promotion. These important statutes and a company's potential liability under them are discussed later in this chapter.

Case law notwithstanding, there is a fine line between unlawful promotion of FDA-regulated articles for unapproved uses and the lawful dissemination of information about unapproved uses for scientific and educational exchange. The FDA does not regulate the practice of medicine and so prescribers are free to prescribe medications and devices to patients for off-label uses. Obtaining information from those most knowledgeable about the product —

[62] GlaxoSmithKline to plead guilty to pay USD3 billion to resolve fraud allegations and failure to report safety data at http://www.justice.gov/opa/pr/2012/July/12-civ-842.html.
[63] Id.

that is, the manufacturer — is an important part of the practice of responsible, ethical medicine. Furthermore, a sponsor's communications about its FDA-regulated products are protected by the First Amendment to the US Constitution. Although the FDA is able to regulate, though not ban, truthful "commercial" speech that promotes an FDA-regulated product, true scientific exchange and academic and educational communications are "pure" speech, entitled the highest protections of the First Amendment to the US Constitution.[64]

In recognition of both the need to inform healthcare providers of off-label uses and the inability to lawfully prohibit academic and scientific information about off-label uses, the FDA issued guidance describing acceptable scientific, medical, and academic communications about unapproved uses. Below, unsolicited requests for information, dissemination of reprints, industry-supported scientific exchange, and scientific exchange regarding unapproved drugs and devices are addressed.

- We caution that distinguishing fully-protected speech (often about off-label uses), which the FDA may not regulate, and unlawful promotion of unapproved drugs or uncleared/unapproved devices, which carries severe risk of enforcement, is a fluid and controversial area of the law. Recent court cases and mounting pressure by industry for greater clarification, particularly when the consequences of "getting it wrong" are so severe, are resulting in close scrutiny of the issue. On 5 July 2011, seven product manufacturers petitioned the FDA requesting clarification of policies for drug products and devices governing communications and activities related to off-label uses of marketed

[64] A full discussion of the constitutional implications of FDA's authority over speech is complex and beyond the scope of this chapter. See, e.g., Washington Legal Foundation v. Friedman, 13 F. Supp. 2d 51 (D.D.C. 1998); Washington Legal Foundation v. Henney, 56 F. Supp. 2d 81 (D.D.C. 1999); (vacated as moot in) Washington Legal Foundation v. Henney, 202 F. 3d 331 (D.C. Cir. 2000) (FDA guidance restricting dissemination of reprints and medical articles discussing off-label uses of drugs violated the First Amendment as unconstitutional restriction on commercial speech); Thompson v. Western States Medical Center, 535 U.S. 357 (2002) (unconstitutional to bar the advertising of "compounded" drugs); Sorrell v. IMS Health Inc., 131 S. Ct. 2653 (2011) (speech in aid of pharmaceutical marketing is a form of expression protected by the Free Speech Clause of the First Amendment). For purposes here, it is assumed that the FDA has authority to regulate truthful, off-label information about prescription drugs and the focus of the discussion in this chapter is upon the current FDA guidances that describe how manufacturers may do so without potentially violating the FDCA.

products and use of products that are not yet legally marketed for any use.[65] On 28 December 2011, the FDA published a notice that it was accepting comments on the issue of communications and activities related to off-label uses of marketed products and use of products not yet legally marketed.[66]

- Manufacturers wishing to engage in dissemination of non-promotional information regarding off-label uses should closely monitor this area and seek the advice of competent legal counsel.

Responding to Unsolicited Requests for Off-Label Information

In December 2011, CDER, CBER, CVM and CDRH jointly issued a Draft Guidance for Industry: Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices ("Unsolicited Requests Draft Guidance").[67]

The Guidance was prompted because the FDA recognizes that while off-label promotion is unlawful, "off-label uses or treatment regimens may be important therapeutic options and may even constitute a medically recognized standard of care."[68] Additionally, the FDA recognized that "the rapid growth of the internet, including social media tools and other emerging technologies, has made it easier for both consumers and healthcare professionals to quickly seek information about medical conditions and treatments. This can cause firms to encounter more requests for off-label information about their products through product websites, discussion boards, chat rooms, or other public electronic forums that they maintain and over which they have full control."[69]

Of critical importance, the FDA states: "If a firm responds to unsolicited requests for off-label information in the manner described in the draft guidance, FDA does not intend to use such responses as evidence of the

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[65] See Docket No. FDA-2011-P-0512, available at http://www.regulations.gov/#!documentDetail;D=FDA-2011-P-0512-0001.
[66] 76 Fed. Reg. 81508 (Dec. 28, 2011), Docket No. FDA–2011–N–0912, http://www.regulations.gov/#!docketDetail;D=FDA-2011-N-0912;dct=FR%252BPR%252BN%252BO%252BSR.
[67] Draft Guidance for Industry: Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices (Dec. 2011), available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM285145.pdf.
[68] Id. at lines 54-56.
[69] Id. at lines 66-72.

firm's intent that the product be used for an unapproved or uncleared use. Such responses would also not be expected to comply with the disclosure requirements related to promotional labeling and advertising."

Firms may choose to respond to unsolicited requests for information about off-label uses of their approved or cleared products in a manner other than that recommended in this draft guidance. Such activity would not constitute a *per se* violation of the law, but could potentially be introduced as evidence of a new intended use.[70]

In sum, disseminating off-label information in compliance with the Unsolicited Requests Draft Guidance appears to create a safe harbor for a drug or device manufacturer.

Unsolicited Requests: "Unsolicited requests" are initiated by persons or entities that are completely independent of the relevant firm.[71] The FDA addresses two types of unsolicited requests: non-public unsolicited requests and public unsolicited requests. "A non-public unsolicited request" is "an unsolicited request that is directed privately to a firm using a one-on-one communication approach," such as via email or a telephone call.[72] A "public unsolicited request" is "an unsolicited request made in a public forum, whether directed to a firm specifically or to a forum at large," such as a question about a specific product made at a public meeting or in a post to a website maintained by the company.[73]

Solicited Requests: "Solicited requests" are prompted by a manufacturer or its representatives. Examples include a firm's sales representative or paid speaker mentioning an off-label use and inviting requests for more information, and dissemination of a phone number, email address or URL that is a word, alpha phrase or alpha representation implying the availability of off-label information. For example, a solicited request would include asking users to post videos about their own uses of its product on third-party video-sharing sites (e.g., YouTube), which result in video postings about an off-label use of the product. Solicited requests for off-label information may be, as the FDA states, evidence of the company's intent to illegally promote the drug for unapproved uses.[74] Responding to Non-Public Unsolicited

[70] Id. at lines 92-99.
[71] Id. at lines 109-110.
[72] Id. at lines 117-124.
[73] Id. at lines 126-140.
[74] Id. at lines 143-195.

Requests: The FDA provides several recommendations if a firm chooses to respond to a non-public unsolicited request for off-label information:

- Information distributed in response to an unsolicited request should be provided only to the individual making the request directly to the firm as a private, one-on-one communication.
- Information distributed in response to an unsolicited request should be tailored to answer only the specific question(s) asked.
- Information distributed in response to an unsolicited request should be truthful, non-misleading, accurate, and balanced.
- Information distributed in response to an unsolicited request should be scientific in nature.
- Responses to unsolicited requests for information should be generated by medical or scientific personnel independent from sales or marketing departments.
- Information distributed in response to an unsolicited request should be accompanied by the following:
    - A copy of the FDA-sanctioned drug PI instructions for use
    - A prominent statement that the FDA has not approved the product as safe and effective for the use addressed in the materials provided
    - A prominent statement disclosing the indication(s) for which the FDA has approved or cleared the product
    - A prominent statement providing all important safety information including, if applicable, any boxed warning for the product
    - A complete list of references for all information disseminated in response
- A firm should maintain the following records:
    - The nature of the request for information, including the name, address and affiliation of the requestor
    - Records regarding the information provided to the requestor
    - Any follow-up inquiries or questions from the requestor[75]

Responding to Public Unsolicited Requests: The FDA recognizes that it is often in the best interest of public health for the firm to respond to unsolicited requests for information about off-label uses of the firm's products that are made in public forums because the company is likely to have the most

[75] Id. at lines 233-327.

accurate and up-to-date medical product information.[76] However, the FDA is also concerned that firms may post detailed public online responses to questions about off-label uses of their products in such a way that they are communicating unapproved use information to individuals who have not requested such information; in short, the communication becomes promotional.[77]

The FDA makes the following recommendations for a firm that chooses to respond to public unsolicited requests for off-label information about its product:

- The firm should respond only when the request pertains specifically to its own named product (and is not solely about a competitor's product).
- A firm's public response to public unsolicited requests for off-label information about its named product should be limited to providing the firm's contact information and should not include any off-label information.
- Representatives who provide public responses to unsolicited requests for off-label information should clearly disclose their involvement with a particular firm.
- Public responses to public unsolicited requests for off-label information should not be promotional in nature or tone.[78]

Dissemination of Reprints

In January 2009, the FDA published a guidance entitled "Guidance for Industry: Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices" ("Good Reprint Practices Guidance").[79] The Good Reprint Practices Guidance provides principles intended to create a safe harbor, allowing

[76] Id. at lines 353-358.
[77] Id. at lines 360-369.
[78] Id. at lines 375-445.
[79] Guidance for Industry: Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices (January 2009), http://www.fda.gov/oc/op/goodreprint.html.

manufacturers to distribute medical and scientific information that discuss unapproved "off-label" uses of drugs and medical devices.[80]

The Good Reprint Practices Guidance describes the types of scientific publication appropriate for dissemination and further describes the manner in which the article discussing the unapproved uses may be distributed to healthcare professionals and healthcare entities. Any article intended for dissemination should:

- be published by an organization with an editorial board that uses experts who have demonstrated expertise in the subject of the article under review by the organization and who are independent of the organization to review and objectively select, reject or provide comments about proposed articles, and that has a publicly stated policy, to which the organization adheres, of full disclosure of any conflict of interest or biases for all authors, contributors, or editors associated with the journal or organization;
- be peer-reviewed and published in accordance with the peer-review procedures of the organization; and
- not be in the form of a special supplement or publication that has been funded in whole or in part by one or more of the manufacturers of the product that is the subject of the article.[81]

Additionally, if the manufacturer distributes a scientific or medical reference publication, the publication should not be:

- primarily distributed by a manufacturer, but should be generally available in bookstores or other independent distribution channels where medical textbooks or periodicals are sold;

[80] Section 401 of the FDAMA (FDCA § 551; 21 U.S.C. § 360aaa) described certain conditions under which a drug or medical device manufacturer could choose to disseminate medical and scientific information discussing unapproved uses of approved drugs and cleared or approved medical devices to healthcare professionals and certain other entities. If these conditions were met, dissemination of reprints would not be evidence of the manufacturer's intent to promote the product for an unlawful, unapproved use. The FDA promulgated regulations implementing the statutory requirements in 21 C.F.R. Part 99. The statutory authority, however, ceased to be effective on 30 September 2006, and the implementing regulations were no longer applicable. FDA issued the Good Reprint Practices Guidance to provide continuing guidance to industry.

[81] See Good Reprint Practices Guidance.

- written, edited, excerpted or published specifically for, or at the request of, a manufacturer; or
- edited or significantly influenced by a manufacturer or any individuals having a financial relationship with the manufacturer.[82]

The information provided in the reprint should address adequate and well-controlled clinical investigations. The information must not be false or misleading or pose a significant risk to the public health.

The Good Reprint Practices Guidance further describes how the manufacturer may disseminate the scientific or medical information about an off-label use. The article or publication should:

- be an unabridged reprint or copy;
- not be marked, highlighted, summarized or characterized by the manufacturer in any way;
- be accompanied by the product's approved PI;
- be accompanied by a comprehensive bibliography, if it exists;
- where it exists, be disseminated with a representative publication that reaches different conclusions regarding the unapproved use; and
- be distributed separately from information that is promotional in nature.[83]

Questions should be referred to the medical/scientific officer or department within the company and that individual or department should be separate from the sales and/or marketing departments.

The scientific or medical information should also be accompanied by a prominently displayed and permanently affixed statement disclosing:

- that the uses are unapproved;
- the manufacturer's interest in the product;
- information about any author's affiliation, if known, and the nature and amount of any financial interest or compensation any author has in the product or manufacturer;
- any person known to the manufacturer who has provided funding for the study; and

[82] See id.
[83] See id.

- all significant risks or safety concerns known to the manufacturer concerning the unapproved use that are not discussed in the journal article or reference text.[84]

Industry-Supported Educational Activities

Manufacturers frequently provide monetary and other support for educational and scientific activities. These events may include discussion of unapproved uses of approved products which would otherwise violate the FDCA. In the Final Guidance on Industry-Supported Scientific and Educational Activities, the FDA advises on how a company may provide financial support to continuing medical education ("CME") and other scientific and educational programs without running afoul of the FDCA.[85] The agency states that it will not regulate "under the labeling and advertising provisions of the act, industry-supported scientific and educational activities that are independent of the influence of the supporting company."[86]

In determining whether an activity is independent of the substantive influence of a company, the agency has identified 12 factors to consider in deciding whether the company has transformed an ostensibly independent program into a promotional vehicle. These factors include the following:

1. The extent to which the company has control of the content and the selection of presenters and moderators
2. Whether there was meaningful disclosure, at the time of the program, to the audience of the relationship between the company and the program
3. Whether the intent of the company and the provider is to produce an independent and non-promotional activity that is focused on educational content and free from commercial influence or bias
4. Whether there are legal, business, or other relationships between the company and the provider of the program that could place the company in a position whereby it may exert influence over the content of the activity
5. Whether individuals employed by the provider of the program and involved in designing or conducting scientific or educational activities

[84] See id.
[85] Final Guidance on Industry-Supported Scientific and Educational Activities; Notice. 62 Fed. Reg. 64,074 (December 3, 1997), http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125602.pdf.
[86] 62 Fed. Reg. at 64,096.

are also involved in advising or otherwise assisting the company with respect to sales or marketing of the company's product
6. Whether the program provider has a history of conducting programs that fail to meet standards of independence, balance, objectivity, or scientific rigor when putting on ostensibly independent educational programs
7. Whether multiple presentations of the same program are held
8. Whether invitations or mailing lists for supported activities are generated by the sales or marketing departments of the supporting company, or are intended to reflect sales or marketing goals
9. Whether there was an opportunity for meaningful discussion or questioning provided during the program
10. Whether information about the supporting company's product presented in the scientific or educational activity is further disseminated after the initial program, by or at the behest of the company, other than in response to an unsolicited request or through an independent provider
11. Whether there are promotional activities, such as presentations by sales representatives or promotional exhibits, taking place in the meeting room
12. Whether any complaints have been raised by the program provider, presenters, or attendees regarding attempts by the supporting company to influence content[87]

The FDA notes that "[o]ne means of documenting the measures taken to ensure independence of an activity is to have a written agreement between the [program] provider and the supporting company. This document should reflect that the provider will be solely responsible for designing and conducting the activity, and that the activity will be educational, nonpromotional, and free from commercial bias. While not required, a written agreement, coupled with the factors described above, can provide valuable evidence as to whether an activity is independent and nonpromotional."[88]

The above factors are "provided to furnish guidance on the design and conduct of such activities, so that they will be educational and nonpromotional in nature."[89] No single factor, by itself, is likely to stimulate

[87] 62 Fed. Reg. at 64,097-099.
[88] 62 Fed. Reg. at 64,099.
[89] 62 Fed. Reg. at 64,096.

an action based on lack of independence. The list of factors "is not intended to be exhaustive and other factors may be appropriate for consideration in a particular case."[90]

Dissemination of Information About Investigational Drugs and Devices

Drug Products: Investigational new drugs — products that are not subject to any FDA approval and approved drugs for new, unapproved indications — may not be promoted at all.[91] However, this prohibition "is not intended to restrict the full exchange of scientific information concerning the drug, including dissemination of scientific findings in scientific or lay media. Rather, its intent is to restrict promotional claims of safety or effectiveness of the drug for a use for which it is under investigation and to preclude commercialization of the drug before it is approved for commercial distribution."[92]

Medical Devices: FDA's investigational device exemption ("IDE") regulations place restrictions on the promotion of devices that are the subject of a clinical investigation or research involving one or more human subjects to determine the device's safety or effectiveness ("investigational device").[93] The principal restriction is that the device may not be promoted or commercialized until after the FDA has approved or cleared the device for commercial distribution.[94] This means, *inter alia*, that sponsors, investigators or persons acting for or on behalf of a sponsor or investigator may not: promote or test market an investigational device until after the FDA has approved or cleared the device for commercial distribution; commercialize an investigational device by charging the subjects or investigators a higher price than that necessary to recover costs of manufacture, research, development and handling; unduly prolong an investigation; or represent that an investigational device is safe or effective.[95] Among others, the following practices are considered to be improper commercialization of investigational devices: enrolling excess investigators or patients in an investigational study; orchestrating undirected mass mailings about an investigational device; and giving volume discounts on an investigational device.

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[90] 62 Fed. Reg. at 64,099.
[91] 21 C.F.R. § 312.7(a).
[92] Id.
[93] 21 C.F.R. Part 812.
[94] 21 C.F.R. § 812.7.
[95] Id.

However, a clinical investigation or research sponsor may solicit for investigators and research subjects to participate in a study. Advertisements should be reviewed and approved by the Institutional Review Board. Advertisements may not claim that the device is safe or effective for the purposes under investigation or that the test article is known to be equivalent or superior to any other device, among other things.[96]

Devices With a Pending 510(k) Clearance

Generally, it is a violation of the FDCA to promote devices that have not been the subject of a 510(k) clearance.[97] However, by policy, the FDA allows promotional advertising and display of a 510(k) device where the device is the subject of a pending 510(k) submission.[98] However, this policy does not provide specific guidance as to what types of pre-510(k) promotional activities are permissible. Rather, it simply says: "Although a firm may advertise or display a device that is the subject of a pending 510(k) — in the hope that FDA will conclude that the device is substantially equivalent to a pre-amendments device — a firm may not take orders, or be prepared to take orders, that might result in contracts for sale for the device unless limited to research or investigational use."[99]

Although the FDA has not issued any formal guidance on the subject, some of the most important basic elements of FDA's more recent pre-510(k) promotion policies are listed below. These elements apply regardless of the type of promotion, e.g., trade show, written materials, verbal statements or website display.

- It is not permissible to give away units.
- It is not permissible to solicit or take orders.
- The FDA does not require that display or promotion of the device be qualified by a disclaimer that a 510(k) is pending for the product and that it is not available for sale in the US. However, it would be prudent to include such a disclaimer nonetheless as it can minimize the chance that the firm would mistakenly be viewed as actually taking orders or being prepared to take orders for the 510(k)-pending product. In addition, such a disclaimer could also provide truthful "balance" to the

[96] Guidance for Industry and FDA Staff: Preparing Notices of Availability of Investigational Medical Devices and for Recruiting Study Subjects (March 19, 1999).
[97] FDCA § 502(o); 21 U.S.C. § 352(o).
[98] See FDA Compliance Policy Guide (CPG) 300.600.
[99] Id.

promotion, letting the target audience know the current US marketing status of the device.

- 510(k)-pending products should not be promoted as "breakthrough."

It is important to note that this policy only applies to promotion of: a new device with a pending 510(k); and a commercially available device where a 510(k) is pending for a design modification.

The policy does not protect promotion of an unapproved use of a commercially available device, if no design modification is required for the new use (even if a 510(k) is pending). In addition, it does not apply to the promotion of a device that needs 510(k) clearance but that is not the subject of a pending 510(k) submission. Rather, the policy only applies to the promotion of unapproved devices with pending 510(k) submissions.

Direct-to-Consumer Advertising

Direct-to-Consumer Drug Advertising

In recent years, considerable attention has been focused on DTC broadcast prescription drug advertising, especially television advertising. There are numerous requirements that are very specific to this medium and so are discussed separately here.

FDA regulations state: "Advertisements broadcast through media such as radio, television, or telephone communications systems shall include information relating to the major side effects and contraindications of the advertised drugs in the audio or audio and visual parts of the presentation and unless adequate provision is made for dissemination of the approved or permitted package labeling in connection with the broadcast presentation shall contain a brief summary of all necessary information related to side effects and contraindications."[100]

Thus, there are three relevant requirements for broadcast advertising:

- The advertisement must include the product's most important risk-related information in the audio or audio and visual parts of the advertisement. This requirement is referred to as the "major statement."

[100] 21 C.F.R. § 202.1(e)(1).

- The broadcast advertisement must contain either a brief summary of the advertised product's risk information or, alternatively, make adequate provision for disseminating the product's approved labeling in connection with the advertisement. Because the brief summary would involve presenting "all necessary information related to side effect and contraindications in the body of the ad, broadcast advertisers opt for the adequate provision of the drug's PI instead. [101]
- In the FDAAA, Congress granted FDA the authority to require "pre-dissemination review" of television advertisement for a prescription drug.[102]

Major Statement

In the broadcast advertisement, the "major statement must include all of the most important risk information related to the product."[103] In television advertising, the major statement must be present in both the audio and visual parts of the advertisement. The major statement for radio and television advertisements "shall be presented in a clear, conspicuous and neutral manner."[104]

The FDA proposed a rule defining what constitutes an adequate "major statement."[105] The proposed rule would require, as under current standards, that advertisements broadcast through radio, television, or telephone communications systems include information relating to the major side effects and contraindications of the advertised drug in the audio or audio and visual parts of the presentation. The rule, if finalized, would provide that a major statement is clear, conspicuous, and neutral if:

- information is presented in language that is readily understandable by consumers;

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[101] These requirements are in addition to those already discussed, e.g., that any prescription drug promotion must be truthful, not misleading, consistent with the approved PI, and fairly balanced with adequate presentation of risk and benefit information.
[102] An additional provision still under review at FDA would also require the body of a DTC broadcast advertisement to include information regarding how to report adverse and side effects to FDA. See 73 Fed. Reg. 72,058 (November 26, 2008).
[103] OPDP Frequently Asked Questions, http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm090308.htm.
[104] 21 U.S.C. § 352(n).
[105] 75 Fed. Reg. 15,376 (Mar. 29, 2010).

- audio information is understandable in terms of the volume, articulation and pacing used;
- textual information is placed appropriately and is presented against a contrasting background for sufficient duration and in a size and style of font that allows the information to be read easily; and
- the advertisement does not include distracting representations (including statements, text, images or sounds, or any combination thereof) that detract from the communication of the major statement.[106]

While the rule is not final, it provides insight on the FDA's expectation of a compliant "major statement" in a prescription drug broadcast advertisements.

Adequate Provision

FDA regulations and guidance mandate that prescription drug broadcast advertisers make "adequate provision" for the consumer to obtain a copy of the advertised drug's PI. The FDA describes the elements of that adequate provision in Guidance for Industry – Consumer-Directed Broadcast Advertisements (August 1999) (Broadcast Guidance).[107] "Adequate provision" of the availability of the PI includes disclosure in the broadcast advertisement of the following:

- A toll-free number; upon calling, consumers should be given the choice of: having the PI mailed to them in a timely manner (e.g., within two business days for receipt generally within four to six days of mailing); or having the PI read to them over the phone (e.g., by offering consumers a selection of prerecorded labeling topics.)
- A concurrently running print advertisement with product information
- internet web page (URL) address with product information
- Healthcare professionals who could provide a copy of the PI[108]

Pre-Dissemination Review

The FDAAA gave the FDA the authority to "require the submission of any television advertisement for a drug . . . not later than 45 days before

[106] 75 Fed. Reg. at 15,387.
[107] Guidance for Industry – Consumer-Directed Broadcast Advertisements (August 1999) (Broadcast Guidance), http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125064.pdf.
[108] Broadcast Guidance at 2-3.

dissemination of the television advertisement."[109] In conducting a review of a television advertisement, the FDA may make recommendations with respect to information included in the label of the drug:

- On changes that are: necessary to protect the consumer good and well-being; or consistent with prescribing information for the product under review.
- If appropriate and if information exists, on statements for inclusion in the advertisement to address the specific efficacy of the drug as it relates to specific population groups, including elderly populations, children, and racial and ethnic minorities.[110]

Pursuant to this authority, the FDA issued a Draft Guidance for Industry: Direct-to-Consumer Television Advertisements – FDAAA DTC Television Ad Pre-Dissemination Review Program (March 2012) ("Pre-Dissemination Review Draft Guidance").[111] The FDA intends to require sponsors to submit television advertisements for pre-dissemination review in the categories listed below.

- Category 1: The initial television advertisement for any prescription drug or the initial television advertisement for a new or expanded approved indication for any prescription drug
- Category 2: All television advertisements for prescription drugs subject to a Risk Evaluation and Mitigation Strategy ("REMS") with elements to assure safe use
- Category 3: All television advertisements for Schedule II controlled substances
- Category 4: The first television advertisement for a prescription drug following a safety labeling update that affects the Boxed Warning, Contraindications, or Warnings & Precautions section of its labeling
- Category 5: The first television advertisement for a prescription drug following the receipt by the sponsor of an enforcement letter for that product that either cites a television advertisement or causes a television advertisement to be discontinued because the television

[109] 21 U.S.C. § 353b(a).
[110] 21 U.S.C. § 353b(b)(1) and (2).
[111] Draft Guidance for Industry: Direct-to-Consumer Television Advertisements – FDAAA DTC Television Ad Pre-Dissemination Review Program (March 2012), http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm29554.pdf

advertisement contained violations similar to the ones cited in the enforcement letter

- Category 6: Any television advertisement that is otherwise identified by FDA as subject to the pre-dissemination review provision[112]

The FDA intends to notify drug sponsors who must submit their television advertisements for pre-dissemination review.[113] Failure to comply with the pre-dissemination review carries enforcement consequences. Failure to comply with the pre-dissemination review is a "prohibited act" under the FDCA, which can be enjoined and subject the advertiser to criminal and civil monetary penalties.[114]

Direct-to-Consumer Medical Device Advertising

As discussed above, the advertisement of restricted devices falls within FDA's statutory authority while the advertising of non-restricted devices falls largely under authority of the FTC. Under the FDCA,[115] manufacturers, packers and distributors who advertise restricted devices distributed or offered for sale in the US are required to include "a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications" ("brief statement") in advertisements for these devices.

Consumer advertising of restricted devices, especially information relating to a device's intended uses, limitations, warnings, precautions, side effects, and contraindications should be presented using consumer-friendly language. Discussions of risk should be presented in a balanced manner. For these reasons, in the case of a restricted device, advertisements using technical jargon or terms understood only by experts would likely be subject to challenge on the grounds that the advertisement failed to provide an adequate "brief statement."

Pursuant to draft agency guidance, entities wishing to use consumer-directed broadcast advertisements may meet the brief statement requirement through an approach that: discloses the most serious and the most common risks associated with the "restricted" device in either the audio or audio/visual parts of the presentation; and makes adequate provision for dissemination of

[112] Pre-Dissemination Review Draft Guidance at lines 63-78.
[113] Id. at lines 161-173.
[114] Id. at lines 280-317.
[115] FDCA § 502(r)(2); 21 U.S.C. 352(r)(2).

the approved or permitted package labeling in connection with the broadcast presentation.[116] According to the FDA, "adequate provision" means that the chosen method will allow most of a potentially diverse audience to have reasonably convenient access to the advertised device's labeling, including many persons with limited access to technologically sophisticated outlets (e.g., the internet) and persons who are uncomfortable actively requesting additional device information or are concerned about being personally identified in their search for device information.[117]

Exempt Communications

Generally speaking, for the FDA to assert regulatory authority over prescription drug or restricted device promotion, the drug or device must be identified (expressly or by implication) and there must be something communicated about the product. When only one of these two elements exists in a promotional item, it is not considered to be promotional and is not regulated by the FDA. As a consequence, there exist certain categories of company-sponsored communications that are exempt from the FDA's labeling and advertising requirements. Such communications do not need to be fairly balanced and do not need to be accompanied by a brief summary (if advertising) or a PI (for drug promotional labeling).

Help-Seeking and Disease Awareness Communications: The FDA has explained certain categories of messages that are exempt from its labeling and promotion requirements in a Draft Guidance for Industry: "Help-Seeking" and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms (January 2004).[118] Help-seeking and disease awareness communications are exempt from the FDA's labeling and promotion requirements. These types of messages:

- discuss a disease or health condition;
- if aimed at consumers, include "see your doctor";
- if aimed at healthcare practitioners, encourage awareness of disease;

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[116] See Draft Guidance for Industry and FDA: Consumer-Directed Broadcast Advertising of Restricted Devices (10 February 2004).
[117] Id.
[118] Draft Guidance for Industry: "Help-Seeking" and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms (January 2004), http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/
UCM070068.pdf.

- do not mention a particular drug or device; and
- do not include any representation or suggestion relating to a particular drug or device.[119]

However, if the product is the only drug/device in its class, the promotion may be unlawful even if the drug/device is not identified by name.[120]

Drug Product Reminder Messages: Reminder labeling and advertising are exempt from FDA promotional requirements. Reminder messages call attention to the name of the product; and do not include any information about indications, dosage, use, or make any other representation about the drug.[121]

A reminder message includes only the drug name. Reminder messages are not permitted for drugs with "boxed warnings" in their PIs.[122] A drug with a boxed warning must be accompanied by, at a minimum, the PI.

The FDA cautions against presenting a communication in which a reminder communication is combined with a disease awareness communication in such a way that it causes the audience to perceive the two pieces as one advertisement or promotional labeling piece.[123] Doing so will cause the agency to treat the two seemingly exempt communications as one full product promotion, thereby triggering FDA requirements, including fair balance, adequate presentation of risk information and accompanying information. The FDA recommends that manufacturers "ensure that their disease awareness communications and reminder promotional pieces or product claim promotional pieces are sufficiently distinctive in terms of their thematic, graphic, visual and other presentation elements so that they will not be perceived as a single promotional piece that includes both a product name and a use, and is thus subject to the requirements for "labeling" or "advertising" mandated by the act and regulations."[124]

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[119] Exempt Communications Draft Guidance at lines 94-107.
[120] See April 21, 2010 Warning Letter http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCcompanies/ucm259229.htm.
[121] 21 CFR § 200.200, § 201.100(f), § 202.1(e)(2)(i).
[122] 21 CFR § 200.200, § 201.100(f), § 202.1(e)(2)(i).
[123] Exempt Communications Draft Guidance at lines 180-187.
[124] Id. at lines 248-253.

Under long practice and a 1994 guidance (no longer available on the FDA website), it is permissible for a company expecting approval of a new drug to run "Coming Soon — DRUG NAME" promotions. However, the communication which the FDA characterizes as a reminder may not contain any other information about the drug, such as its intended use. Furthermore, "Coming Soon" communications are not permitted for drugs with boxed warnings.[125]

Institutional Promotion: Institutional promotions are about the company itself, its research interests and its expertise. Institutional promotions may identify areas in which the company is conducting research, but in order to be exempt from FDA requirements, they may not identify a drug or device by name.[126]

Under long practice and a 1994 guidance (no longer available on the FDA website) with drugs that are soon coming to market, the FDA permits a manufacturer to use either a "Coming Soon" reminder campaign or an institutional campaign, but not both. The two may not be combined and, as stated above, if it is anticipated that the drug will have a boxed warning, the manufacturer is limited to institutional communications and may not use "Coming Soon" communications for its drug.

Other Communications Activities

As a general matter, the FDA's requirements regarding other manufacturer-sponsored communications about FDA-regulated articles are the same regardless of the medium or context, and the same rules will apply. The communication must be:

- truthful, not misleading;
- fairly balanced, with adequate disclosure of risk information;
- accompanied by and consistent with the PI, if it exists, for a drug product;[127] or

[125] See, e.g., example of "Coming Soon" advertisement in FDA presentation, http://www.fda.gov/downloads/Drugs/NewsEvents/ UCM182603.pdf.
[126] See, e.g., example of "Institutional" advertisement in FDA presentation, http://www.fda.gov/downloads/Drugs/NewsEvents/ UCM182603.pdf.
[127] It is assumed that most other communications activities a company employs, other than communications in broadcast, newspapers, journals and magazines, are all promotional labeling, not advertising. As discussed above, prescription drug advertising is a limited category of communications which must be accompanied by a

- consistent with the device's cleared/approved indications for use(s), for a medical device.

Some of these other, alternative communications are discussed below.

Comparative Claims

Drug Comparative Claims: Comparative claims that one prescription drug is superior to another on some parameter are a frequent area of FDA enforcement. All comparative claims must be supported by substantial clinical evidence.[128] However, the FDCA provides greater flexibility for the provision of "health care economic information" to formularies and other entities responsible for selecting drugs for managed care and other similar organizations.[129] Healthcare economic claims must be supported by "competent and reliable scientific evidence" and relate to the drug's approved indications.[130] Healthcare economic information provided to formularies need not comply with the general requirements applicable to promotional labeling and advertising, e.g., fair balance and inclusion of the PI.[131]

Medical Device Comparative Claims: FDA's regulations state that, "[a]mong representations in the labeling of a device which render such device misbranded is a false or misleading representation with respect to another device or a drug or food or cosmetic."[132] Comparative claims can be expressed; for example, as "Our product is safer and/or more effective than another brand of product." Comparative claims can also be implied, which tend to be vague assertions of superiority over another product.

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brief summary which may be, but is not necessarily, the full PI. All other communications are promotional labeling and must be accompanied by the full PI.

[128] A promotion is false, lacking in fair balance, or otherwise misleading if it contains a representation or comparison that a drug is better, more effective, useful in a broader range of conditions, or that patients are safer, have fewer, or less incidence of, or less serious side effects or contraindications than has been demonstrated by substantial evidence or substantial clinical experience. 21 C.F.R. § 202.1(e)(6)(i)-(ii).

[129] "Health care economic information" is defined as "any analysis that identifies, measures, or compares the economic consequences, including the costs of the represented health outcomes, of the use of a drug to the use of another drug, to another health care intervention, or to no intervention." 21 U.S.C. § 352(a).

[130] 21 U.S.C. § 352(a).

[131] Id. ("The requirements set forth in section 355(a) of this title [drugs] or in section 262(a) of title 42 [biologics] shall not apply to health care economic information provided to such a committee or entity in accordance with this paragraph").

[132] 21 C.F.R. § 801.6.

The FDA tends to more closely scrutinize advertising or promotional materials that compare one device with another because the agency considers these to more likely be misleading. For example, the FDA expects comparative claims to be supported by reliable scientific data, which may include a study that directly compares the products. Any study discussion must point out the positive and negative data from the study.

The FTC requires sufficient substantiation of claims made in medical device advertising. Comparative claims may need to be supported by balanced, scientific clinical studies or other controlled "head-to-head" analyses that support claims of superiority. Also, comparative advertising should not involve discussions or comparisons of a competitor's device with respect to uses for which the competitor's product is not intended, cleared or approved.

Press Releases

The FDA asserts regulatory authority over company press releases. If a company press release identifies a drug or device product, the FDA can treat such communications as promotional labeling. As such, product-specific press releases should otherwise meet FDA's requirements discussed above.

Press releases may discuss development of new drugs and approved drugs for new unapproved indications. The FDA permits "the full exchange of scientific information concerning the drug, including dissemination of scientific findings in scientific or lay media."[133] Press releases, however, should not suggest that the product is safe or effective for the new use.[134] Press releases discussing clinical results should factually present the information and not characterize the clinical results.

Coupons, Vouchers, Samples and Other Remuneration

FDA regulation of manufacturer-sponsored offers, whether to patients or healthcare professionals, like all manufacturer-sponsored communications, must be truthful, not misleading, consistent with the FDA-sanctioned indications for use, and fairly balanced. Coupons, vouchers and other offers for prescription drugs are treated as reminder communications exempt from FDA requirements if they mention only the drug name and are not for a drug that bears a boxed warning.[135] Drug companies also provide healthcare

[133] 21 C.F.R. § 312.7(a).
[134] Id.
[135] 21 CFR § 200.200, § 201.100(f), § 202.1(e)(2)(i). See discussion of reminder promotions above.

professionals and patients with materials that have drug logos and names on them, such as magnets, pens, office equipment and prescription pads. These are also treated as reminder pieces.

The Prescription Drug Marketing Act ("PDMA") of 1988 amended the FDCA to, among other things, establish requirements for the distribution of prescription drug samples. The FDCA prohibits the distribution of a drug sample except by the manufacturer or an authorized distributor of record.[136] The FDA also issued implementing regulations regarding the distribution of samples.[137] The regulations set forth various recordkeeping and other requirements for the distribution of prescription drug samples to healthcare practitioners.

Additionally, the Affordable Care Act included a new provision requiring the annual submission of certain drug sample information to the FDA, including the identity and quantity of drug samples requested, and the identity and quantity of drug samples distributed.[138] The FDA issued a draft guidance on the implementation of these requirements in April 2012.[139] Further information concerning the distribution of prescription drug samples is beyond the scope of this chapter.

Apart from FDA regulatory requirements, coupons, vouchers, samples, gifts and other remuneration to healthcare professionals, as well as expenses to promote products to consumers and healthcare professionals, are governed by numerous federal laws, including the Anti-Kickback Statute,[140] the False Claims Act,[141] and the Physician Payment "Sunshine" reporting provisions of the Affordable Care Act.[142] Many states also regulate samples and prescription drug promotion, and require reporting of or ban gifts and other items of value to healthcare professionals.[143]

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[136] 21 U.S.C. § 353(d).
[137] 21 C.F.R. Part 203, Subpart D.
[138] 42 U.S.C. 1320a-7i.
[139] Draft Guidance for Industry: Compliance Policy on Reporting Drug Sample Distribution Information (April 2012), http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM297848.pdf.
[140] 42 U.S.C. § 1320a-7b.
[141] 31 U.S.C. §§ 3729 et seq.
[142] 42 U.S.C. § 1320a-7h.
[143] 18 V.S.A. § 4631a; 18 V.S.A. § 4632 (Vermont law on gift bans and reporting of samples and promotional expenditures); MASS. GEN. LAWS ANN. ch. 175H, § 3

CE Mark and Medical Devices

Marketing of drugs and medical devices without the CE mark is not prohibited in the US as long as the applicable FDA requirements are satisfied. Conversely, bearing the CE mark does not eliminate the need for compliance with FDA requirements. However, because the requirements for obtaining the CE mark are similar to FDA requirements in many respects, having the CE mark would be helpful in meeting the FDA requirements.

Before and After Images

While there are no specific requirements applicable to the use of "before and after" images in labeling and advertising, this practice may be subject to higher scrutiny as to whether such images are false and misleading.

Product Testimonials

Promotional labeling or advertising using testimonials is acceptable in general. However, such testimonials may be scrutinized to ensure that they are not false or misleading and do not suggest an unapproved use. The advertiser may not use a testimonial to make claims it could not otherwise make in the absence of a testimonial. Pursuant to FTC guidance, advertisements containing testimonials must reflect honest opinions, findings and beliefs of the endorser.[144] Expert testimonials must be made by individuals with appropriate credentials and experience and must be supported by an appropriate investigation by the expert.[145]

Internet and Social Media

The FDA requirements for the labeling and promotion of FDA-regulated products were developed prior to the internet. However, the FDA has taken the position that the requirements applicable to print advertisements in journals and newspapers and printed promotional labeling apply to online media as well.

Furthermore, the same FDA requirements apply regardless of the space and characters available, such as on a Facebook page, sponsored link from an

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(Massachusetts limits upon co-pay assistance and other discounts for purchase of certain prescription drugs); MASS. GEN. LAWS ANN. ch. 111N (Massachusetts code of conduct for pharmaceutical and medical device manufacturers).

[144] 16 C.F.R. §§ 255.0-255.5.

[145] 16 C.F.R. § 255.3.

internet search engine, microblogging site such as Twitter, or website "widget." If the company's sponsored message identifies the FDA-regulated article by name and makes any representation about it, the normally applicable requirements for a drug or device product otherwise apply to the message.

In April 2009, the FDA sent Notice of Violation Letters to 14 pharmaceutical manufacturers regarding their use of sponsored links. The enforcement letters were clear that manufacturers may not sponsor a hyperlink that identifies a drug by name and includes information about the disease the drug is intended to treat. Because the sponsored links included information about diseases and the drug name, the FDA deemed the sponsored links to be full product promotions, not reminders, that must include fairly balanced risk information (though the PI could be available via a link click-through).[146] The FDA took the same approach with a Facebook widget that permitted the sharing of content. The FDA sent a Notice of Violation letter to one global pharmaceutical company regarding a widget that made representations about the efficacy of drug, but failed to communicate any risk information.[147]

Consequences of Non-Compliance Under the FDCA

Under the FDCA, penalties for committing (or allegedly committing) a prohibited act relating to a drug or medical device can include the following.

Issuance of a Warning Letter or Untitled Letter

Using its administrative authority, the FDA can issue a firm a Warning Letter or an Untitled Letter (also referred to as a "Notice of Violation" or "NOV") in response to a firm's violative promotional activities. A Warning Letter is an FDA communication notifying an individual or firm that the agency considers one or more of its products, practices, processes or other activities to be in violation of the FDCA, and that failure of the responsible party to take appropriate action may result in administrative and/or regulatory

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[146] See, e.g., Notice of Violation Letters sent 2 April 2009 http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm055773.htm.

[147] July 29, 2010 Notice of Violation Letter http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM221325.pdf.

enforcement action without further notice.[148] An Untitled Letter is a way for the agency to communicate with a firm about violations that do not reach the same threshold of regulatory significance as violations that result in a Warning Letter.[149]

Seizure, Injunction, Criminal Prosecution and Civil Penalties

The FDA is authorized to take a number of actions in response to the actual or alleged commission of a prohibited act. If a firm fails to correct its violative activities, or if the violations in question are particularly serious, the FDA may utilize one or more of its main enforcement tools: seizure, injunction, criminal prosecution and civil penalties.

- Seizure: The FDA, through the US Attorney, can initiate a legal action in federal district court to seize and condemn allegedly violative products.[150] In addition, the FDA is authorized to administratively order the detention of a medical device for up to 30 days.[151] Administrative detention often precedes a seizure action in court.
- Injunction: The FDA, through the US Attorney, can initiate a legal action in federal district court to enjoin a drug or device firm and its officers from violating the FDCA, e.g., promoting and distributing allegedly violative drugs or medical devices.[152] The FDA is not required to demonstrate that the law has been broken in order to seek an injunction. It is only necessary to show that there is a likelihood that the law may be violated if an injunction is not entered. According to the FDA, an injunction should be considered for any significant "out of compliance" circumstance, but particularly when a health hazard related to the violation has been identified.[153] The FDA may consider an injunction to be appropriate when violations are pervasive and affect many different products.
- Criminal Prosecution: The FDA, through the US Attorney, can initiate criminal proceedings in federal district court against a drug or device firm and/or its officers for violating the FDCA. For misdemeanor violations, criminal intent is not required. An FDCA misdemeanor is punishable by incarceration for a maximum of one year, and a fine of

[148] FDA Office of Regulatory Affairs, Regulatory Procedures Manual, § 4-1.
[149] Id. at § 4-2.
[150] FDCA §304; 21 U.S.C. § 334.
[151] FDCA § 304(g); 21 U.S.C. § 334(g).
[152] FDCA § 302; 21 U.S.C. § 332.
[153] FDA Office of Regulatory Affairs, Regulatory Procedures Manual, § 6-2.

USD100,000 for an individual and USD200,000 for a corporation. FDCA felonies involve violations where there was "intent to defraud or mislead" or where the violation represents a repeat offense. An FDCA felony is punishable by incarceration for a maximum of three years, and a fine of USD250,000 for an individual and USD500,000 for a corporation.[154]

Under what has come to be known as the "Park Doctrine," company officers can be held personally responsible for FDCA violations in both criminal prosecution and civil monetary proceedings.[155] Courts have found that persons in management have an affirmative duty to ensure that FDA-regulated products are safe and effective. Executives of a company that violate the FDCA can be criminally prosecuted in federal court, even if they did not personally engage in, or ever know about, the activity. Courts have viewed such executives as being obligated to prevent and correct violative acts, and will hold them responsible.[156]

- Civil Penalties:
  - Drugs: The FDA does not have express statutory authority to obtain civil penalties for drug product misbranding. However, in the recent large settlements for off-label promotion of prescription drugs, drug companies have agreed to pay civil penalties and restitution to states and the federal government under the False Claims Act.[157] Additionally, a person who holds an FDA-approved application for a prescription drug or biologic and who disseminates or causes another party to disseminate a false or misleading DTC advertisement can be subject to civil penalties. The penalty for the first violation is up to USD250,000 in any three-year period, not to exceed USD500,000 for each subsequent violation in any three-year period.[158] Failure to comply with the pre-dissemination review of DTC television advertisements described above is a separate prohibited act under the FDCA that may be enjoined and subject to criminal penalties and fines.[159]

[154] FDCA § 303(a); 21 U.S.C. § 333(a) and 18 U.S.C. § 3571.
[155] See, e.g., U.S. v. Park, 421 U.S. 658 (1975).
[156] Id.
[157] 31 U.S.C. 3729 et seq.
[158] 21 U.S.C. § 333(g).
[159] 21 U.S.C. § 331(kk); 21 U.S.C. § 332(a); 21 U.S.C. § 333(a).

- Devices: In an administrative proceeding, the FDA can impose civil monetary penalties for FDCA violations related to medical devices. The maximum civil penalty for an individual or corporation is USD15,000 per violation, not to exceed USD1 million for all violations in a single proceeding.[160]

Other Generally-Applicable Administrative Enforcement Tools

In addition to its statutory authority, the FDA has several administrative enforcement tools at its disposal.

- Import Detentions and Refusals of Admission – The FDA can detain and refuse admission to devices for import which appear to violate the FDCA.[161]
- Voluntary Recalls – The FDA can attempt, through publicity or otherwise, to pressure a firm to conduct a voluntary recall where it views a device as violative under the FDCA.[162]
- Safety Communications – The FDA can attempt to pressure a firm to issue a public health notification regarding a drug or device or issue one itself.

Administrative Enforcement Tools Applicable to Medical Devices

As to medical devices, the FDA has a number of other administrative enforcement tools at its disposal:

- PMA Suspension and Withdrawal – On various grounds, the FDA can temporarily suspend and/or withdraw approval of a PMA application.[163]
- Banning a Device – In general, the FDA can ban a device which presents substantial deception or an unreasonable and substantial health risk.[164]
- Notification Orders – Where the FDA determines that: a device presents an unreasonable risk of substantial harm; notification is necessary to eliminate the risk; and no more practical means exist to eliminate such risk, the FDA may order that a party provide adequate

[160] FDCA § 303; 21 U.S.C. § 333.
[161] FDCA § 801; 21 U.S.C. § 381.
[162] See 21 C.F.R. Part 7 for guidelines on voluntary recalls.
[163] FDCA § 515(e); 21 U.S.C. § 360e(e).
[164] FDCA § 516; 21 U.S.C. § 360f and 21 C.F.R. Part 895.

notification of the risk to all healthcare professionals who prescribe or use the device and to any other person (including manufacturers, importers, distributors, retailers and device users) who should properly receive such notification in order to eliminate such risk.[165]

- IDE Withdrawal – After an opportunity for an informal hearing, the FDA may order the withdrawal of an IDE approval on various grounds.[166]
- CD&N Orders and Mandatory Recall – Where the agency finds there is a reasonable probability that a device would cause serious adverse health consequences or death, it can issue a "cease distribution and notification" (CD&N) order directing the appropriate person to immediately cease distribution of the device and immediately notify health professionals and device user facilities of the order, instructing them not to use the device.[167] Such orders provide for an informal hearing on whether the order should be amended to require a mandatory recall. If, after providing an opportunity for such a hearing, the FDA determines that inadequate grounds exist to support the actions required by the order, the agency is required to vacate the order. If, after providing an opportunity for an informal hearing, the agency determines that the order should be amended to include a recall of the device, the FDA must amend the order to require a recall.[168]

Professional Codes of Conduct

PhRMA Codes of Conduct

The Pharmaceutical Research and Manufacturers of America ("PhRMA"), the trade association representing research-based pharmaceutical and biotechnology companies, has adopted voluntary codes of conduct. Although the codes are not enforceable, individual companies may agree to adhere to one or both codes voluntarily. A company's agreement to comply with a code may also be written into contractual agreements with trading partners and, in the event of a separate enforcement action, become part of a corporate compliance agreement. In theory, legislators and regulators might codify the codes into law.

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[165] FDCA § 518(a); 21 U.S.C. § 360h(a).
[166] FDCA § 519(g)(5); 21 U.S.C. § 360j(g)(5) and 21 C.F.R. § 812.30.
[167] 21 U.S.C. § 360h(e); 21 C.F.R. Part 810.
[168] 21 C.F.R. § 810.13. FDA rarely exercises its mandatory recall authority, as firms typically agree to conduct a recall voluntary rather than incur the negative publicity associated with being ordered to recall defective product.

Two PhRMA codes of note are:

- PhRMA: Code of Interactions with Healthcare Professionals;[169] and
- PhRMA Guiding Principles: Direct to Consumer [DTC] Advertising about Prescription Medicines.[170]

Code of Interactions with Healthcare Professionals

PhRMA's Code of Interactions with Healthcare Professionals ("Healthcare Professionals Code") addresses how company representatives interact with healthcare professionals. Areas covered in the Code include the following:

- Presentations by company representatives and meals
- Entertainment, gifts, educational items and recreation
- Support for Continuing Medical Education and third-party educational meetings
- Consultants and speakers
- Speaker programs and training
- Company training[171]

PhRMA adopted its Healthcare Professionals Code in April 2002 and published revisions in July 2008. It states that interactions with healthcare professionals are critical to achieving these goals because they enable pharmaceutical and biotechnology companies to: inform healthcare professionals about the benefits and risks of products to help advance appropriate patient use; provide scientific and educational information; support medical research and education; and obtain feedback and advice about products through consultation with medical experts.[172]

Under PhRMA's Healthcare Professionals Code, items that primarily benefit patients may be offered to healthcare professionals if they are not of a

[169] PhRMA: Code On Interactions With Healthcare Professionals (July 2008), http://www.phrma.org/sites/default/files/108/phrma_marketing_code_2008.pdf ("PhRMA Healthcare Professionals Code").
[170] PhRMA Guiding Principles: Direct to Consumer Advertising about Prescription Medicines (December 2008), http://www.phrma.org/sites/default/files/106/phrma_guiding_principles_dec_08_final.pdf ("DTC Guiding Principles").
[171] PhRMA Healthcare Professionals Code.
[172] Id. at Preamble.

substantial value, i.e., USD100 or less.[173] Items intended for healthcare professionals' use "that do not advance disease or treatment education," however, even those that are practice-related items of minimal value (e.g., pens, note pads, mugs and other "reminder" items featuring product or company logos), should not be offered to healthcare professionals or staff, even when accompanied by patient- or physician-focused educational materials.[174] PhRMA supports this restriction because the practice "may foster misperceptions that company interactions with healthcare professionals are not based on informing them about medical and scientific issues."[175]

The Healthcare Professionals Code also suggests that manufacturers not provide entertainment and recreational activities for healthcare professionals, even if such activities are connected with presentations by medical experts or other seminars.[176] Pursuant to the PhRMA Code, "companies should not invite healthcare professionals to sporting events, concerts, or shows, or provide them with recreational activities such as hunting, fishing, boating, ski trips, or golf outings, even if those entertainment events or recreational activities are intended to facilitate informational exchanges between the company representative and the healthcare professional."[177]

Furthermore, pharmaceutical representatives may purchase modest meals for healthcare professionals if the purpose of the meal is to discuss information of scientific or educational value during the meal. Spouses or guests, however, should not be invited.[178] Nor should a representative "drop off" food to a healthcare provider, e.g., delivering dinner to a provider's staff that is to be consumed without a manufacturer's representative being present.[179]

In terms of sponsoring continuing medical education ("CME"), under the Healthcare Professionals Code, companies should separate CME-related grant-making functions from sales and marketing departments. Moreover, "financial support for CME is intended to support education on a full range of treatment options and not to promote a particular medicine."[180]

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[173] Id. at 12.
[174] Id. at 11.
[175] Id.
[176] Id. at 23.
[177] Id. at 25.
[178] Id. at 4-5.
[179] Id. at 5.
[180] Id. at 6.

Ultimately, the focus of any manufacturer-physician relationship should be on communicating scientific information to physicians for the benefit of patients.

PhRMA Guiding Principles: DTC Advertising about Prescription Medicines

PhRMA published its most recent set of Guiding Principles: Direct to Consumer ("DTC") Advertising about Prescription Medicines ("DTC Guiding Principles") in December 2008. The Code sets forth numerous core principles aimed at ensuring accurate and not misleading DTC information.

As a general matter, PhRMA notes that FDA requires that all DTC material should be accurate and not misleading, should make claims only when supported by substantial evidence, should reflect balance between risks and benefits, and should be consistent with FDA-approved labeling.[181] Working with the FDA, companies should continue to responsibly alter or discontinue a DTC advertising campaign should new and reliable information indicate a serious, previously unknown safety risk.[182]

Moreover, in order to foster responsible communication between patients and healthcare professionals, companies should spend an appropriate amount of time to educate health professionals about a new medicine or indication, and to alert them to the upcoming advertising campaign before commencing the first DTC advertising campaign.[183] Specifically, companies should submit all new DTC television advertisements to the FDA before releasing these advertisements for broadcast.[184] DTC print advertisements for prescription medicines should include FDA's toll-free MedWatch telephone number and website for reporting potential adverse events, and DTC television advertisements should direct patients to a print advertisement containing FDA's toll-free MedWatch telephone number and website, and/or should provide the company's toll-free telephone number.[185]

Companies that choose to feature actors in the roles of healthcare professionals in a DTC television or print advertisement that identifies a particular product should acknowledge in the advertisement that actors are being used. If actual healthcare professionals appear in such advertisements,

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[181] DTC Guiding Principles at 4.
[182] Id. at 6.
[183] Id.
[184] Id.
[185] Id.

the advertisement should include an acknowledgement if the healthcare professional is compensated for the appearance.[186] Furthermore, if a DTC television or print advertisement features a celebrity endorser, the endorsements should accurately reflect the opinions, findings, beliefs or experience of the endorser.[187]

DTC television and print advertising should include information about the availability of other options such as diet and lifestyle changes where appropriate.[188] The DTC Guiding Principles further provide that DTC television advertising that identifies a product by name should clearly state the health conditions for which the medicine is approved and the major risks associated with the medicine being advertised (i.e., no "reminder" television advertising that mentions only the drug name).[189]

Ultimately, DTC television and print advertising should be designed to achieve a balanced presentation of both the benefits and the risks. DTC television and print advertisements should be targeted to avoid audiences that are not age appropriate for the messages involved and the substance of relevant boxed warnings should be presented with reasonably comparable prominence to the benefit information.[190]

Finally, companies are encouraged to promote health and disease awareness as part of their DTC advertising.[191]

American Medical Association and Accreditation Council on Continuing Medical Education Codes

Manufacturers also should be aware of ethical constraints that may apply to healthcare professionals. Healthcare professionals who violate applicable ethical standards may be subject to disciplinary review or other penalties. For example, the American Medical Association ("AMA") ethical guidelines state that physicians:

- may properly accept gifts of insubstantial value that primarily entail a benefit to their patients;

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[186] Id.
[187] Id.
[188] Id. at 7.
[189] Id.
[190] Id.
[191] Id.

- should not accept gifts given by manufacturers to reward favorable prescribing practices;
- should not accept direct payments from manufacturers to defray CME program registration fees, or as compensation for personal expenses or time spent in attendance; and
- may accept modest meals and attend modest social events in connection with CME programs.[192]

With respect to CME, manufacturer-sponsorship may affect whether a seminar may receive industry accreditation from the Accreditation Council on Continuing Medical Education ("ACCME"). ACCME is a non-profit corporation created by a number of healthcare industry associations to promote standards for continuing education in the medical field. ACCME accreditation standards are generally consistent with FDA requirements for deeming industry-sponsored CME seminars to be independent of the sponsor, as described above. State law may allow physicians to count the CME programs of ACCME-accredited CME providers toward their state-mandated CME requirements. ACCME has issued standards regulating the manufacturer-CME provider relationship. These standards provide that:

- the CME provider may not allow a manufacturer to involve itself in the development of CME activities;
- after a CME program, the provider must ascertain from the audience whether bias was perceived, and if it was, the provider must take steps to prevent such biased presentations in the future;
- textbooks and journal articles disseminated by manufacturers at a CME program may not contain product-specific advertising or references and must disclose that they are manufacturer-provided materials;
- providers must disclose their (and their presenters') relationships with manufacturers; and
- presenters must warn the audience when a use being discussed lacks FDA approval.[193]

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[192] American Medical Association Code of Medical Ethics: Current Ethical Opinions, Opinion 8.061, http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion8061.page.

[193] See generally ACCME Accreditation Criteria (December 2011), http://www.accme.org/requirements/accreditation-requirements-cme-providers/accreditation-criteria; Standards for Commercial Support: Standards to Ensure Independence in CME Activities, http://www.accme.org/requirements/accreditation-requirements-cme-

Thus, PhRMA Code requirements and AdvaMed Code requirements (discussed below) relating to gifts and seminars largely comport with requirements that may apply to recipients and CME sponsors as well.

AdvaMed Code

The member companies of the Advanced Medical Technology Association ("AdvaMed") produce medical devices, diagnostic products and health information systems. Its members produce nearly 90 percent of the healthcare technology purchased annually in the United States and more than 50 percent purchased annually around the world. AdvaMed adopted a voluntary Code of Ethics ("AdvaMed Code"). The AdvaMed Code is intended to facilitate the members' ethical interactions with individuals or entities that purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe AdvaMed members' medical technology products in the United States.

Gifts to Healthcare Professionals: AdvaMed members may provide modest gifts to healthcare professionals that benefit patients or serve a genuine educational function. Such gifts should have a fair market value of less than USD100 unless they are textbooks or anatomical models used for educational purposes. The AdvaMed code prohibits the distribution of non-educational, branded promotional items even if the items are of minimal value and related to the healthcare professional's work or are for the benefit of patients (e.g., pens, notepads and mugs). Cash or cash equivalents may not be given as gifts.

Training and Education; Related Hospitality and Travel: AdvaMed members may provide training and education programs to healthcare professionals. Such programs should be conducted in clinical, educational, conference or other settings conducive to learning.

Where there are objective reasons to support the need for out-of-town travel to efficiently deliver appropriate training and education, members may pay for reasonable travel and modest lodging costs of the attending healthcare professionals. It is not appropriate to pay for the meals, refreshments, travel or other expenses for guests of healthcare professionals or for any other person who does not have a bona fide professional interest in the information being shared at the meeting.

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providers/standards-for-commercial-support; and Examples of Compliance and Noncompliance (April 2012), http://www.accme.org/requirements/accreditation-requirements-cme-providers/examples-compliance-noncompliance.

AdvaMed members may also support third-party educational conferences by providing educational grants directly to the conference sponsor to reduce conference costs or to a training institution to allow attendance of medical students, fellows, and other healthcare professionals in training. However, the faculty and attendees should be selected by an independent third-party and the conference sponsor should independently control and be responsible for the selection of program content, faculty, educational methods, and materials.

Research Grants: AdvaMed members may make research grants to support genuine medical research. In doing so, member companies are required to develop objective criteria for making grants, and implement procedures to ensure grants are not used as unlawful inducements. In addition, although sales personnel may provide input about the suitability of a proposed grant, sales personnel may not control or unduly influence the decision as to the recipient or the amount of the grant. The purpose of the grant should be well-documented.

Donations: AdvaMed members may make donations to charitable organizations or to individuals engaged in genuine charitable missions for support of that mission. An example of a permitted donation to individuals would be to those individuals who perform volunteer disaster relief abroad who are acting as independent volunteers and not under a not-for-profit charitable organization.

Donations should be properly documented. Donations may not be made for the purpose of unlawfully inducing the purchase, lease, recommendation or use, or arranging for the purchase, lease or prescription of a member's products. Member companies are also required to develop objective criteria for making donations, and implement procedures to ensure donations are not used as unlawful inducements. Likewise, although sales personnel may provide input about the suitability of a proposed charitable donation, sales personnel may not control or unduly influence the decision as to the recipient or the amount of the donation. Furthermore, donations may only be made to *bona fide* charitable organizations or in rare instances, to individuals engaged in genuine charitable activities for the support of a *bona fide* mission.

The provision of medical devices free of charge is not expressly permitted. A totality of circumstances analysis would be applied to the arrangement. The intent of the gift would also be considered.

Other Liability Under Federal Criminal and Civil Law

In addition to FDA requirements, promotional efforts relating to medical products may also be reviewed by the US Department of Health and Human Services' Office of the Inspector General ("OIG"), as well as the US Department of Justice ("DOJ") under various anti-kickback and anti-fraud statutes, including the Anti-Kickback Statute.[194] The Anti-Kickback Statute broadly prohibits the solicitation, receipt, offer, or payment of any remuneration for referring or furnishing any item or service for which payments may be made by a federal health program.[195] As discussed below, these requirements generally are intended to ensure that the federal government does not pay artificially-inflated prices for products covered by healthcare reimbursement programs such as Medicare and Medicaid, and that treatment decisions relating to services paid for under these programs are not influenced by offers of remuneration. Some federal and state laws apply more broadly to all arrangements and not just to those involving federal or state healthcare programs. Because many commonly accepted business practices in other industries may be viewed as suspect by the OIG and other federal and state law enforcement officials, manufacturers that promote pharmaceutical products in the US should carefully evaluate their marketing practices, lest they face potential scrutiny Although a detailed discussion of the Anti-Kickback Statute is beyond the scope of this handbook, the following section provides a brief summary of the statute and its enforcement.

Anti-Kickback Statute

The federal Anti-Kickback Statute[196] provides that:

(1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind —

[194] 42 U.S.C. § 1320a-7b(b).
[195] Id. While a complete description of federal healthcare payment programs is beyond the scope of this chapter, the Medicare and Medicaid programs, which cover healthcare services to elderly, disabled and low-income individuals, establish reimbursement rates applicable to the state and federal government based, in part, on price and sales data supplied by pharmaceutical manufacturers.
[196] 42 U.S.C. § 1320a-7b(b).

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a federal healthcare program, or
(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under federal healthcare program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than USD25,000 or imprisoned for not more than five years, or both.

(2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person —

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a federal healthcare program, or
(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a federal healthcare program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than USD25,000 or imprisoned for not more than five years, or both.

Thus, the Anti-Kickback Statute makes it a criminal offense to knowingly and willfully offer, pay, solicit or receive any remuneration to induce the purchase or recommendation to purchase items or services reimbursable by a federal healthcare program. As amended by the Patient Protection and Affordable Care Act ("PPACA"),[197] signed into law in 2010, the Anti-Kickback Statute provides that "a person need not have actual knowledge of [the Anti-Kickback Statute] or specific intent to commit a violation" thereof in order to be liable.[198] Also under amendments pursuant to the PPACA, any submitted claim that results from a referral made in violation of the Anti-

[197] Pub. L. 111-148, 124 Stat. 119 (2010).
[198] 42 U.S.C. § 1320a-7b(h).

Kickback Statute automatically "constitutes a false or fraudulent claim for purposes of" the FCA.[199]

Parties on both sides of an impermissible transaction are subject to criminal liability under the Anti-Kickback Statute. Violation of the statute constitutes a felony. Individuals who violate the Anti-Kickback Statute may be punished by a fine of up to USD250,000 under the Alternative Fines Act,[200] not more than five years imprisonment, or both. Organizations that violate the Anti-Kickback Statute are subject to fines of up to USD500,000 under the Alternative Fines Act.[201] Conviction under the Anti-Kickback Statute also leads to automatic exclusion from federal healthcare programs.[202] Exclusion is "permissive" for a provider is determined by the Secretary of Health and Human Services in an administrative proceeding to have committed an act that would violate the Anti-Kickback Statute.[203] Additionally, under certain circumstances, the OIG may also impose a civil monetary penalty of USD50,000 per violation, plus three times the remuneration paid.[204] Violations of the Anti-Kickback Statute may give rise to liability under many federal anti-fraud statutes, including, without limitation, the Federal False Claims Act ("FCA").[205] Violations of the FCA include, among other actions, the knowing use of, or deliberate ignorance or reckless disregard for the truth or falsity of, a false record or statement material to a false or fraudulent claim paid by the federal government.

The Anti-Kickback Statute is broad. Moreover, the term "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind. The statute has also been interpreted to cover an arrangement in which one purpose of the remuneration was for past referrals or to induce future referrals. At a minimum, therefore, the statute establishes the general principle that the referral of a government program patient or arranging for the referral of a government program patient, or the purchase, lease or order of a service or item covered by the government programs or arranging for the purchase, lease or order of a service or item covered by the government programs may not be the quid pro quo for any payment of money or other item of value. The term "federal healthcare program"

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[199] 42 U.S.C. § 1320a-7b(g).
[200] 18 U.S.C. § 3571.
[201] Id.
[202] 42 U.S.C. § 1320a-7(a)(1).
[203] 42 U.S.C. § 1320a-7(b)(7); 42 C.F.R. § 1001.951
[204] 42 U.S.C. § 1320a-7a(a)(7).
[205] 31 U.S.C. § 3728, et seq.

includes generally any plan or program that provides health benefits which is funded directly, in whole or in part, by the United States government, or any state healthcare program approved for or receiving federal funding.[206]

Because of the breadth of the Federal Anti-Kickback Statute, the OIG has promulgated the "Safe Harbor Regulations."[207] These safe harbors are intended to protect beneficial and innocuous payment and business practices among parties, including manufacturers and healthcare providers. The OIG requires that manufacturers and healthcare providers seeking to benefit from the protection of the safe harbor provisions demonstrate strict adherence to those provisions. To fit within any of the more than 20 safe harbors, including equipment rental, personal services and management contracts, discounts and bona fide employees, the arrangement must meet all of the criteria for that safe harbor. However, the failure of an arrangement to fit within a safe harbor does not necessarily mean that the arrangement violates the statute. Rather, a traditional analysis of the federal Anti-Kickback Statute would be necessary to determine whether any activity that does not fit precisely within the prescribed safe harbors is defensible. In such instances, case law and administrative interpretations, including OIG Special Fraud Alerts and OIG advisory opinions, provide guidance.

There is no safe harbor provision that protects the giving of gifts, sample products, hospitality, entertainment, or sponsorship for training, research or events. There is also no *de minimis* exception to the statute.

OIG enforcement efforts have been directed at the prevention of using discounts, promotions or samples to manipulate the amounts state and federal governments pay for drug products, or to encourage unnecessary utilization of products or services. For example, the agency has expressed the concern that manufacturers' remuneration to healthcare providers may interfere with the providers' professional judgment in making treatment decisions.[208] However, federal regulations permit some discounts for drug products for which reimbursement may be sought by healthcare professionals pursuant to Medicare or Medicaid, provided that the requirements of OIG's safe harbor are strictly followed. In general, the safe harbor applicable to discounts

[206] 42 U.S.C. § 1320a-7b(f).
[207] See 42 C.F.R. § 1001.952.
[208] See Special Fraud Alert: Prescription Drug Marketing Schemes, issued Aug. 1994, *reprinted at* 59 Fed. Reg. 65,372 (Dec. 1994).

requires that the manufacturer must fully and completely report the value of the discount.[209]

OIG guidance documents, including its advisory opinions, alerts and bulletins, have specified a number of activities in addition to general promotional activities that have been identified by the OIG as creating potential issues under the Anti-Kickback Statute. Detailed discussion of the Anti-Kickback Statute and relevant regulations is beyond the scope of this handbook.

Civil False Claims Act

The civil False Claims Act ("FCA")[210] has become the statute of choice for the government and *qui tam* relators who file actions against manufacturers for the off-label promotion of drugs and medical devices. Indeed, the DOJ announced in December 2011 that it had secured more than USD3 billion in settlements and judgments in civil FCA cases involving fraud against the government in the fiscal year ending 30 September 2011. This amount includes USD2.4 billion in recoveries involving fraud committed against federal healthcare programs. 2011 is the second year in a row that the DOJ has surpassed USD3 billion in recoveries under the FCA, bringing the total since January 2009 to USD8.9 billion. Although this is the largest three-year total in DOJ history, several more recent settlements with healthcare companies during 2012 promise to break all annual records set to date. The theory underlying such legal actions is that manufacturers who "knowingly" promote off-label prescription drugs or medical device products, and thereby receive Medicare or Medicaid payments, have committed fraud that is subject to the severe sanctions imposed by the FCA. Recent amendments to the FCA,[211] made by Congress to promote the successful litigation of such cases, ensure that the statute will continue to be the government's primary litigative

[209] 42 C.F.R. § 1001.952(h)(2).

[210] 31 U.S.C. §§ 3729, et seq.

[211] In 2009 Congress passed the Fraud Enforcement and Recovery Act ("FERA"), Pub. L. No. 111-21, 123 Stat. 1617, which amended and renumbered certain sections of the FCA. The amendments to § 3729(a)(2) eliminate the requirement that the government or relator prove that the defendant made or used a false record or statement "to get" a false or fraudulent claim paid (*See Allison Engine Co., Inc. v. United States ex rel. Sanders*, 553 U.S. 662 (2008)). The revised statute provides that a person violates the FCA if he "knowingly makes, uses, or causes to be made or used, a false record or statement *material* to a false or fraudulent claim" (emphasis added). Congress made these amendments effective on 7 June 2008 for all "claims... pending" on or after that date.

weapon in off-label and other healthcare cases. The FCA imposes liability for conduct falling within seven enumerated categories, but most cases are brought under one or both of the first two sections of the Act.[212] The statute imposes liability on "any person" (either a natural person or a business entity) who:

- knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; or
- knowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent claim.

A manufacturer who violates FDA regulations does not thereby automatically violate the FCA. To prove a manufacturer liable under the FCA, the government or *qui tam* relator must show that: the manufacturer made a false statement or engaged in fraudulent conduct; such statement or conduct was done "knowingly"; the statement or conduct was material to the government's decision to pay a "claim"; and the manufacturer's actions caused the government to pay out or forfeit funds.

The FCA defines a "claim" as:

> [A]ny request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that –
>
> - is presented to an officer, employee, or agent of the United States; or
> - is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government –
>   - provides or has provided any portion of the money or property requested or demanded; or
>   - will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded; and
>   - does not include requests or demands for money or property that the Government has paid to an individual as

[212] 31 U.S.C. § 3729(a)(1)(A) & (B), as amended by Fraud Enforcement and Recovery Act of 2009 ("FERA"), Pub. L. No. 111-21, 123 Stat. 1617 (2009).

> compensation for Federal employment or as an income subsidy with no restrictions on that individual's use of the money or property. [213]

A claim can be either "factually" or "legally" false. A factually false claim is one which involves an incorrect description of goods or services provided, or a request for reimbursement of goods or services never provided. A legally false claim is one that is true on its face but which does not comply with a statute, regulation or contractual term that is imposed on the contractor.

An FCA violation requires more than evidence showing that a manufacture acted negligently. The evidence must rise to the level of a "knowing" violation to support a finding of liability. But proof of specific intent to defraud the government is not required under the FCA's broad definition of scienter. Under the FCA, a person acts "knowingly" if he/she:

- has actual knowledge of the information;
- acts in deliberate ignorance of the truth or falsity of the information; or
- acts in reckless disregard of the truth or falsity of the information.

Not all false statements are sanctionable under the Act — only those that are "material" to the government's funding decision, meaning that the statement must have the "natural tendency to influence, or [be] capable of influencing" the payment or receipt of money. [214]

Where a violation is proved, a manufacturer may be liable for three times[215] the amount of actual damages sustained by the government plus statutory penalties of USD5,500 to USD11,000 per claim. This "one-two" punch of damages and penalties can result in settlements and awards of millions — and sometimes billions.

The FCA does not state how damages should be calculated or provide guidance regarding the calculation of the number of claims. In computing damages, the US Supreme Court has held that "[t]he Government's actual damages are equal to the difference between the market value of the [items] it received and retained and the market value that the [items] would have had if they had been of the specified quality."[216] However, in some cases, especially

[213] 31 U.S.C. § 3729(b)(2).
[214] 31 U.S.C. § 3729(b)(4).
[215] 31 U.S.C. § 3729(a).
[216] *United States v. Bornstein*, 423 U.S. 303 (1976).

those involving fraud in the inducement or programmatic fraud, courts have approved damages awards up to three times the total amount of money paid out by the government — without requiring proof of actual damages.

FERA amended the FCA to extend liability to any person who "knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government."[217] Under this "reverse false claims" provision, a person can violate the FCA without presenting a false claim for payment or using a false record material to a false or fraudulent claim. Liability arises if a person knowingly retains an overpayment from the government. The PPACA,[218] signed into law in 2010, defines "overpayments" as "any [Medicare or Medicaid] funds that a person receives or retains … to which the person, after applicable reconciliation, is not entitled." Overpayments must be reported and returned to the Government within 60 days of the time they are identified or, in the case of a healthcare provider, from the date any corresponding cost report is due. Failure to return an overpayment within the specified time may constitute a "reverse false claim" resulting in FCA liability.

In most civil litigation, the rules normally prohibit discovery until after the lawsuit is actually filed. Here, too, the FCA is different from other statutes. Prior to FERA, the government was authorized to use Civil Investigative Demands ("CIDs") to obtain interrogatory responses, documents and sworn testimony from potential FCA defendants. However, the procedure was cumbersome, and, in practice, the government rarely used CIDs. FERA changed that amending the FCA to simplify the procedures for obtaining CIDs and "clarifying that CIDs may be used during the investigation of *qui tam* allegations prior to the Government's intervention decision." The government now regularly uses CIDs to investigate potential FCA cases before they are actually filed.[219]

Whistleblower or *Qui Tam* Actions

The *qui tam* provision of the FCA allows private persons, called "relators," to bring civil false claims actions on behalf of the government.[220] Relators file their cases under seal, and the target of a *qui tam* action may not even know about the case until months later. The first indication that a case has been

[217] 31 U.S.C. § 3729 (a)(1)(G).
[218] Pub. L. 111-148, 124 Stat. 119 (2010).
[219] 31 U.S.C. § 3733.
[220] 31 U.S.C. § 3730(b)(1).

filed may be the service of a CID by the government. Even then, the sealing order may restrict the government's ability to confirm that it is investigating a *qui tam* case, until a partial unlifting of the seal is obtained from the court. In the meantime, the putative defendant may be left to read the "tea leaves" and speculate about the source of its newfound problem.

Congress intended that the FCA's *qui tam* provision would create an almost limitless army of "private attorneys general" ready to ferret out fraud that is undetected by the government. The provision — which generously rewards successful relators — is the most significant factor in the recent explosion in the number of FCA case filings. If the government intervenes and takes over the case, the relator is entitled to 15 percent to 25 percent of the award or settlement proceeds. If the government declines to intervene, the relator can receive 25 percent to 30 percent of the proceeds of the action or settlement. In addition, courts will award successful relators reasonable expenses, attorney's fees, and legal costs. [221]

Given the considerable "bounties" authorized by the FCA's *qui tam* provisions, it is no surprise that on occasion, persons with only second- or third-hand knowledge of wrongdoing may try to benefit from lawsuits filed against off-label and medical device manufacturers. Congress tried to prevent such abuses by requiring that a relator be an "original source"[222] of the information alleged in his *qui tam* complaint. However, when Congress enacted PPACA, it relaxed the FCA's "direct and independent" knowledge requirement. This will have the intended effect of allowing more *qui tam* suits by persons without "direct" knowledge of the alleged wrongdoing. The PPACA also eased the "public disclosure" bar by amending the FCA to prohibit only those actions based on disclosures from federal sources or the news media.[223]

The FCA provides protection against retaliation to whistleblowers or relators. Any employee who is discharged, demoted, suspended, threatened, harassed or otherwise discriminated against in his employment for conduct such as investigating, initiating, providing testimony for, or assisting in an action filed or to be filed, is entitled to all relief necessary to make him or her whole. Relief includes reinstatement with the same seniority, two times the amount of back pay plus interest, and compensation for special damages

[221] 31 U.S.C. § 3730(d).
[222] 31 U.S.C. § 3730(e)(4)(B).
[223] 31 U.S.C. § 3730(e)(4)(A).

sustained as a result of the retaliation, including litigation costs and attorneys' fees. [224]

Criminal Prosecution of False Claims

The civil FCA has a companion criminal provision that provides for imprisonment of up to five years and payment of fines. Making or presenting a claim known to be false, fictitious or fraudulent upon or against the federal government triggers the statute.[225] The decision to pursue a case under either the civil or criminal FCA depends on the discretion of the responsible government attorneys and is influenced by their evaluation of the scienter and motives of the defendant.

Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act ("FCPA") generally prohibits issuers, US persons or, under certain circumstances, non-US persons from paying or giving, or offering or promising to pay or give any money or any other thing of value, "corruptly," directly or indirectly to any foreign government official, foreign political party, or candidate for foreign political office for the purpose of influencing such recipients to do or omit to do certain acts or to secure any improper advantage, in order to obtain or retain business or direct business to any person.[226]

Prohibited Conduct

The phrase "anything of value" is very broadly defined to include gifts, entertainment, meals, travel expenses, product samples, donations (including charitable donations), discounts on products or services, incentive payments, employment, share ownership, or consultancies. Proscribed purposes include: to obtain or retain business (e.g., product sales, product approvals, favorable pricing decisions); to direct business to any person or firm; to obtain any other unfair advantage (e.g., tax reduction, exemption or benefit); reclassification or under-valuation for customs purposes; issuance of a license or permit; or a waiver of penalties for non-compliance with law.[227]

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[224] 31 U.S.C. § 3730(h).
[225] 18 U.S.C. § 287. "Whoever makes or presents to any … department or agency [of the United States] …any claim … knowing such claim to be false, fictitious, or fraudulent, shall be imprisoned not more than five years [and subject to fine].
[226] 15 U.S.C. §§ 78dd-1-3.
[227] Id.

In contrast, certain payments are permissible, such as "facilitating payments"; gratuities given to government officials for performing "routine" actions that do not involve the exercise of discretion; and reasonable and bona fide expenditures directly related to the promotion of products or services or the performance of a contract with a foreign government or agency.[228] These are typically tricky areas to navigate. Clear and detailed company policy and procedures can provide employees with guidance.

Penalties

Penalties under the FCPA may include substantial criminal and civil fines, disgorgement of profits and collateral penalties, such as debarment from government contracts, loss of export privileges and imposition of a compliance monitor. Individuals are subject to substantial fines and imprisonment.[229]

State Laws

Regulated industries also should be aware that there are state law counterparts to the Federal Anti-Kickback Statute and False Claims Act. For example, Minnesota and Vermont enacted laws requiring manufacturers to report gifts and marketing expenditures to regulatory agencies.[230] In both states, manufacturers are required to report annually identifying payments made to healthcare professionals for promotional purposes. Similar measures have been considered in other states as well.[231] Furthermore, although the FCPA does not have a state law counterpart, there are state laws that govern corruption and procurement activities.[232]

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[228] 15 U.S.C. §§ 78dd-1(b)-(c), -2(b)-(c), -3(b)-(c).

[229] Manufacturers may also face potential liability under the federal conspiracy statute relating to Anti-Kickback Statute claims. 18 U.S.C. § 371. Potentially applicable federal conspiracy claims are: (1) conspiracies to commit any offense against the United States, and (2) conspiracies to defraud the United States. While the former claims generally are brought in conjunction with an underlying claim pursuant to another statute, such as the Anti-Kickback Statute, a conspiracy to defraud does not require an underlying violation of another statute. Violations of the federal conspiracy statute are generally felony criminal offenses. Id.

[230] See Minn. Stat. Ann § 151,461m et seq., Vt. Stat. Ann. § 33 2005.

[231] In 2006, approximately 20 state legislatures proposed laws that included marketing reporting requirements or other marketing restrictions. See National Conference of State Legislatures, 2006 Prescription Drug Legislation (20 November 2006).

[232] See, e.g., TEX. PENAL CODE ANN. § 36.03.

Recommendations

To comply with FDA requirements and minimize the likelihood of FDA enforcement actions, pharmaceutical and device manufacturers should be especially mindful to promote their products consistent with product uses that the agency has approved or cleared and, where applicable, in compliance with requirements and guidance regarding adequate disclosure of risk information. Manufacturers should carefully review their promotional activities that may involve discussions of off-label or unapproved uses of drug and device products, including the dissemination of peer-review journal articles discussing off-label uses or the sponsorship of seminars in which unapproved uses of the manufacturer's product may be discussed to ensure compliance with agency regulations and guidance in this area.

The Anti-Kickback Statute and False Claims Act have served as the basis for several high-profile and significant claims against pharmaceutical manufacturers. The fact that a promotional activity benefits either patients or professionals does not, in and of itself, protect a manufacturer from a potential anti-kickback inquiry; if only one of the intended purposes of the activity is to influence federal healthcare business referrals, a manufacturer may face a potential anti-kickback claim. Off-label promotion has resulted in enormous fines and penalties being levied against manufacturers in recent years. Manufacturers should also be aware that the OIG and other enforcement agencies may infer intent from actions or inactions, and not just from stated intentions.

In addition, manufacturer promotional efforts should be conducted in accordance with internal codes of conduct — codes that manufacturers should implement and periodically review. Gifts to healthcare providers should be made only after a careful consideration of applicable ethical guidelines. Payments to providers for services should reflect the fair-market value of legitimate services rendered. In selected cases, manufacturers with concerns about specific programs may wish to consider seeking an advisory opinion from the OIG.[233] In addition, manufacturers should be cognizant of state law differences.

In implementing their internal codes of conduct and making their compliance programs a reality, manufacturers should establish suitable safeguards — such as training and monitoring the appropriate employees, creating

[233] Such requests may be sought pursuant to the Anti-Kickback Statute, 42 U.S.C. § 1320a-7d, for the limited purposes specified in OIG regulations, 42 C.F.R. Part 1008.

firewalls, and ensuring that effective auditing and reporting programs are in place. These safeguards are designed to help pharmaceutical product and medical device manufacturers demonstrate that activities that might be perceived as having been intended to influence drug purchases — activities such as seminar sponsorship or participation in drug formulary-related actions, to cite just two examples — are unrelated to sales or marketing efforts. In particular, manufacturers interested in sponsoring physician internet websites or providing related services to healthcare providers should keep in mind that they face the specter of potential claims under the Anti-Kickback Statute if those activities may be intended to generate federal healthcare program business opportunities. Moreover, pharmaceutical manufacturers should keep in mind that practices considered acceptable in other commercial settings may violate the Anti-Kickback Statute. To demonstrate good faith efforts to comply with applicable laws, manufacturers should implement compliance programs recommended by the OIG, PhRMA and AdvaMed, if applicable.

Because recent amendments to federal Medicare and Medicaid statutes have created additional reporting requirements, manufacturers should incorporate these requirements in their compliance programs and train their employees on the requirements of the Prescription Drug Act. Similarly, manufacturers should review the call for new safe harbor regulations and keep abreast of these ever-changing areas of the law to ensure that their compliance program policies and procedures, monitoring programs, reporting processes and judgments are up-to-date.

Latin America

Argentina

Vanina Caniza, Camila Pampuro

Introducción

La industria farmacéutica está fuertemente regulada en la Argentina. Las principales autoridades sanitarias a nivel nacional son el Ministerio de Salud de la Nación ("MinSal") y la Administración Nacional de Medicamentos, Alimentos y Tecnología Médica ("ANMAT"). Además, cada provincia cuenta con su propio Ministerio de Salud Provincial y, en ciertos casos, permisos municipales podrían requerirse.

En términos generales, el MinSal se encarga de emitir y supervisar el cumplimiento de políticas ambientales y de salud pública como así también de coordinar y controla las actividades de las autoridades sanitarias provinciales.

La mayoría de la legislación sanitaria (Ej.: registro de medicamentos y dispositivos médicos, autorizaciones para comercializar medicamentos y dispositivos médicos, publicidad de medicamentos y dispositivos médicos, importaciones, ensayos clínicos, etc.) es emitida por la ANMAT. La ANMAT es un organismo gubernamental descentralizado e independiente que controla, a nivel nacional, el proceso de autorización, registro y control de dispositivos médicos, medicamentos y alimentos. A pesar de contar con independencia económica, la ANMAT debe seguir las instrucciones técnicas y científicas emitidas por el MinSal.

Legislación sobre Publicidad de Medicamentos

Marco Regulatorio

Las principales normas aplicables a la promoción y publicidad de medicamentos y dispositivos médicos son las siguientes:

- Ley 16,463 (Ley de Medicamentos)
- Decreto Reglamentario 9763/64 (Reglamenta la Ley de Medicamentos)
- Resolución MinSal 20/05 (Publicidad de Medicamentos de Venta Libre)
- Disposición ANMAT 4980/05 (Publicidad de Medicamentos de Venta Libre)

Argentina

Vanina Caniza, Camila Pampuro

Introduction

The pharmaceutical industry is heavily regulated in Argentina. The main sanitary authorities at the national level are the National Ministry of Health ("MOH") and the National Administration of Drugs, Food Products and Medical Technology ("ANMAT"). Additionally, each province has its own Provincial Ministry of Health and, in some cases, even municipal permits may be required.

In general terms, the MOH is in charge of drafting and enforcing health and environmental public policies as well as coordinating and monitoring the activities of provincial sanitary authorities.

Most sanitary legislation (e.g., registration of pharmaceuticals and medical devices, authorizations to commercialize pharmaceuticals and medical devices, promotion of pharmaceuticals and medical devices, imports andclinical trials) is passed by ANMAT, a decentralized and independent governmental body that controls, at the national level, the processes of authorization, registration and surveillance of medical devices, pharmaceuticals and food products. Even though ANMAT has economic independence, it follows technical and scientific rules and instructions issued by the MOH.

Regulatory Framework

The main laws and regulations applicable to the promotion of pharmaceuticals and medical devices are as follows:

- Law 16,463 (Pharmaceuticals Law)
- Executive Order/Regulatory Decree 9763/64 (Regulating Pharmaceuticals Law)
- MOH Resolution 20/05 (Advertisement of Over-the-Counter ["OTC"] Pharmaceuticals)
- ANMAT Decision 4980/05 (Advertisement of OTC Pharmaceuticals)

- Resolución MinSal 627/07 (Publicidad de Medicamentos de Venta Bajo Receta)
- Disposición ANMAT 1631/09 (Publicidad de Medicamentos de Venta Libre)
- Disposición ANMAT 2845/11 (Programa para Monitoreo y Fiscalización de Publicidad de Productos Sujetos a Vigilancia Sanitaria)
- Ley 24,240 (Ley de Defensa del Consumidor)
- Ley 22, 802 (Ley de Lealtad Comercial)
- Ley 25,156 (Ley de Defensa de la Competencia)

En todos los casos sus respectivas modificaciones y correspondientes normas reglamentarias están incluidas.

Prácticas Permitidas y Prohibidas

En Argentina, la publicidad y promoción de medicamentos y dispositivos médicos está permitida, aunque fuertemente regulada.

En primer lugar, se encuentra prohibida la publicidad de medicamentos y dispositivos médicos que no han sido previamente registrados ante ANMAT.

Las reglas sobre promoción y publicidad de medicamentos y dispositivos médicos varían según cual sea su condición de venta (venta libre/venta bajo receta para el caso de medicamentos) o indicación de uso (de uso directo por pacientes o consumidores/de uso con la intervención de profesional médico para dispositivos médicos).

Está prohibida la publicidad al público en general de (i) medicamentos de venta bajo receta (por oposición a medicamentos de venta libre) y (ii) dispositivos médicos que, por su naturaleza intrínseca y uso propuesto, no puedan ser utilizados o indicados para su uso de manera directa por los pacientes y/o consumidores no profesionales (“dispositivos médicos de uso profesional”).

Como consecuencia, las compañías farmacéuticas y de dispositivos médicos podrán dirigir la publicidad relativa a medicamentos de venta bajo receta y dispositivos médicos de uso profesional únicamente a la comunidad médica.

- MOH Resolution 627/07 (Good Practices in the Promotion of Prescription Drugs)
- ANMAT Decision 1631/09 (Advertisement of OTC Pharmaceuticals)
- ANMAT Decision 2845/11 (Program for Control and Fiscalization of Advertisement of Products under Sanitary Surveillance)
- Law 24,240 (Consumer's Protection Law)
- Law 22,802 (Commercial Loyalty)
- Law 25,156 (Competition Law)

In all cases, corresponding amendments and regulatory decrees are included.

Permitted and Prohibited Practices

In Argentina, promotion and advertising of pharmaceuticals and medical devices is permitted, though heavily regulated.

First and foremost, promotion of pharmaceuticals and medical devices that have not previously obtained the corresponding authorization for commercialization (i.e., product registration with ANMAT) is strictly forbidden.

Rules on promotion and advertisement of pharmaceuticals and medical devices vary depending on the condition of sale (OTC/prescription pharmaceuticals) or indicated use (for patients/consumers' direct use/for use with the intervention of a healthcare provider for medical devices).

Promotion to the general public of prescription pharmaceuticals (as opposed to OTC pharmaceuticals), and medical devices which, due to their intrinsic nature and proposed use, may not be directly used, or are not indicated for direct use, by patients and/or non-professional consumers ("prescription medical devices") is forbidden.

Consequently, pharmaceutical and medical device companies are only allowed to advertise registered prescription pharmaceuticals and medical devices to the medical community.

General Rules

In general terms, the content of promotional materials should be consistent with the information on the product submitted to ANMAT at the time of product registration. Information should be objective, true, accurate, and shall avoid misleading or confusing language.

Reglas Generales

En términos generales, el contenido de la publicidad debe ser consistente con la información sobre el producto que fue presentada a la ANMAT al momento de la solicitud de registro de dicho producto. La información debe ser objetiva, veraz, clara y precisa y no deberá inducir a error.

Asimismo, las regulaciones aplicables establecen que la publicidad deberá estar respaldada por evidencia científica y técnica (información que deberá estar a disposición de ANMAT).

Las empresas farmacéuticas y de dispositivos médicos deberán llevar el registro y archivo de los materiales promocionales y su soporte bibliográfico.

Autorización de Material Publicitario

En principio, no se requiere autorización previa de los materiales de promoción por parte de la autoridad sanitaria, para los medicamentos y dispositivos médicos de venta libre. De acuerdo con lo dispuesto por la Resolución 20/05 del Ministerio de Salud, el contenido publicitario de dichos productos estará sujeto a la fiscalización posterior de la autoridad sanitaria.

Por el contrario, de acuerdo con la Resolución 627/07 (Buenas Prácticas de Promoción de Medicamentos Bajo Receta), se requerirá autorización expresa de la ANMAT para efectuar publicidad masiva respecto a medicamentos de venta bajo receta dirigidas al cuerpo médico y/o farmacéutico, debiendo invocarse las razones que justifican el uso de esa vía de comunicación.

Para el caso de dispositivos médicos, en ausencia de una norma específica que regule la publicidad de dispositivos médicos de uso profesional, se podría aplicar por analogía lo dispuesto para medicamentos de venta bajo receta, y requerir entonces autorización expresa de ANMAT, para la publicidad de dispositivos médicos de uso profesional en medios masivos de comunicación.

Algunas Acciones de Marketing

Muestras Gratis

En el caso de medicamentos, de acuerdo a la Disposición 4980/05 se podrán entregar al público muestra gratis de medicamentos de venta libre únicamente a través y bajo responsabilidad de, un médico o farmacéutico. Está prohibida la entrega de muestras gratis a menores de edad. Para medicamentos de venta bajo receta, en base a lo establecido en la Resolución 627/07, se podrán entregar también muestras gratis a profesionales médicos.

Additionally, applicable regulations indicate that advertisements must be based on scientific and technical evidence (which shall be available to ANMAT).

Pharmaceutical and medical device companies are required to keep a registry of the advertisement materials and the supporting information.

Authorization of Promotional Materials

In principle, previous authorization by sanitary authorities is not required for promotional materials of OTC pharmaceuticals and medical devices. Pursuant to Ministry of Health Resolution 20/05, the content of any such advertising shall be subject to subsequent supervision by the sanitary authority.

In contrast, and according to Ministry of Health Resolution 627/07 (Good Practices for the Promotion of Prescription Pharmaceuticals, "Resolution 627/07"), express authorization of ANMAT for public (mass media) advertisements directed to the medical and/or pharmaceutical community is required for prescription pharmaceuticals. In addition, the need for mass media advertising must be justified.

In the case of medical devices, due to the absence of specific legislation regulating the advertisement of prescription medical devices, express authorization of ANMAT for promotional materials directed to the medical and/or pharmaceutical community could be required if Resolution 627/07 is applied by way of analogy.

Certain Marketing Practices

Samples

In the case of pharmaceuticals, according to Decision 4980/05, free samples of OTC pharmaceuticals may be supplied to the general public only through physicians or pharmacists, who shall be responsible for their distribution.

The supply of free samples to minors is forbidden. Based on Resolution 627/07, delivery of samples of prescription pharmaceuticals to medical professionals is also permitted.

In the case of medical devices, Decision 4980/05 provides that, depending on the product's risks, free samples of medical devices may be supplied to physicians, dentists, pharmacists and any government entity authorized to that effect.

En el caso de dispositivos médicos, la Disposición 4980/05 establece que sólo podrán distribuirse muestras gratuitas al público de dispositivos médicos, en función del riesgo del producto, por medio de los médicos, odontólogos, farmacéuticos y cualquier organismo público estatal autorizado para ello.

Atenciones y Regalos

La Ley 17,132 (Ejercicio de la Medicina) prohíbe a los profesionales médicos recibir beneficios de empresas que elaboren, distribuyan o vendan medicamentos, cosméticos, suplementos dietarios, prótesis o cualquier otro elemento que se utilice para el diagnóstico y prevención de una enfermedad.

Por otra parte, dado que en Argentina la mayoría de los profesionales médicos presta servicios tanto en el sector privado como en el público (E.j.: hospitales, profesores en universidades públicas, etc.), un médico podría calificar como oficial público. En consecuencia, desde la perspectiva de las regulaciones anticorrupción (principalmente contenidas en el Código Penal Argentino), los beneficios a dichos médicos también estarán prohibidos.

Medicamentos: La Resolución 627/07 prohíbe a las compañías farmacéuticas otorgar, directa o indirectamente, a los profesionales autorizados a prescribir medicamentos, cualquier tipo de incentivo o beneficio.

Dispositivos Médicos: No existen normas que prohíban expresamente a compañías elaboradoras de dispositivos médicos ofrecer o entregar atenciones, regalos o cualquier beneficio a profesionales médicos, excepto cuando el médico califique como oficial público (en cuyo caso las sanciones contenidas en regulaciones sobre anti-corrupción serán aplicables). Sin embargo, de acuerdo a lo mencionado anteriormente, la Resolución 627/07 podría aplicarse por analogía y en consecuencia, las compañía de dispositivos médicos podrían ser sancionadas en caso de que ofrezcan y entreguen cualquier incentivo o beneficio a un profesional médico.

Eventos Científicos y/o Educativos

De acuerdo con la Resolución 627/07, las compañías farmacéuticas podrán otorgar becas, patrocinio y/o invitar a médicos a participar en congresos, simposios u eventos científicos siempre y cuando se informe públicamente a los médicos las condiciones de acceso a dicho patrocinio y el procedimiento de selección de los aspirantes (que deberá ser equitativo y transparente).

Hospitality and Gifts

As a preliminary comment, it is important to note that Law 17,132 (Practice of Medicine) prohibits physicians from obtaining benefits from manufacturers, distributors or sellers of pharmaceuticals, cosmetics, dietary products, prostheses or any other elements used in the diagnosis, treatment or prevention of illnesses.

Additionally, because in Argentina most physicians render services both in the private and the public sector (e.g., in hospitals and as teachers at public universities), a physician may qualify as a public official. Consequently, from an anti-corruption perspective, benefits to physicians will also be prohibited (anti-corruption regulations are mainly contained in the Argentine Criminal Code).

Pharmaceuticals: Resolution 627/2007 prohibits pharmaceutical companies from directly or indirectly granting, offering or promising incentives or benefits of any nature to healthcare professionals.

Medical Devices: There are no regulations that expressly prohibit companies that manufacture medical devices from offering or giving physicians hospitality, gifts or any kind of benefit, except when the physician qualifies as a public official (in such case, sanctions set out in anti-corruption regulations shall apply). However, as already mentioned, Resolution 627/07 may be applied by way of analogy and as a consequence, medical device companies could be sanctioned if they offer or give any incentive or benefit to a healthcare professional.

Scientific and/or Educational Events

According to Resolution 627/07, pharmaceutical companies may grant fellowships, sponsorship and/or invite physicians to participate in congresses, symposia or scientific events if they publicly inform physicians of the terms and conditions that will enable them to participate in such events, as well as the selection mechanisms (which should be equitable/fair and transparent). Again in this case, no express regulation exists for medical device companies, but Resolution 627 could apply by way of analogy.

In any event, any expenses related to a congress, symposium or scientific event that a pharmaceutical company will be financing, shall be reasonable and not lavish, and strictly related to the event (in this sense, the recommendation is to avoid using luxurious venues, avoid paying for entertainment or leisure activities).

Nuevamente, en el caso de compañías elaboradoras de dispositivos médicos no existe una regulación expresa pero la Resolución 627 podría aplicarse por analogía.

Cualquier gasto relacionado con el congreso, simposio u evento científico, que la compañía farmacéutica o de dispositivos médicos financie, deberá ser razonable y no excesivo, estrictamente relacionado con el evento (es decir, recomendamos evitar el uso de instalaciones excesivamente lujosas, evitar financiar actividades de entretenimiento u ocio).

Consecuencias en Caso de Infracción

En caso de infracción a las normas sobre promoción y publicidad de medicamentos y/o dispositivos médicos, el Director Técnico y/o la compañía farmacéutica o de dispositivos médicos podrían ser pasibles de diversas sanciones, según la infracción cometida y su gravedad. A continuación delineamos las principales sanciones:

El Director Técnico y el titular del registro del producto en infracción serán solidariamente responsables siendo de aplicación las sanciones de la Ley 16,463:

- Apercibimiento
- Multas
- Clausura, total o parcial, temporal o definitiva, según la gravedad de la causa o reiteración de la misma;
- Suspensión o inhabilitación en el ejercicio de la actividad o profesión hasta un lapso de tres años, en caso de extrema gravedad de las infracciones, la inhabilitación podrá ser definitiva
- Comiso de los productos en infracción y
- Cancelación de la autorización para vender y elaborar los productos

Códigos de Conducta Profesional

Existen Códigos de Conducta/Ética emitidos por cámaras de comercio que agrupan a ciertas compañías relacionadas a la industria de la salud (hay cámaras que agrupan a compañías farmacéuticas específicamente y otras que agrupan a compañías de dispositivos médicos). El principal objetivo de estos códigos es crear un mecanismo para auto-regular la industria.

Dichos códigos establecen, principalmente, reglas relativas a (i) la interacción con los profesionales médicos y (ii) las prácticas de marketing y

Consequences of Breach

In the event of a breach of the regulations regarding promotion and advertisement of pharmaceuticals and/or medical devices, the technical director and/or the pharmaceutical or medical device company may be subject to various penalties that vary depending on the type of infringement, its relevance and whether there is repeat infringement.

From a Health Regulations perspective, the technical director and the titleholder of the product registry will be jointly and severally liable under Law 16,463 for the following penalties:

- Warnings
- Fines
- Total or partial, temporary or final, business closure, depending on the relevance of the infringement or whether or not there is repeat infringement
- Suspension or disqualification in the exercise of the activity or professional practice for up to three years. If the infringement is egregious, the disqualification may be permanent
- Seizure of infringing products
- Cancellation of the authorization to sell and manufacture the products

Professional Codes of Conduct

Local chambers of commerce, to which health related companies may belong (there are specific chambers for pharmaceutical companies and specific chambers for medical device companies) have enacted codes of conduct/ethics for purposes of self-regulating the industry.

These codes mainly address interactions with healthcare professionals, and rules on marketing practices and promotion of pharmaceuticals and/or medical devices. These codes may not override Argentine legislation. In general terms, these codes have a more lenient approach by comparison to the Argentine Regulatory Framework.

Criminal and Civil Liability

Depending on the case and type of infringement, additional penalties to the ones described above under “Consequences of Breach” may apply from a Consumers’ Protection Law and/or Commercial Loyalty perspective.

promoción de medicamentos y/o dispositivos médicos. Estos códigos no pueden anular o ir en contra de la Legislación Argentina. Por lo general, estos códigos tratan los asuntos antes mencionados de una manera más benévola en comparación con el Marco Regulatorio Argentino aplicable.

Responsabilidad Penal y Civil

Dependiendo de las características del caso y el tipo de infracción, además de las sanciones descriptas en el título "Consecuencias en caso de infracción", las sanciones incluidas en la Ley de Defensa al Consumidor y/o Ley de Lealtad Comercial podrían resultar aplicables.

Adicionalmente, si los profesionales de salud califican como oficiales públicos, sanciones de índole penal contenidas en el Código Penal Argentina también resultarían aplicables si, por ejemplo, las compañías farmacéuticas realizan ciertas prácticas prohibidas tal como ofrecer, prometer u otorgar beneficios a dichos profesionales de salud.

Contratos con el Gobierno

En términos generales, para ser considerados válidos los actos administrativos (incluyendo contratos con el gobierno) deben cumplir con ciertos requisitos:

- Deben ser realizados por una organismo/departamento del gobierno con competencia administrativa suficiente (es decir, el organismo/departamento que esté legalmente facultado para emitir dicho acto administrativo).
- Deben basarse en la legislación que resulte aplicable considerando las circunstancias de hecho del caso en particular (tanto la legislación como las circunstancias de hecho deben servir como causa para cualquier acto administrativo).
- El propósito debe estar claramente definido y ser posible tanto legalmente como en la práctica.
- La opinión del Ministerio Público de la Nación podría requerirse cuando ciertos derechos o intereses legítimos pudieran verse afectados.
- Las razones de su emisión deben ser precisamente establecidas.
- Deben seguir aquellas normativas que le otorgan las facultades relevantes al organismo/departamento gubernamental involucrado y deben considerar siempre el interés público involucrado, directa o indirectamente.
- Como regla general, deben dictarse por escrito.

In addition, if healthcare professionals qualify as public officials, criminal sanctions contained in the anti-bribery provisions of the Argentine Criminal Code may also apply. For example, if pharmaceutical companies engage in certain prohibited practices such as offering, promising or giving benefits to healthcare professionals, anti-bribery.

Finally, the Argentine Criminal Code contains a special chapter for offenses against public health. The provisions in this chapter are mainly aimed at sanctioning the individuals or companies that commercialize false or contaminated pharmaceuticals.

Public Procurement

In general terms, to be valid, administrative acts (including public contracts) must comply with several requirements:

- They must be performed by a competent administrative agency/body (i.e., the agency/body that is legally authorized to issue the administrative act).
- They must be based on applicable law taking into consideration factual circumstances (both the law and the facts serve as grounds for any administrative act).
- The purpose must be clearly defined and physically and legally possible.
- The opinion of the state's attorney must be requested when rights or legitimate interests could be affected.
- The reasons and findings for its issuance must be precisely stated.
- They must follow the rules that grant relevant powers to the issuing agency and must always bear in mind the public interest directly or indirectly involved.
- As a general rule, they shall be in writing.
- In Argentina there are general and particular rules governing public procurement contracts, both at the national and provincial levels.

Contracts with Healthcare Professionals and Medical Institutions

Pharmaceutical and medical device companies are permitted to engage healthcare professionals for service agreements (e.g., consulting and speaker services). Payments to physicians for such services are not prohibited. However, the fees to be paid for the services should be reasonable, taking into consideration the type of service and market practices.

En Argentina hay normas generales y particulares que regulan las contrataciones con el Gobierno tanto a nivel nacional como provincial.

Contratos con Profesionales de la Salud e Instituciones Médicas

Las compañías farmacéuticas y de dispositivos médicos pueden celebrar contratos de servicios con profesionales de la salud (Ej.: servicios de consultoría, servicios de oratoria etc.). Los pagos a profesionales de la salud con motivo de la realización de dichos servicios no están prohibidos.

De todas maneras, el precio pagado a los profesionales de la salud en concepto de dichos servicios deberá ser razonable, considerando el tipo de servicio y el valor de mercado.

Además, antes de celebrar un contrato de servicios con un profesional de la salud, las compañías farmacéuticas y de dispositivos médicos deberían realizar un análisis del curriculum vitae y actual ocupación del profesional de la salud, es decir, analizar si califica o no como oficial público, teniendo en cuenta que los oficiales públicos pueden estar sujetos a incompatibilidades que le impidan realizar los servicios y/o recibir un pago.

Recomendaciones

La publicidad de medicamentos y dispositivos médicos está fuertemente regulada en Argentina. Por ello, las compañías farmacéuticas deben tomar especial consideración al redactar y preparar el material publicitario de cada producto.

Para minimizar el riesgo de ser sancionadas, las compañías farmacéuticas deberían tener en cuenta las siguientes recomendaciones:

- No otorgar ciertos beneficios a profesionales de la salud salvo que se lleve a cabo el mecanismo de selección descripto más arriba bajo el título “Prácticas Permitidas y Prohibidas: Eventos Científicos y/o Educativos” o que dicho beneficio se otorgue como contraprestación por un servicio otorgado por el profesional de la salud.
- No otorgar beneficios que estén relacionados con ventas.
- Antes de otorgar ciertos beneficios o de ejecutar contratos con instituciones médicas, públicas o privadas, obtener la autorización escrita de la máxima autoridad de dicha institución.
- Redactar un código de conducta.

Additionally, prior to executing a services agreement with a healthcare professional, an analysis of the nature of the healthcare professional (whether he/she is a public official) should be conducted, considering that public officials could be subject to conflict of interest.

Recommendations

The promotion and advertisement of pharmaceuticals and medical devices is heavily regulated in Argentina. Thus, special consideration should be taken when drafting promotional and advertisement materials for each product.

In order to lower the risks of facing sanctions, pharmaceutical companies should bear in mind the following recommendations:

- Do not structure benefits to physicians unless you have followed the selection mechanism described above, under "Permitted and Prohibited Practices: Scientific and/or Educational Events" or unless this benefit is in consideration for a service rendered by the physicians.
- Do not give benefits that are linked to a sales transaction.
- Procure written authorization from the principal authority of healthcare institutions for the grant of unilateral benefits and the execution of contracts.
- Draft a company code of conduct.

Brazil

Esther Flesch, Heloisa Uelze, Henrique Frizzo

Introdução

O setor farmacêutico é altamente regulado no Brasil. A Agência Nacional de Vigilância Sanitária ("ANVISA") foi criada em 1999 pela Lei 9.782/99 e aumentou ainda mais o nível de regulamentação do setor. A ANVISA possui competência bastante ampla e é a principal agência envolvida no controle e regulamentação de produtos de interesse da saúde.

A ANVISA edita uma série de resoluções para regulamentar as áreas sob sua competência. Juntamente com a Lei 6.360/76 e o Decreto 79.094/77, as resoluções da ANVISA formam a base da regulação de produtos farmacêuticos. Também é importante mencionar a Lei 6.437/77, a qual prevê penalidades aplicáveis àqueles que descumprem as lei e regulamentos sanitários.

Abaixo, explica-se com detalhe qual o tratamento dado pela ANVISA à propaganda farmacêutica e como outras Leis e Decretos influenciam o tema.

Legislação Sobre Propaganda Farmacêutica

A Estrutura Regulamentar

A matriz da estrutura regulamentar brasileira para a propaganda de produtos médicos é a Constituição Federal, que prevê a liberdade de informação, mas com restrições quanto à propaganda de tabaco, bebidas alcoólicas, agrotóxicos, medicamentos e terapias, que será estabelecida por lei.

Com apenas algumas exceções, a propaganda é geralmente uma área não regulamentada, sujeita apenas a um órgão autorregulamentador, o Conselho Nacional de Autorregulamentação Publicitária "CONAR", que rege as práticas aceitáveis com base nas disposições do Código de Defesa do Consumidor ("CDC").

A Lei 6.360/76, regulamentada pelo decreto 79.094/77, institui a Vigilância da Saúde para medicamentos, drogas ou produtos relacionados. De acordo com as suas disposições, a propaganda deste tipo de produtos está sujeita à autorização do Ministério da Saúde, nos termos dos seus regulamentos

Brazil

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Introduction

The pharmaceutical sector is highly regulated in Brazil. The National Health Surveillance Agency ("ANVISA") has broad jurisdiction and is the main agency involved with the control and regulation of health-related products. Since its creation in 1999 by Law 9,782/99, the agency has increased the level of surveillance in the sector.

ANVISA has issued a series of rulings to regulate the areas under its competence. Together with Law 6,360/76 and Decree 79.094/77, ANVISA's rulings form the basis for the regulation of pharmaceuticals. Law 6,437/77 is also worth mentioning, as it provides for penalties applicable to those who violate sanitary laws and regulations.

Below, we describe ANVISA's treatment of pharmaceutical advertising and how other laws and decrees influence this subject.

Pharmaceutical Advertising Legislation

The Regulatory Framework

The Brazilian regulatory framework for the advertisement of medical products is based on the Federal Constitution, which provides for freedom of information, but with restrictions regarding the advertisement of tobacco, alcoholic beverages, pesticides, medical drugs and therapies to be established by law.

With a few exceptions, advertising is generally a non-regulated area, subject to a self-regulatory body, the National Council for Advertisement Self-Regulation ("CONAR"). The Council rules on acceptable practices based on the provisions of the Consumer Defense Code ("CDC").

Law 6,360/76, regulated by Decree 79,094/77, institutes Health Surveillance for medicines, drugs or related products. According to its provisions, the advertising of these types of products is subject to authorization by the Ministry of Health, pursuant to its own regulations. This law limits the advertising and marketing of prescribed medicines to medical professionals and prohibits such activities in relation to consumers.

próprios, embora nenhuma regra tenha sido promulgada exigindo um controle prévio da propaganda - exceto para os medicamentos controlados. Esta lei já limita as atividades de propaganda e *marketing* de medicamentos prescritos aos profissionais da área, que proíbe tais atividades para o consumidor.

O Código Defesa do Consumidor (Lei 8.078/90), além de abranger a proteção do consumidor, define propaganda abusiva e enganosa e estabelece as sanções relacionadas.

Em 1996, foi promulgada a Lei 9.294 que estabelece as restrições para o uso e propaganda de tabaco, bebidas alcoólicas, medicamentos, terapias e pesticidas, conforme determinado pela Constituição Federal, bem como sanções no caso de violação das suas disposições. No que diz respeito aos medicamentos e terapias, o artigo 7 basicamente estabelece basicamente que:

- Exceto pelos anódinos e medicamentos OTC [remédios que se vendem nos balcões de drogarias e farmácias, sem necessidade de receitas], medicamentos e terapias só podem ser anunciados em publicações científicas, médicas e especializadas, dirigidas direta e especificamente para os profissionais e instituições de saúde;
- A propaganda de medicamentos e terapias não deve conter afirmações que não podem ser cientificamente comprovadas, nem usar depoimentos de profissionais que não sejam legalmente qualificados para fazê-las;
- O anúncio deve conter advertência sobre a necessidade de consultar um médico caso os sintomas persistam.

Esta lei é regulamentada pelo Decreto 2.018/96, que exige a autorização do Ministério da Saúde para a publicidade de medicamentos que são vendidos no balcão (OTC).

Em conformidade com as disposições das leis supracitadas que determinam prévia autorização do Ministério da Saúde para publicidade de medicamentos, foi promulgada por esta autoridade a Portaria 344/98, que estabelece regras gerais para a comercialização e propaganda de substâncias e medicamentos sujeitos a controle especial (drogas narcóticas, psicotrópicas e imunossupressoras).

Finalmente, a Agência Nacional de Vigilância Sanitária (ANVISA) foi criada pela Lei 9.782/99, que define a sua competência para estabelecer normas,

The Consumer Protection Code ("Law 8,078/90") covers consumer protection, defines abusive and misleading advertisements and establishes the related sanctions.

In 1996, Law 9,294, was enacted, establishing restrictions on the use and advertising of tobacco, alcoholic beverages, medicine, therapies and pesticides, as determined by the Federal Constitution, as well as sanctions for violation of these provisions. With regard to medicines and therapies, Article 7 sets out that:

- except for anodynes and over-the-counter ("OTC") drugs, medicines and therapies can only be advertised in scientific, medical and specialized publications, addressed directly and specifically to healthcare professionals and medical institutions;
- the advertisement of medicines and therapies shall not contain statements that cannot be scientifically evidenced, nor use testimony of professionals who are not legally qualified to provide such; and
- the advertisement must contain a warning about the need to consult a doctor in case the symptoms persist.

This law is regulated by Decree 2,018/96, which requires the Ministry of Health's authorization for advertising OTC medicines.

In accordance with the provisions of the abovementioned laws requiring previous authorization from the Ministry of Health for the advertising of medicines, Ordinance 344/98 was enacted, and establishes general rules for the commercialization and advertising of substances and medicines subject to special control (narcotic, psychotropic and immunosuppressant medicines).

Finally, ANVISA itself was created by Law 9,782/99, which sets out its competence to establish rules, control and supervise, pursuant to the sanitary legislation, the advertisement and publicity of products subject to sanitary surveillance.

As the regulatory authority that ensures compliance surrounding the promotion of medicines, ANVISA issued Resolution RDC 102/00 which was later revoked by Resolution RDC 96/08. Those resolutions provide specific rules for the regulation of advertising, publicity, information and other practices aimed at commercially promoting medicines, produced nationally or abroad, whatever the method of publication thereof, including those transmitted during the regular schedule of TV and radio stations.

controlar e supervisionar, nos termos da legislação sanitária, a propaganda e a publicidade de produtos submetidos à vigilância sanitária.

Sendo a autoridade reguladora que fiscaliza o cumprimento das regras para a promoção de medicamentos, a ANVISA publicou a Resolução RDC 102/00 que foi posteriormente revogada pela Resolução RDC 96/08. Essas leis regulamentadoras objetivaram regras específicas para a regulamentação da propaganda, publicidade, informação e outras práticas envolvendo a promoção comercial ou de divulgação de medicamentos, produzidos domesticamente ou no exterior, sejam quais forem as formas e os meios de sua divulgação, incluindo aqueles transmitidos durante a programação normal das estações de rádio e da TV.

Outra entidade que também é responsável pela supervisão dos anúncios de medicamentos é o Conselho Nacional de Autorregulamentação Publicitária ("CONAR"), que é uma associação formada pelas empresas e cujas funções são realizadas independentemente da ANVISA. Observe que o CONAR inspeciona todos os tipos de publicidade, não apenas aquelas relacionadas com os medicamentos/a legislação sanitária, como a ANVISA, a fim de verificar a sua regularidade de acordo com o Conselho Nacional de Autorregulamentação Publicitária. Este Código contém normas aplicáveis à promoção de produtos e serviços em geral e capítulos específicos que abordam a promoção de (i) profissionais da área de saúde serviços e tratamentos hospitalares, e (ii) medicamentos no mercado de balcão.

A Resolução RDC 96/08 da ANVISA, que está em vigor desde 18 de junho de 2009, contém limites muito mais rigorosos e rígidos para medicamentos e promoção de medicamentos, em comparação com a regra anterior, a Resolução RDC 102/00. A nova resolução criou regras mais amplas para técnicas e exigências de propaganda, participação de celebridades, propaganda indireta, entre muitas outras. Devido à intervenção dura promovida pela Resolução RDC 96/08 da ANVISA, a sua validade tem sido questionada pela Advocacia Geral Da União, sob o entendimento de que a ANVISA ultrapassou os seus limites constitucionais e legais, legislando em áreas além de sua competência, tais como Proteção do Consumidor e Telecomunicações.

A ANVISA não levou em conta o parecer, o que faz com que a Resolução RDC 96/08 da ANVISA ainda esteja válida e em vigor. Após este conflito com o Advogado Geral da União, a aplicabilidade da resolução foi submetida a contestações judiciais por algumas empresas e entidades. Como esta

Another entity responsible for supervising advertisements is CONAR, a non-governmental association of medical, advertising and media entities whose duties are performed independently from ANVISA. Unlike ANVISA, CONAR is responsible for ensuring that all publicity, not just healthcare-related advertising, complies with the Brazilian Code for Advertising Self-Regulation. This code contains rules regarding the promotion of products and services in general, and includes specific chapters addressing the promotion of healthcare professionals, hospital services, treatments and OTC drugs.

ANVISA Resolution RDC 96/08, in force since 18 June 2009, contains stricter and more severe limits on medicine and drug promotion as compared to the previous rule, Resolution RDC 102/00. The new resolution creates broader rules for advertising techniques and requirements, participation of celebrities and indirect advertisement, among other things. As such, the validity of ANVISA Resolution RDC 96/08 has been questioned by the General Attorney of the Brazilian Government, on the basis that ANVISA has surpassed its constitutional and legal limits, legislating in areas beyond its competence, such as consumer protection and telecommunication.

ANVISA has disregarded the General Attorney's opinion and the resolution remains valid and in force. However, since the General Attorney's challenge, the resolution's enforceability has been subject to judicial challenges by certain companies and entities. As this legislation is quite recent, the number of cases and decisions is very limited, but injunctions have been granted that overrule the sections that addressed the communication format and other technical issues related to advertisements.

Resolution RDC 96/98 is not applicable to medical devices. However, the following rulings issued by ANVISA do apply:

- Resolution RDC No. 185/2001, which sets forth the requirements for the registration, labeling and instructions of use of medical devices:
- Resolution RDC No. 59/2000, which provides for Good Manufacturing Practices requirements
- Resolution RDC No. 55/2005, which governs the recall of medicinal products (drugs) but can be used as best practice in analyzing device issues
- Resolution RDC No. 260/2002, which provides for the enrollment of low-risk medical devices

Finally, there are a number of other statutes that provide additional rules for the marketing and promotion of drugs and medical devices. The codes of conducts and ethics codes of industry associations and healthcare

legislação é recente (em vigor desde 18 de junho de 2009), o número de casos e decisões é muito limitado, mas, basicamente, liminares foram concedidas para anular as seções que abordavam o formato de comunicação e outras questões técnicas relacionadas com propaganda.

Observe que a Resolução RDC 96/98 não se aplica para os dispositivos médicos; portanto, as principais restrições de que as regras não são aplicáveis à esta indústria. No entanto, as seguintes normas emitidas pela ANVISA se aplicam:

- Resolução RDC nº 185/2001, que estabelece os requisitos para o registro, rotulagem e instruções de uso dos dispositivos médicos;
- Resolução RDC nº 59/2000, dispõe sobre os requisitos de Melhores Práticas de Fabricação;
- Resolução RDC nº 55/2005, aplicável ao recall de medicamentos (drogas), mas pode ser usado como melhor prática na análise de questões de dispositivos, e
- Resolução RDC nº 260/2002, que prevê a inscrição de dispositivos médicos de baixo risco.

Finalmente, há uma série de outros estatutos que prevêem regras adicionais para atividades de *marketing* e promocionais de medicamentos e dispositivos médicos. Os códigos de conduta e códigos de ética de associações industriais e conselhos profissionais de saúde[1] também são uma fonte valiosa de informações de práticas aceitas. Mesmo quando um determinado código não é diretamente aplicável, pode servir de guia para a relação ética entre os fabricantes de drogas e dispositivos médicos e os profissionais da área de saúde.

Práticas Permitidas e Proibidas

Além da proibição geral para as atividades de *marketing* direto e promocionais sobre os produtos médicos com necessidade de receita, a legislação brasileira geralmente visa evitar o *quid pro quo* entre os profissionais de saúde e a indústria farmacêutica. Portanto, a relação entre a indústria e os profissionais de saúde e/ou instituições médicas deve ser

[1] O código de ética do Conselho Federal de Medicina não se aplica à indústria, somente aos médicos e terapeutas, mas pode ser usado para compreender as práticas aceitáveis.

professional councils[1] are also a valuable source of information on admitted practices. Even when a certain code is not directly applicable, it should serve as guidance for the ethical relationship between drugs and medical device manufacturers and healthcare professionals.

Permitted and Prohibited Practices

Besides the general prohibition on direct marketing of medical products under prescription, Brazilian legislation generally aims at avoiding a *quid pro quo* between healthcare providers and the industry. Therefore, the relationship between industry and healthcare professionals and/or medical institutions must always be conducted in a transparent and documented way. Fair market practices and adequate remuneration, considering the time spent on the services, are also crucial elements.

Another core principle regarding the promotion of medical products is the compatibility between the claims and the information contained in the medical product registration. Such claims must be supported by evidence presented at the time of the product's registration with ANVISA. All marketing and promotional materials must clearly refer to the supporting evidence for the claims.

The health legislation, especially the controversial Resolution RDC 96/08 from ANVISA, covers a broad range of subjects, but transparency in the promotional practices is a core element. Despite the fact that ANVISA's Resolution RDC 96/08 only regulates the promotion of drugs, it can also be used as a best practice guide for the medical devices area.

Note that the rules outlined below are applicable to private practice doctors only, as dealings with governmental officials involve another set of regulations. However, the issue of a physician's possible public function is a broad concept which is not fully defined in Brazilian law. The main consideration is that a physician who works for a governmental or a public-funded entity should not have any decision-making powers. This includes holding administrative/managerial functions within the institution or participating in the elaboration of technical specifications for public bids/tenders.

[1] The Federal Council of Medicine (*Conselho Federal de Medicina*) ethics code is not applicable to the industry, only to doctors and physicians, but can be used to understand the admissible practices.

realizada sempre de forma transparente e documentada. Práticas justas de mercado e uma remuneração adequada, considerando o tempo gasto com os serviços, também é um elemento crucial.

Outro princípio fundamental sobre propaganda e atividades promocionais de produtos médicos é a compatibilidade entre as alegações e as informações presentes no registro do produto junto à ANVISA. Claro que tais reclamações devem ser suportadas por evidências devidamente apresentadas no momento do registro do produto. Todo o *marketing* e materiais promocionais têm que incluir uma referência clara aos elementos de suporte às alegações.

A legislação da saúde, especialmente a controversa Resolução RDC 96/2008 da ANVISA, abrange uma ampla g ama de assuntos, mas a transparência nas práticas de promoção é um elemento central. Apesar do fato da Resolução RDC 96/2008 da ANVISA regular apenas a promoção de medicamentos, ela pode ser usada como uma boa prática também para a área de produtos para saúde.

Observar que as regras que serão delineadas a seguir são aplicáveis para os médicos de prática privada apenas, pois lidar com funcionários do governo sujeita a empresa a outro conjunto de regras. No entanto, a questão de quando um médico é considerado como portador de uma função pública é um conceito amplo e não está totalmente definido na legislação brasileira. O elemento principal é que o médico que trabalha em uma entidade governamental ou uma entidade financiada por verbas públicas não deve ter qualquer poder de decisão; por exemplo, manter funções administrativas/gerenciais dentro da instituição ou participar na elaboração das especificações técnicas de licitações públicas.

As dificuldades em definir quais são os limites quando se trata de médicos de prática pública resultam em uma revisão cuidadosa desta prática e cada caso deve ser analisado separadamente.

Presentes, seminários, hospitalidade e entretenimento

Preocupado com as práticas de promoção e *marketing* e o relacionamento entre a indústria e os profissionais, os principais reguladores (ANVISA, Conselho Federal de Medicina) e as associações de indústrias (ABIMED, INTERFARMA, e outras) emitiram regras mais rigorosas para atividades de *marketing* e de promoção. As restrições a esses tipos de práticas são descritas a seguir:

The difficulties in defining where the limits lie when it comes to public practice physicians should result in a careful review of this practice and each case should be analyzed on a case by case basis.

Gifts, Seminars, Hospitality and Entertainment

Concerns about the relationship between medical professionals and the industry spurred major regulators (ANVISA Medicine Federal Council) and associations (ABIMED, INTERFARMA, and others) to issue stricter rules on marketing and promotional activities. The restrictions on these practices are outlined below:

Gifts

ANVISA Resolution RDC 96/08, Article 5 provides that pharmaceutical companies cannot offer gifts, benefits or anything else of value to physicians who can prescribe medicines, whether or not the intent was *quid pro quo*.

However, low-value gifts (pens, notebooks, etc.) are still authorized. Prescription pads cannot contain the company logo or promote a drug. Materials containing scientific information such as magazines and medical journals can be freely distributed.

Note that industry codes of conduct and the physicians' professional councils impose additional restrictions on marketing activities and that anti-corruption laws also apply to public practice physicians.

Seminars, Hospitality and Entertainment

Any contribution, including travel expenses, meals and hospitality to support healthcare professionals' attendance in medical conferences and scientific events (national or international) is allowed. However, the support or sponsorship may not be conditional on the prescription, distribution and/or advertisement or promotion of any kind of medicine. In addition, any such relationship must be clearly declared by the physician and the company, in the prospectus, brochure or leaflets of the seminar and in the application form.

The sponsorship relationship and the payment of costs related to admission, hospitality and meals must be duly documented. The healthcare professional and the company must also disclose any potential conflict of interest. A clause to this effect should be included in the relevant instrument governing the sponsorship.

Presentes

Resolução RDC 96/2008, artigo 5 da ANVISA estabelece que as empresas farmacêuticas não estão mais autorizadas a oferecer presentes, benefícios, vantagens ou valores aos profissionais prescritores, independentemente da existência ou não de uma intenção de *quid pro quo*. Assim, a regra excluiu a necessidade de um vínculo de prescrição para a caracterização da infração.

No entanto, presentes de pequeno valor ainda são autorizados (canetas, caderninhos). Blocos de receita não podem conter o logotipo da empresa ou a promoção de uma droga. Materiais que contenham informações científicas, como revistas e revistas médicas podem ser distribuídas gratuitamente.

Observar que os códigos de conduta das indústrias e os Conselhos Profissionais dos Médicos impõem restrições adicionais e as leis anticorrupção se aplicam aos médicos de prática pública.

Seminários, Hospitalidade e Entretenimento

Qualquer apoio ou patrocínio, incluindo despesas de viagem, alimentação e hospitalidade, em favor dos profissionais de saúde para participar em congressos médicos e eventos científicos, nacionais ou internacionais, é autorizado, mas é obrigatório que o apoio ou patrocínio não seja condicionado à prescrição, distribuição e/ou propaganda ou divulgação de qualquer tipo de medicamento. Outrossim, tais relações devem ser claramente informadas pelo médico e a empresa, no prospecto, brochura ou folhetos do seminário e no formulário de candidatura.

A relação de patrocínio e o pagamento das despesas relacionadas com a admissão, a hospitalidade, as refeições devem ser devidamente documentadas. É também importante que tanto o profissional de saúde como a empresa divulgue qualquer conflito potencial de interesses. Uma cláusula nesse sentido deve ser incluída no instrumento que rege o patrocínio.

A idéia é que a decisão profissional sobre o melhor tratamento para um caso específico deve ser livre de qualquer interesse comercial. Por este motivo, os eventos devem ter uma real natureza educacional ou científica, apesar do fato de que a legislação não prevê a proporção entre educação e entretenimento que é considerada aceita. A legislação também não é clara sobre a restrição para pagamentos de entretenimento, mas a maioria dos códigos da indústria proíbe as empresas farmacêuticas de fornecer ou pagar por entretenimento.

Since a medical professional's decision as to the best treatment for that specific case must be free of any commercial interest, any such events must have a real scientific or educational nature. However, legislation does not provide the level of education and entertainment that is considered acceptable. The legislation is also not clear about restrictions on entertainment, but most industry codes prohibit pharmaceutical companies from providing or paying for entertainment.

The rules do not clarify how the sponsorship can be implemented, but best practice recommends that a company should reimburse expenses rather than give funds to the healthcare professional. Finally, the payments cannot be extended to relatives, spouses or any other person.

Other Promotional Activities

ANVISA Resolution RDC 96/08 regulates the advertising of medicines on the internet, but is restricted as far as prescribed medicines are concerned. It provides that the online promotion of such medicines shall only be accessible to professionals qualified to prescribe or distribute medicines, by means of an electronic registration system, and a liability statement setting out the legal restrictions on access shall be provided.

Any prescribing information/package insert that is published over the internet without restricted access, must be up-to-date and correspond to the one approved by ANVISA. It cannot present designations, symbols, figures, drawings, slogans or any advertising arguments related to the medicine.

Therefore, companies can put any information on a website, except information about prescription medicines, which shall only be available for physicians.

ANVISA Resolution RDC 96/08 forbids "off-label promotion." Off-label promotion is the marketing of a medicine for use not approved by ANVISA. This is because all statements contained in the advertising or publicity regarding the medicine's effect, indications, usage, adverse reactions, efficacy, security, quality and other characteristics must be compatible with the information registered with ANVISA. Independent websites are also forbidden to disclose off-label data, which is likely to be in the pharmaceutical company's interest. Penalties can be imposed for such conduct.

As regras não esclarecem como o patrocínio pode ser implementado, mas uma boa prática recomenda medidas diretas por parte da empresa e o reembolso de despesas, em vez de conceder verba ao profissional de saúde. Finalmente, os pagamentos não podem ser estendidos aos familiares, cônjuges ou qualquer outra pessoa.

Outras Atividades Promocionais

A Resolução RDC 96/08 da ANVISA regulamenta a propaganda de medicamentos através da internet, mas é restritiva, no que diz respeito aos medicamentos que só podem ser vendidos com receita, permitindo apenas se a publicidade na internet for acessível somente aos profissionais habilitados a prescrever ou distribuir medicamentos, por meio de um sistema eletrônico, e uma declaração de responsabilidade informando a restrição legal de acesso.

Informações de prescrição/bula quando publicadas através da internet, sem acesso restrito, devem ser atualizadas e correspondem às aprovadas pela ANVISA e não podem apresentar designações, símbolos, figuras, desenhos, *slogans* ou qualquer argumento publicitário relacionado ao medicamento.

Portanto, as empresas podem colocar qualquer informação em um *website*, com exceção de informações sobre medicamentos sob prescrição médica, que só estarão disponíveis para os médicos.

A Resolução RDC da ANVISA proíbe "promoção *off-label*" [promoção não indicada no rótulo], de modo que extensões com *link* de *websites* promocionais patrocinados pela empresa de um *website* independente que divulgue "dados *off label*" também estão proibidas. Pode ser muito claro para a ANVISA que a promoção de um site independente provavelmente tenha o interesse da empresa farmacêutica envolvido, de forma velada, assim, penalidades podem ser impostas para essa conduta.

"A promoção *off-label*" é a promoção de um medicamento para uma indicação não aprovada pela ANVISA, o que é ilegal de acordo com a Resolução 96/08 da ANVISA, uma vez que prevê que todas as declarações contidas na propaganda ou publicidade sobre a ação do medicamento, indicações, como usar, reações adversas, eficácia, segurança, qualidade e outras características do medicamente podem ser compatíveis com as informações registradas na ANVISA.

Companies can provide information about unauthorized medicines to health professionals, but only if the disclosure of the information is for scientific purposes. They may not be promoted. Moreover, such information must be strictly disclosed to health professionals or health students.

There are no guidelines for the disclosure of off-label information at scientific meetings, but all disclaimers must be provided in a very clear manner, warning that the specific indication is not registered with the regulatory authority and the current level of the trials.

Price comparisons directed at consumers can only be done between interchangeable medicines (generic and reference medicines). When directed to professional prescribers, the price comparison can be done between non-interchangeable medicines, based on market information, as long as they have the same active ingredients. Note that the comparison must be made between the treatment costs or, in case of continuous use of medicine, between the defined daily doses. Price comparison is forbidden with biological medicines.

Samples

ANVISA Resolution RDC 60/09 imposes various restrictions on the distribution of free samples, such as the obligation to deliver to the professional directly, by means of documented acceptance.

It is prohibited to distribute free samples of biological medicines that require special attention for conservation and transportation, as registered with ANVISA, and compounded drugs and formulas.

Free samples must contain at least 50 percent of the contents of the original presentation registered with ANVISA and commercialized by the company, with the exception of antibiotics and contraceptives, which are subject to a special treatment.

Free samples must present the same traceability and authenticity mechanisms defined by the sanitary authority for the original medicine and the package can only differ from the original medicine in terms of its size and volume. Any modification of the package material must be approved at the registry.

Statements on the labeling and the layout of the samples, as well as the prescribing information/package inserts, shall be identical to those approved by ANVISA to be included in the original package.

As empresas podem fornecer informações sobre o medicamento não registrado ou indicações não aprovadas aos profissionais de saúde, apenas se a divulgação da informação for para fins científicos, de modo que nenhum a promoção é permitida. Da mesma forma, essas informações devem ser divulgadas estritamente aos profissionais de saúde e estudantes de medicina.

Não há diretrizes para a divulgação de informações *off-label* em reuniões científicas, mas todas as declarações devem ser feitas de uma maneira muito clara, especialmente advertindo que a indicação específica não está registrada com a Autoridade reguladora e o nível atual dos testes.

Comparação de preços dirigida aos consumidores somente pode ser feita entre medicamentos intercambiáveis (genéricos e medicamentos de referência). Quando dirigido aos profissionais que preparam as receitas dos medicamentos, a comparação dos preços pode ser feita entre medicamentos não intercambiáveis, com base em informações de mercado, contanto que tenham os mesmos ingredientes ativos. No caso de medicamento biológico, a comparação de preços é proibida. Observar que a comparação deverá ser feita entre os custos de tratamento ou, no caso do medicamento de uso contínuo, entre as doses diárias definidas.

Amostras

As amostras grátis são regulamentadas pela Resolução RDC 60/09 da ANVISA. Essa regra impõe várias restrições sobre a distribuição de amostras grátis, tais como a obrigação de entrega ao profissional diretamente, por meio de aceitação documentada.

É proibido distribuir amostras grátis de (i) medicamentos biológicos que requerem atenção especial para a conservação e transporte, conforme registrado na ANVISA, e (ii) medicamentos manipulados e fórmulas.

As amostras grátis devem conter pelo menos 50 por cento do conteúdo da apresentação original registrada na ANVISA e comercializada pela empresa, com exceção aos antibióticos e anticoncepcionais, sujeitos a um tratamento especial.

As amostras grátis deverão apresentar a mesma rastreabilidade e mecanismos de autenticidade definidos pela autoridade sanitária para os medicamentos originais e a embalagem só pode diferir do medicamento original quanto ao

Consequences of Breach

Infractions of advertising, promotional and marketing rules can subject the company and individuals involved to serious administrative sanctions. In addition to these penalties, the parties involved may also be subject to criminal and civil liabilities.

Law 6,437/77 establishes penalties for infractions of sanitary legislation, which are:

- warning;
- fine;
- product apprehension, destruction or interdiction;
- suspension of the sale/manufacture of the advertised medicine;
- partial or complete interdiction of the company;
- prohibition of advertising;
- cancellation of the operation authorization;
- cancellation of the operation license; and
- intervention in the company that receives public resources.

Fines vary according to the seriousness of the infraction:

- in less severe infractions, from BRL2,000 to BRL75,000;
- in serious infringements, from BRL75,000 to BRL200,000;
- and gross and severe infractions, from BRL200,000 to BRL1.5 million.

In the event of recurrence, the fine may be doubled.

Law 9,294/96 establishes different penalties from those set out in Law 6,437/77. Breaching the provisions of Law 9,294/96 subjects the breaching company to the following penalties: warning; suspension of any other advertisement of the product for a period of up to 30 days; an obligation to publish a correction; seizing of the product; punitive fine of BRL5,000 to BRL100,000; and suspension of the radio/TV programs for 10 minutes for each minute or fraction of the duration of the advertisement transmitted in breach of the law.

While the penalties addressed by Law 6,437/77 are generally imposed as a result of breaches to sanitary legislation, the penalties established by Law 9,294/96 are applicable to breaches regarding the advertising of medicine and therapies. The rule to be used is determined on a case by case basis.

seu tamanho e volume, sendo vedada qualquer modificação do material da embalagem aprovado no registro.

Declarações sobre a rotulagem e o *layout* das amostras, bem como as informações de modo de usar/bulas, devem ser idênticas às aprovadas pela ANVISA e incluídas na embalagem original.

Consequências da Violações

Quaisquer infrações às regras de publicidade ou aos princípios de promoção e *marketing* podem sujeitar a empresa e as pessoas envolvidas a graves sanções administrativas. Além dessas penalidades, as partes envolvidas na infração também podem estar sujeitas à responsabilidade penal e civil.

A Lei 6.437/77 estabelece as penalidades por infração à legislação sanitária, que são: (i) advertência; (ii) multa; (iii) apreensão do produto, destruição ou interdição; (iv);suspensão da venda/fabricação do medicamento anunciado; (v) interdição total ou parcial da empresa; (vi) proibição da propaganda; (vii) cancelamento da autorização da operação; (viii) cancelamento da licença de operação, e (ix) intervenção na empresa que recebe recursos públicos.

A pena de multa variará de acordo com a gravidade da infração: (i) em infração menos grave, de R$ 2.000,00 (dois mil reais) a R$ 75.000,00 (setenta e cinco mil reais); (ii) em infrações graves, a partir de R$ 75.000,00 (setenta e cinco mil reais) a R$ 200.000,00 (duzentos mil reais), e (iii) em infrações brutas e sérias, de R$ 200.000,00 (duzentos mil reais) a R$ 1.500.000,00 (um milhão e quinhentos mil reais), e no caso de reincidência, pode ser aplicado o valor em dobro.

É importante destacar que a Lei 9.294/96 estabelece sanções diferentes daquelas previstas na Lei 6.437/77. A violação das disposições dessa lei submete a empresa infratora às seguintes penalidades: (i) advertência; (ii) suspensão, no meio de comunicação onde a publicidade foi publicada, de qualquer outra propaganda do produto por um período de até 30 dias; (iii) imposição da publicação do comunicado corretivo; (iv) apreensão do produto; (v) multa punitiva de R$ 5.000,00 a R$ 100.000,00, e (vi) suspensão de programas de rádio/TV, durante 10 minutos por cada minuto ou fração da duração do anúncio transmitido em violação da lei.

If the unlawful act involves the corruption of public officials, then the company can be subject to Law No. 8,429/92 ("Anti-Corruption Law"), as well as the relevant provisions of the Criminal Code. If the act or omission is also considered a violation of the rules of the Consumer Defense Code, the infringing company and individuals may be subject to criminal and civil liabilities.

Finally, in addition to these consequences, irregular marketing and promotional activities can also be considered a violation of competition rules.

Enforcement

ANVISA has significantly increased enforcement activities lately. The chart[2] below shows the increase in the number of fines imposed over the years.

Year	Amount of Fines (BRL)	Administrative procedures
2008	3,658,000	190
2009	8,224,120	171
2010	12,217,000	280

The table below represents the total numbers from the department responsible for the surveillance and inspection of marketing, advertisement and promotional activities.

Numbers of the Advertisement Inspection (2010)[3]	Total
Sanitary assessment imposed as a result of irregular advertisement	1325
Specific resolutions for advertisement suspension	32
Notifications issued for adequacy of the advertisement or requests of promotional materials	226

[2] http://portal.anvisa.gov.br/wps/wcm/connect/f8b9aa804885dbaeba8cbafa35813921/RelatorioGestaoGPROP_2010_baixa_11072011.pdf?MOD=AJPERES

[3] Idem.

Embora as sanções dirigidas pela Lei 6.437/77 são geralmente impostas como resultado de violações à legislação sanitária, as penalidades estabelecidas pela Lei 9.294/96 são aplicáveis às infrações relativas à propaganda de medicamentos e terapias. Portanto, a definição de qual regra deve ser utilizada é verificada caso a caso.

Se o ato ilegal envolver a corrupção de funcionários públicos, então a empresa pode estar sujeita a Lei no.8.429/92 (Lei Anticorrupção), assim como aos dispositivos do Código Criminal. Se o ato ou omissão também for considerado uma violação das regras do Código de Defesa do Consumidor, a empresa infratora e indivíduos estarão sujeitos à responsabilidade penal e civil.

Finalmente, além destas conseqüências, as atividades promocionais e de *marketing* irregulares também podem ser consideradas uma violação às regras de concorrência.

Aplicação

A ANVISA tem aumentado significativamente as atividades de aplicação das leis recentemente. A tabela;[2] abaixo mostra o aumento no número de multas impostas ao longo no decorrer dos anos.

Ano	Quantidade de multas (R$)	Procedimentos administrativos
2008	3.658.000,00	190
2009	8.224.120,00	171
2010	12.217.000,00	280

[2] http://portal.anvisa.gov.br/wps/wcm/connect/f8b9aa804885dbaeba8cbafaa35813921/RelatorioGestaoGPROP_2010_baixa_11072011.pdf?MOD=AJPERES

Numbers of the Advertisment Inspection (2010)	Total
Memoranda for the Management of Medical Products Inspection ("GFIMP") forwarded denounces non-registered products detected through advertisement or promotional materials	33
Decisions of closing of case due to lack of evidence	59
Decisions of closing of case for lack of sanitary irregularities	431
Meetings performed as requested by companies for clarification of advertisement and promotional materials	43
Procedures rules with imposition of fines	280

Criminal and Civil Liability

In addition to the administrative penalties mentioned above, companies and individuals involved in an act or omission considered a violation of the relevant sanitary, consumer and anti-bribery provisions can be subject to severe criminal and civil liability.

If patients (either individually or organized under patient associations) believe they have suffered damage, they may sue the medical device company that breaches the laws or rules on promotion of medical devices, and claim indemnification for damages.

Likewise, if the district attorney determines that the breach of the laws or rules on the promotion of medical devices is a threat to the society or public order, a public civil lawsuit may be brought against the medical device company.

It is considered a crime under Article 7, item VII of Law 8,137/1990 to induce consumers by providing a false or misleading declaration about the product being advertised. The penalty in such case is imprisonment for two to five years, plus a fine

Furthermore, the general principles of providing accurate and clear information to consumers must be obeyed in view of criminal implications, since the Brazilian Consumer Defense Code ("CDC") establishes several crimes in the case of an advertiser's noncompliance. The CDC considers it a crime to:

- not inform consumers through publicity about the risks or hazards offered by the product;

A tabela abaixo representa os números totais do departamento responsável pela vigilância e inspeção de atividades de *marketing*, propaganda e de promoção.

Números de Inspeção de Anúncios (2010)[3]	Total
Avaliação sanitária imposta em consequência de propaganda irregular.	1325
Resoluções específicas para suspensão de propaganda.	32
Notificações emitidas para reajuste da propaganda ou solicitação de materiais de promoção.	226
Memorandos para a Gestão de Inspeção de Produtos Médicos (GFIMP) encaminhando denúncias de produtos não registrados detectados através de materiais de propaganda ou promocionais.	33
Decisões de fechar o caso devido à falta de provas	59
Decisões de fechar o caso devido à falta de irregularidade sanitária	431
Reuniões realizadas conforme solicitadas pelas empresas para esclarecimento de materiais promocionais e de propaganda	43
Regras de procedimentos com imposição de multas	280

Responsabilidade Penal e Civil

Além das sanções administrativas acima mencionadas, empresas e indivíduos envolvidos em um ato ou omissão considerado uma violação às disposições sanitárias relevantes, de consumidor e anti suborno podem ser sujeitas à responsabilidade civil e criminal grave.

[3] Idem.

- give false or misleading information, or abstain from giving information about the nature, characteristic, quality, durability, price or warranty of the product;
- produce abusive or misleading publicity;
- produce publicity that could induce consumers to behave in prejudicial or dangerous ways to their health or safety; and
- abstain from organizing empirical, scientific and technical data that supports the publicity.

Depending on the infraction, the following penalties may apply: one month to two years imprisonment, fine, temporary suspension of rights, and community service. If convicted, the company may be required to publicize the crime and the sentence in the local media.

Furthermore, as stated by article 273, paragraph 1-B, item I of the Brazilian Criminal Code, responsible individuals may be subject to imprisonment for 10 to 15 years plus a fine if products which require sanitary registration are exposed to sale without it. The products intended for pharmaceutical and medical purposes are expressly included in this provision.

Moreover, granting benefits to government officials and healthcare professionals from the public sector who are involved in procurement is considered corruption, and established in Articles 317 and 333 of the Brazilian Criminal Code. According to the code, corruption consists of offering or promising to offer to public employees any benefit related to an express or implied request or suggestion that the public employee performs or refrains from performing, or even delays or expedites any act within the scope of his duties. Any gratuity or gift granted in order to obtain advantages in the sales of medical devices to public entities is considered bribery in Brazil. In such cases, the penalty is imprisonment up to 12 years, plus a fine.

The criminal consequences provided here apply to individuals involved in the infringement (typically the statutory directors of the company) but not to the company in its capacity as legal entity. With very few exceptions, Brazilian laws typically do not contemplate crimes committed by legal entities.

Contracts with Healthcare Professionals and Medical Institutions

Service relationships with healthcare professionals (usually with the key opinion leaders), and partnerships and cooperation arrangements with medical institutions, must be analyzed carefully for irregularities. In fact,

Se os pacientes (individualmente ou organizados em associações de pacientes) puderem construir um caso de dano, que poderiam processar a empresa do dispositivo médico que viole as leis ou regras sobre a promoção de dispositivos médicos e solicitem indenização por perdas e danos.

Da mesma forma, se o membro do Ministério Público verificar que a violação das leis ou regras sobre a promoção de dispositivos médicos pela empresa de dispositivos médicos representa uma ameaça à ordem pública ou à sociedade, uma ação civil pública poderá ser movida contra a empresa de dispositivos médicos.

Quanto aos aspectos penais, nos termos do artigo 7º, item VII da Lei 8.137/1990, é considerado um crime induzir os consumidores a erro fazer uma declaração falsa ou enganosa sobre o produto que está sendo anunciado. A pena neste caso é prisão de 2 a 5 anos, além de multa.

Ademais, os princípios gerais de informações precisas e claras aos consumidores devem ser obedecidos também em vista das implicações penais, uma vez que o Código Brasileiro de Defesa do Consumidor (CDC) estabelece vários crimes no caso do anunciante não cumprir com eles também. De acordo com o CDC, artigos 61 e subsequentes, por exemplo, considera-se crime (i) não informar os consumidores através da publicidade sobre os riscos ou perigos oferecidos pelo produto; (ii) dar informação falsa ou enganosa, ou abster-se de dar informações, sobre a natureza, característica, qualidade, durabilidade, preço ou garantia do produto; (iii) fazer publicidade abusiva ou enganosa; (iv) fazer publicidade que possa induzir os consumidores a se comportarem de forma prejudicial ou perigosa à sua saúde ou segurança; (v) abster-se de organizar dados empíricos, científicos e técnicos que apoiem a publicidade. Dependendo da infração, as seguintes penalidades podem ser aplicadas: de 1 mês a 2 anos de prisão, multa, suspensão temporária de direitos, e serviços comunitários. Ademais, em caso de condenação, a empresa pode ser obrigada a divulgar sobre o crime e a sentença na mídia local.

Outrossim, conforme afirmado pelo Código Penal Brasileiro, artigo 273, parágrafo 1-B, item I, os responsáveis podem estar sujeitos à pena de reclusão de 10 a 15 anos e multa, se os produtos que necessitarem de registro sanitário estiverem expostos à venda sem o mesmo. Os produtos destinados a fins médicos e farmacêuticos são expressamente incluídos nesta disposição.

observing the necessary formalities can be as important as complying with the rules.

Transparency in the relationship is important, as flaws in documentation can raise suspicions of fraud and unlawful behavior. This becomes more important when the healthcare professional is also a public servant or when the medical institution is government-owned.

Research and Consulting Contracts

Using healthcare professionals or medical institutions to conduct clinical trials and clinical studies is common and necessary in the industry.

Another common practice in the industry is the retention of healthcare professionals as marketing, medical or research and development consultants.

Because of the importance to the industry of retaining such services, legislation does not prohibit such practices. On the other hand, there are few rules for these kinds of arrangements. Because of the risk that relationships between the industry and healthcare professionals can be used to violate advertisement and promotional activities legislation, as well as to disguise corrupt practices, companies should monitor such activities closely.

The main consideration is to keep relationships transparent and at arm's length. When arrangements are directly with healthcare professionals or medical institutions, it is always important to document the relationship and abide by fair market practices.

Contracted healthcare professionals or medical institutions must be chosen for their expertise in respect of the services to be provided under the agreement. No commercial reason may be used as grounds for the choice and the healthcare professional or medical institution shall not be obligated to use/prescribe the company's products (i.e. no *quid pro quo* intent).

The services agreement must be documented in a formal instrument, detailing the services to be performed, the consideration to be paid for the services and other customary provisions in this type of arrangement. One important clause that should be included is the reciprocal obligation of the company and the healthcare professional (or medical institution) to disclose the relationship whenever a potential conflict of interest arises. As the activities performed by the healthcare professional might involve relationships with several regulatory authorities, the usual anti-corruption and compliance clause should be included in the instrument.

Além disso, a concessão de quaisquer benefícios aos funcionários públicos e profissionais de saúde do setor público envolvidos com aquisições, é entendida como prática de corrupção, e estabelecida nos artigos 317 e 333 do Código Penal Brasileiro. Segundo o Código Penal Brasileiro, a corrupção consiste na oferta ou promessa de oferecer aos funcionários públicos qualquer benefício relativo a um pedido expresso ou implícito ou sugestão de que o funcionário público executa ou se abstenha de realizar, ou até mesmo atrasar ou acelerar qualquer ato dentro do escopo de suas tarefas. Qualquer gratificação ou presentes concedidos a fim de beneficiar, por exemplo, em processos de vendas de dispositivos médicos a entidades públicas é considerada crime de suborno no Brasil. A pena neste caso é prisão de até 12 anos, além de multa.

As conseqüências penais previstas aqui se aplicariam aos indivíduos envolvidos na prática da infração (normalmente os diretores estatutários da empresa), mas não à empresa na qualidade de pessoa jurídica. Com muito poucas exceções, a legislação brasileira não contempla crimes cometidos por pessoas jurídicas.

Contratos com Profissionais de Saúde e Instituições Médicas

Uma prática comum na indústria, o relacionamento de serviços com profissionais de saúde (geralmente com os líderes de opinião) e parcerias e acordos de cooperação com instituições médicas devem ser analisados com cuidado, pois pode ser uma fonte de irregularidades. Na verdade, observar as formalidades necessárias pode ser tão importante como estar em conformidade com as regras.

Buscar-se-á sempre transparência na relação, devido ao fato de que falhas na documentação podem levantar suspeitas de fraude e o envolvimento em ato ilícito. Isso se torna mais relevante quando o profissional de saúde também é um funcionário público ou quando a instituição médica é governamental.

Pesquisa e Contratos de Consultoria

Usar os profissionais de saúde ou a instituição médica para realizar testes e estudos clínicos é um fato comum e necessário para a indústria. Outra prática comum por parte da indústria de dispositivos médicos e farmacêuticos é manter os profissionais de saúde como consultores de *marketing*, de área médica e de pesquisa e desenvolvimento.

The consideration for services must be commensurate with market practices. Preferably, the healthcare professional or medical institution may only be remunerated for specific services, and the company must obtain something objective in return. The amounts paid must be by reference to a fair market value. Documentary evidence of the performance of services (such as the reports and schedule of appointments) must be kept by the company.

Reimbursement for accommodation, meal and transportation can only be paid for expenses directly related to the services provided, and the amounts must be reasonable and not exaggerated. It is recommended not to offer the amounts covering the expenses in advance, but rather to reimburse the expenses upon presentation of the respective receipts.

Entertainment-related expenses are not reimbursable and the payment of lodging must be limited to attending the seminar, meeting, event, etc. For longer trips, the company may pay for expenses related to the day before and the day after the event

Finally, if the healthcare professional is also a government official, even on a part-time basis, or the medical institution is government-owned or funded, additional precautions should be taken, as the risks of an improper relationship increase significantly.

Speakers' Contracts and Exhibitors' Agreements

A company may offer financial support to organizations promoting conferences and to healthcare professionals attending such conferences. Such third-party conferences must be of a professional/scientific or charitable nature. The same principles that relate to service agreements apply, thus formalization in a written document, lack of *quid pro quo* intent and transparency (publicity) of the relationship must be taken into account.

The hospitality offered to the healthcare professional (travel costs, meals, overnight stay and registration fees paid by the company) must remain an accessory and be necessary to the attendance of the healthcare professional; must be reasonable in level and must not benefit other persons (e.g., spouses). Payment or reimbursement of expenses related to entertainment is not acceptable. This applies to conferences and training. For longer trips, the company can pay for expenses related to the day before and the day after the event.

RDC 96/08 provides that, in relation to conferences concerning medicines, the sponsoring of a healthcare professional must be disclosed to the

Tendo em vista a importância de manter esses serviços pela indústria de produtos médicos, a legislação não proíbe tal prática. Por outro lado, não há muitas regras para este tipo de acordos. Considerando que a relação entre a indústria e os profissionais de saúde pode ser usada para violar a legislação das atividades da propaganda e da promoção, assim como para disfarçar práticas de corrupção, as empresas devem se preocupar em acompanhar de perto essas atividades.

O principal aspecto a ser considerado é a manutenção de um relacionamento transparente e razoável. Sempre que o arranjo for diretamente com o profissional de saúde ou com a instituição médica, é importante documentar a relação e cumprir com as práticas justas de mercado.

A instituição médica ou o profissional de saúde contratado deve ser escolhido por sua experiência no âmbito do contrato de serviço; razões comerciais não podem ser usada como base para a escolha e não pode haver obrigação do profissional de saúde ou da instituição médica de usar/prescrever os produtos da empresa (ausência de intenção de *quid pro quo*).

O acordo de serviços deve ser documentado em um instrumento formal, detalhando os serviços a serem prestados, a remuneração a ser paga pelos serviços e outras disposições costumeiras neste tipo de acordo. Uma cláusula importante que deve estar presente é a obrigação recíproca da empresa e o profissional de saúde (ou a instituição médica) de divulgar a relação sempre que surgir um potencial conflito de interesses. Como as atividades a serem desempenhadas pelo profissional de saúde podem envolver relações com várias autoridades reguladoras e tais atribuições são principalmente sob a responsabilidade do profissional de saúde, as costumeiras cláusulas anticorrupção e *compliance* devem estar incluídas no instrumento.

O pagamento pelos serviços deve ser adequado para as práticas de mercado e, de preferência, o profissional de saúde ou a instituição médica só podem ser remunerados por serviços específicos, e a empresa deve obter algo objetivo em troca. Os valores pagos devem ser de acordo com o valor justo de mercado. Provas documentais do desempenho dos serviços (tais como os relatórios, o calendário das consultas, etc.) devem ser mantidas pela empresa.

Reembolso de refeições, alojamento e transporte só podem ocorrer com relação a custo diretamente relacionado com os serviços prestados e os valores devem ser razoáveis e não exagerados. Recomenda-se a não oferecer os montantes para cobrir as despesas com antecedência, em vez disso, reembolsar as despesas mediante a apresentação dos respectivos recibos.

organizers of the conference. The sponsorship must also be disclosed in the event program and at the beginning of each lecture presented by the healthcare professional. Finally, the sponsorship must be registered in the conference records and the companies may not advertise drugs in the events' materials.

The entity responsible for the organization of the event/seminar must inform ANVISA three months in advance about the possibility of sponsored events. Hence, it is recommended to highlight obligations in relevant agreements with the organizer.

Donations to Medical Institutions, Charitable Organizations and NGOs

Donations to charitable organizations, medical institutions and non-governmental organizations are allowed, but should be reviewed carefully by the appropriate personnel within the company. The same rule of transparency, formalization and lack of *quid pro quo* intent applies.

It is recommended to have an agreement, a letter-agreement or similar instrument in place outlining the major characteristics of the donation. Also, the donation should be made in goods or payment of necessary services (such as work), rather than monetary grants. Reimbursement of expenses is also acceptable as long as there is a provision ensuring good use of the money (for instance, request for three price proposals).

In addition, the donation should not be conditional on future purchases or business. For instance, the donation of a machine should not be dependent on any future relationship withthe donating company. Any hidden intent can be considered a fraudulent attempt to circumvent the legislation. We are aware of a practice involving the donation of funds to a supposed charitable organization, which then sponsored lawsuits against the government, government, ultimately benefiting the pharmaceutical company[4].

Finally, companies should be aware of donations to medical institutions or other legal entities that can be used for one's personal benefit. Donating diagnostic equipment to a medical institution is different from donating several computer tablets/notebooks to the institution (as they will ultimately be used by the officer of the institution).

[4] The law enforcement authorities considered such practice as fraud against the public health financing system.

As despesas com entretenimento não podem ser sujeitas a reembolso e o pagamento do alojamento deve ser limitado ao período para participar do seminário, reunião, evento, etc. Em viagens longas, a empresa pode pagar as despesas relacionadas com o dia anterior e o dia seguinte ao evento.

Finalmente, se o profissional de saúde também for um funcionário do governo, mesmo em um trabalho de tempo parcial, ou a instituição médica for governamental ou receber verba do governo, então precauções adicionais devem ser tomadas, pois os riscos de relação imprópria aumentam significativamente.

Contratos dos Palestrantes e Acordos de Expositores

Empresas podem oferecer apoio financeiro a organizações que promovem conferências e a profissionais de saúde que participam destas conferências. Essas Eventos de Terceiros devem ser de natureza profissional /científica ou para fins de caridade. Os mesmos princípios dos acordos de serviços se aplicam, portanto, a formalização de um documento escrito, a falta de intenção *quid pro quo* e a transparência (publicidade) da relação devem ser observadas.

A hospitalidade oferecida ao profissional de saúde (despesas de viagem, refeições, pernoite e taxas de inscrição pagas pela empresa) deve permanecer suplementar e necessária para a participação do profissional de saúde, deve ser razoável em nível, e não deve beneficiar outras pessoas além do profissional de saúde (ex. cônjuges). O pagamento ou reembolso de despesas com entretenimento não é aceitável. Isto se aplica tanto a Conferências como Treinamento. Em viagens longas, a empresa pode pagar as despesas relacionadas com o dia anterior e o dia após o evento.

A RDC 96/08 prevê que, em relação às Conferências que dizem respeito aos medicamentos, o patrocínio de um profissional de saúde deve ser divulgado para os organizadores da Conferência. O patrocínio também deve ser divulgado no programa do evento e no início de cada palestra apresentada pelo profissional de saúde. Finalmente, o patrocínio deve ser registrado nos registros da Conferência e as empresas não podem fazer qualquer tipo de propaganda de medicamentos nos materiais do evento.

A entidade responsável pela organização do evento/seminário deve informar à ANVISA, com três meses de antecedência, sobre a possibilidade de eventos patrocinados. Por isso, é recomendável destacar a obrigação nos acordos pertinentes com o organizador.

Recommendations

Advertising and promotion of medical products in Brazil can entail some potential (and severe) risks. In addition to the administrative sanctions that can be imposed by regulatory authorities, mainly ANVISA (which has been improving its enforcement activities), the broad range of legal matters involved in the marketing practice can bring about criminal and civil liabilities due to violations of anti-corruption statutes, consumer defense provisions, and sanitary and competition legislation. The following recommendations can mitigate the risks connected with a company's promotional and advertising efforts:

- Review the gifts and benefits policies.
- Know the local regulations, as they change frequently and can impact some ongoing practices.
- Never make any benefit conditional on the prescription of drugs or the purchase of equipment (avoid *quid pro quo* practices).
- Always be transparent.
- Formalizing and gathering evidence of the performances of the arrangements is crucial. It is not only important to be honest, but also to look honest.
- Look for the real value of the healthcare professionals and medical institutions as services providers.

Doações a Instituições Médicas, Organizações de Caridade e ONGs

Doações para organizações de caridade, instituições médicas não governamentais são permitidas, mas devem ser revistas cuidadosamente por pessoal apropriado dentro da empresa. A mesma regra de transparência, formalização e falta de intenção *quid pro quo* se aplica.

Na verdade, é recomendável ter um acordo, carta-contrato ou instrumento similar, descrevendo as características principais da doação. Além disso, a doação deve ser feita preferencialmente em bens ou o pagamento dos serviços necessários (como um trabalho), em vez de uma doação em dinheiro. Reembolso de despesas também pode ser aceito, desde que haja uma disposição que garanta o bom uso do dinheiro (por exemplo, pedido de três propostas de preços).

No mais, a doação não deve ser condicionada a futuras compras ou negócios. Por exemplo, a doação de uma máquina não deve ser dependente da futura compra de consumíveis ou de manutenção da empresa doadora. Qualquer intenção oculta pode ser considerada uma tentativa fraudulenta de burlar a legislação. Há uma prática que consiste na doação de fundos para a suposta organização de caridade, que então patrocinou ações judiciais contra o governo, beneficiando a empresa farmacêutica em última análise.[4]

Finalmente, atente-se para doações para instituições médicas ou outras entidades legais que, em última análise podem ser usadas para benefício pessoal de um indivíduo. Doar equipamentos de diagnóstico para uma instituição médica é diferente de doar vários *tablets/notebooks* para a instituição (pois será, em última análise, usado pelo executivo da instituição).

Recomendações

As atividades de publicidade e promocionais para produtos médicos no Brasil é uma necessidade que pode incorporar alguns riscos potenciais (e graves). Conforme mencionado acima, além das diversas sanções administrativas que podem ser impostas pelas autoridades reguladoras, principalmente a ANVISA (que tem melhorado suas medidas de fiscalização), o amplo leque de questões legais envolvidas nas atividades promocionais também pode trazer responsabilidades civis e criminais, devido a violações à legislação de

[4] As autoridades de aplicação de lei consideraram essa prática como uma fraude ao sistema de financiamento da saúde pública.

anti corrupção, disposições de defesa do consumidor, legislação sanitária e da concorrência. As seguintes recomendações podem mitigar os riscos associados aos esforços de promoção e publicidade da empresa:

- Revisar as políticas de presentes e benefícios.
- Conhecer os regulamentos locais, pois eles mudam com freqüência e podem afetar algumas práticas em andamento.
- Nunca condicione qualquer tipo de benefício para a prescrição dos medicamentos ou a compra do equipamento (nunca pratique o *quid pro quo*).
- Seja transparente, sempre.
- A formalização e coleta de provas dos execução dos acordos é essencial. Não só é importante ser honesto como também parecer honesto.
- Procure o valor real agregado pelos profissionais de saúde e das instituições médicas prestadores de serviços.

Chile

Rafael Pastor, Sebastian Doren

Legislation on Medical Product Advertising

The law governing on pharmaceutical advertising is mainly regulated by Supreme Decree No. 1876-1895 of the Ministry of Health, which approved the Regulations for the National Control System of Pharmaceutical Products, Food for Medical Use and Cosmetics.

Other rules pertaining to this matter are scattered in several other laws and rules that are stated below.

The rationale behind the Chilean legal provisions on advertising of medical products is to prevent healthcare professionals and consumers from receiving misleading information about medical products which could lead to health risks for consumers in the market.

Chile is not as heavily regulated when it comes to pharmaceutical advertising.

The Regulatory Framework

Pharmaceutical advertising is mainly regulated by Supreme Decree No. 1876-1895 of the Ministry of Health ("DS N° 1876/95") dated 5 July 1995, which approved the Regulations for the National Control System of Pharmaceutical Products, Food for Medical Use and Cosmetics.

Pharmaceutical advertising is also regulated in the following pieces of legislation:

- Sanitary Code Decree with Force of Law (D.F.L.) No 725/67
- Supreme Decree No. 404/83, corresponding to the Regulation on Narcotic Drugs
- Supreme Decree No. 405/83, which corresponds to Regulations on Psychotropic Products
- Consumer Protection Law No. 19.496 ("Consumer Law")
- Antitrust Decree Law No. 211 which regulates Free Competition
- Unfair Competition Law No. 20.169
- Ethics Code of the Medical Association of Chile
- Public Procurement Law No. 19886

Definition of Advertising

DS N° 1876/95 article 4y defines advertising as "... set of procedures used to raise awareness, highlight, distinguish directly or indirectly to the public, via any means or diffusion, the characteristics, terms of distribution, sale and use of the products covered by this regulation and in accordance with its provisions on the subject matter."

DS N° 1876/95 article 4z defines promotions to professionals in the following terms: "...set of communication procedures, aimed at professionals legally authorized to prescribe pharmaceutical products, as appropriate, in order to publicize and report on the products covered by this regulation."

The differentiation between advertising and promotions to professionals is not irrelevant because according to DS N° 1876/95, advertising can only be carried out in relation to over-the-counter pharmaceutical products ("OTC"). However, advertising regarding prescribed pharmaceutical products is strictly prohibited, except for promotions targeted at professionals who are authorized to actually prescribe pharmaceuticals.

Permitted and Prohibited Practices

The Institute of Public Health ("ISP") is the public institution responsible for granting sanitary registrations for pharmaceutical products. Being a titleholder of a sanitary registration (marking approval registration) is a legal requirement to import, produce and distribute these products in Chile.

In this sense, the advertising and/or promotion of pharmaceutical products does not require prior approval by the ISP but is nonetheless subject to various conditions.

For example, products sold under medical prescription may be announced to qualified professionals authorized for prescribing and dispensing the same, through advertisements intended to publicize their entry into or presence in the market, containing only the official name adopted by the ISP in the sanitary registration, together with their identification on the main label, the name of the manufacturing laboratory or importer and the badge of the establishment, if any, or by fully replicating their approved labels or packages in their sanitary registration or in a later resolution issued by ISP.

The promotion of pharmaceutical products sold under medical prescription and retained medical prescription should be directed solely to professionals

legally authorized to prescribe pharmaceutical products, and chemical engineers who are responsible for dispensing medications.

The scientific information included in the promotion that is delivered to the professional to promote products sold under medical prescription and retained medical prescription must be true, accurate, complete and testable, and must be in line with the therapeutic use and properties approved when the sanitary registration was issued. It must also state the formula, the indications, interactions, contraindications, precautions and warnings, as well as collateral and side effects, dose and risk of toxicity and its treatment. All information must be supported by recognized scientific literature when the sanitary registration of the product is granted as well as its subsequent amendments. Information on side and collateral effects must be backed up by studies that indicate their occurrence and that they are available for professionals upon request.

Information regarding the demonstrated biodisponibility of products sold under a medical prescription in appropriate cases must be stated in information brochures for professionals. This brochure must also state whether the product is a therapeutic equivalent with respect to other previously registered.

When it comes to the advertising and/or promotion of OTC pharmaceutical products, it is mandatory to only use a complete and accurate reproduction of your tags and labels, patient information brochures, text, and attachments that have been approved by the ISP when the sanitary registration was actually granted or when it is expressly requested in connection to a product that is already registered.

Furthermore, the advertising or promotion of pharmaceutical products can only refer to the therapeutic indication approved by the ISP when granting a sanitary registration. This advertising or promotion should also include use directions or indications, precautions, contraindications, interactions, adverse reactions and other warnings as appropriate. If the pharmaceutical product has other therapeutic indications but these have not been previously approved by the ISP, advertising or promotion of such indications would be considered illegal.

Advertising and promotion of pharmaceutical products can not contain titles, figures, references or interpretations that are not verifiable or, in any way, are not in accordance with the nature of the product or its approved properties.

It is strictly prohibited to donate, deliver or distribute freely pharmaceutical products for advertising and promotional purposes, except for medical samples that correspond to a unit of a registered medicinal product that is exclusively distributed freely to professionals who are legally entitled to prescribe them. These products must also have labeling identical to the registered product, which may include information for the professional.

Advertising and promotion of simple homeopathic preparations listed in the Chilean Pharmacopoeia, in Wilmar Schwabe Pharmacopoeia, or other recognized ones by the Ministry of Health of Chile for pharmaceuticals products, and that are presented by their generic name, and also others that respond to trading names that are simple or form mixtures, herbal medicines, which are labeled and finished pharmaceutical products with active substances that are exclusively herbal drugs or preparations of vegetables, and products for parenteral administration, whatever their composition, properties or effects, can not include statements or indicate certainty of results that are not scientifically verifiable.

In order to control advertising or promotion, the ISP can request from manufacturers and importers any information, clinical studies, scientific papers and any other item used for such purposes, as well as request this information or data to any corporation (company) or person that holds the same.

The amendments to the promotion authorized by the sanitary registration may be requested by the owner of the same, which shall be approved or rejected by resolution issued by the ISP within 10 working days of receipt. The ISP may also, based on a grounded resolution, modify the authorized promotion by providing notice to the holder of the sanitary registration of at least five working days, so that they can take appropriate action.

It is important to note that DS N° 1876/95 does not directly prohibit the handing out of gifts or donations to medical professionals. However, DS N° 1876/95 does prohibit the use of incentives of any kind, aimed at professionals responsible for prescribing and dispensing of pharmaceuticals products, which tend to lead to irrational drug use.

Furthermore, money donations for any purpose must be justified in order to be recognized tax wise as a necessary expense for any company, so this kind of practice should be managed very carefully when undertaken.

Consequences of Breach

The ISP has the authority to suspend or prohibit advertising and promotion of pharmaceutical products based on a grounded administrative decision or resolution.

The sanitary registration of a pharmaceutical product may be canceled if significant changes are confirmed in terms announced in the labeling, advertising or promotion to the professional, that have not been ISP-approved in sanitary registration.

The sanitary registration of a pharmaceutical product may also be canceled if the proven breach of the provisions relating to advertising and promotion actually compromises public health.

Breaches of the legal standards set by DS N° 1876/95 are sanctioned by the ISP, prior to the fulfillment of administrative proceedings, in accordance with the provisions of Section X of the Sanitary Code and other provisions in the legislation

All decisions issued by the ISP on matters referred to in DS N° 1876/95 can be challenged before the Ministry of Health by filing a complaint appeal within five days from the date on which the respective resolutions were served or notified.

Breach of any of the rules in the DS N° 1876/95, except for those provisions that have a special sanction, are punished with a fine that ranges from one-tenth of a monthly tax unit (USD8) to one thousand tax units (USD80,000). Re-offenses can be punished with up to twice the original fine.

The aforementioned breaches may all be punished with the: closure of facilities, buildings, houses, buildings, places of work where the offense was committed; cancellation of operating licenses or permits issued; or cessation of works and confiscation, destruction and distortion of products, where appropriate.

Competitors can enforce their rights against breaches of rules on advertising of pharmaceutical products established in the DS N° 1876/95, either by filing an action before the Antitrust Court or a Civil Court if the offense can be considered an act of unfair competition, for which you can claim compensation for damages and the cessation of acts of unfair competition, among other actions. Obviously, those affected can also file actions before the ISP in order to seek the respective administrative responsibilities.

Professional Codes of Conduct[1]

The Code of Ethics of the Medical Association of Chile requires the doctor to abide by the following:

- Sustain independent professional relationship with companies that produce or distribute goods of pharmaceutical or clinical use. The decisions that affect their patients should always ensure their best interest, and should never pursue personal benefit.
- Only accept modest gifts or invitations to meetings or conferences provided by companies of pharmaceutical or clinical products, when they do not limit or restrict their professional independence.
- Only accept full or partial funding of vocational training programs from medical product companies or private health institutions when these programs are taught by recognized academic institutions, and the funding is disclosed to all concerned parties. In any case, the acceptance must never compromise professional freedom of the doctor to ensure the interests of the patient.

According to the Code of Ethics of the Medical Association, the acceptance of funding from companies of pharmaceutical clinical products, in whole or in part, to activities outside the medical profession, such as travel for tourism purposes, or similar means, is a breach of professional ethics.

Likewise, the professional who accepts donations that are not in harmony with those which, according to custom, are acceptable, considering the amount and nature of the given object, also entails the same offense.

The doctors must inform the Medical Association of Chile of any activities of companies of pharmaceutical or clinical products which are inclined to restrict their professional independence or condition their medical action to favor the interests of these companies.

Penalties for breaches of the rules of professional conduct set forth in the Code of Ethics of the Medical Association of Chile are as follows:

- Warning
- Censorship

[1] The Code of Ethics of the Medical Association of Chile is only mandatory for those physicians who are members of the Association of professionals. It is not mandatory in Chile for an MD to become a member of the Association to practice medicine.

- Fine
- Suspension as a partner
- Ineligibility to hold office unions positions
- Expulsion from the Medical Association of Chile

Criminal and Civil Liability

The Criminal Code of Chile establishes simple crimes and crimes against public health, and in Article 313 d, holds an offense according to the following description:

"The person who manufactures or knowingly in any capacity sells medicinal substances that are deteriorated or adulterated in their kind, quantity, quality or proportions, in order to be hazardous to health due to their harmfulness or the erosion of their healing properties, shall be punished by imprisonment in its medium degree up to a maximum fine of six to fifty monthly tax unit.

"If the manufacture or sale is clandestine, this shall be considered as an aggravating circumstance."

This is an offense that is punishable with a penalty that ranges from a fine of 50 UTM (USD3700) up to a penalty of incarceration (ranging from 541 days to three years and one day to 819-1095 days).

With regard to civil liability, in the case of a pharmaceutical product that causes damage to health, the affected individuals have the right to sue the manufacturer or distributor in order to seek compensation, based on tort regulations set in Chile's Civil Code.

Additionally, it is important to bear in mind the Consumer Law that also enables consumers to file legal actions against the manufacturer or distributor of a pharmaceutical product. The action can be filed both individually or collectively, in order to seek compensation and payment of fines.

Responsibility of Public Officials in Public Procurement Processes[2]

Public Procurement Law No. 19886 does not establish any offense when it comes to procurement fraud, so in order to determine criminal responsibility of a public official, it is necessary to resort to general statutory law.

Bribery

Bribery is defined as the active or passive conduct of a public official that seeks an unlawful retribution in the fulfillment of their position or post. It also entails an active or passive conduct of a person that seeks to give a public official an unlawful retribution in the fulfillment of their position or post. Provisions 248 to 251 state and describe the different kinds of bribery that are considered an offense.

Bribery by the fulfillment of a duty (provision 248 of the Criminal Code): Any civil servant who solicits or accepts gratuities in excess of those afforded to his position, or a benefit for himself or any third party for performing or having performed activities within his purview of responsibility and, therefore, is not entitled to any such gratuities, shall be punished with suspension as applicable and a fine ranging from 50 percent to 100 percent of the solicited or accepted gratuities or bribes.

Bribery by the infringement of a duty (provision 248 bis of the Criminal Code): Any civil servant who solicits or accepts any bribe for himself or any third party to not perform or having failed to perform any activity within his purview of responsibility or to engage or for having engaged in any activity that constitutes a breach of his duties, shall be punished with lesser imprisonment in its minimum to medium degrees and exceptionally or completely disbarred from any temporary civil service positions or duties in any degree, and fined a sum amounting to 100 percent to 200 percent of the solicited or accepted bribes.

Bribery by committing a public administrative felony (provision 249 of the Criminal Code): Any civil servant who solicits or accepts bribes for himself or a third party for committing any of the felonies or misdemeanors indicated herein or in paragraph 4 of Title III, shall be exceptionally disbarred from permanent civil service positions and completely disbarred from temporary

[2] This part is based on Transparency and Integrity Manual of the State Administration, published by the Government of Chile. Available from: www.serviciocivil.gob.cl/sites/.../141009_Manual_transparencia.pdf.

civil service positions, or else completely disbarred from permanent civil service positions, and fined from 100 percent to 300 percent of the solicited or accepted benefit.

The foregoing is notwithstanding the penalty applicable to the crime committed by the civil servant, which shall not be lower, in any case, to the lesser imprisonment in medium degree.

Bribery (provision 250 del Criminal Code): Whoever offers or consents to give any civil servant a bribe, in his benefit or the benefit of a third party, to engage in actions or fail to act indicated in Articles 248, 248-bis and 249, or for having incurred or committed the same, shall be penalized with the same monetary and disbarment as provided therein.

With regard to bribes consented to or offered in connection with the actions or failures to act indicated in Article 248-bis, the briber shall be further sanctioned with lesser imprisonment in the medium degree in case of the benefit offered, or lesser imprisonment in the minimum degree in case of the consented benefit.

In the case of bribes consented to or offered in connection with felonies or misdemeanors indicated in Article 249, the briber shall be sanctioned also with lesser imprisonment in the medium degree in case of the benefit offered, or lesser imprisonment in its minimum to medium degree in case of the consented benefit. In these cases, the briber may not also be sanctioned for the responsibility he may have had in the felony or misdemeanor committed by the civil servant.

Recommendations

When granting a sanitary registration, the ISP will not indicate which advertising materials to be used by the registrant meet the requirements established by DS N° 1876/95. However, the only material that can be used are brochures for promotion to professionals and information brochures for patients, as well as advertising texts previously approved by the ISP.

Promotional materials for pharmaceutical products share the same general advertising requirements applicable to all products in order to prevent consumers from receiving information that is false, misleading or error-inductive. However, the provisions governing the advertising of these products provide additional requirements and thus, the ISP monitors very closely any promotional materials used in connection to these kind of products.

In this respect, before investing in any promotional material or advertising for pharmaceutical products, it is highly advisable to check thoroughly that the material only uses the scientific denominations that correspond to the registered product, along with the name of the producer, or alternatively, an exact reproduction of the labels approved by the sanitary registration granted by the ISP, as well as only therapeutic indications indicated in the same and not other indications that the product does not bear.

Failure to follow these recommendations could result in a risk that registered pharmaceutical products are kept in the market and could include the potential cancellation or suspension of sanitary registrations, as well as fines and possible judgments that order compensation for damages.

Colombia

Georgette Olga Otero

Introducción

En Colombia, la promoción de los productos médicos se deberá hacer de conformidad con leyes y decretos nacionales y resoluciones de órganos del estado que regulan directamente los parámetros bajo de los cuales tal promoción se puede hacer. En adición, normas legales que se dirigen a conducto penal, protección del consumidor, competición desleal, concursos/ juegos de azar, y el conducto de los médicos también afecta como se puede promocionar los productos médicos legalmente. Por último, también se debe considerar normas éticas no obligatorias.

Marco regulatorio para la promoción de productos médicos

¿Cuáles leyes rigen la promoción de productos médicos?

En Colombia la promoción de dispositivos médicos se rige esencialmente por el Decreto 4725 de 2005. La promoción de medicamentos se rige esencialmente por el Decreto 677 de 1995. Además, la publicidad de medicamentos de venta libre está reglamentada por la Resolución 4320 de 2004 del Ministerio de Protección Social (ahora denominado el Ministerio de Salud y Protección Social). Ambos el Ministerio de Salud y Protección Social y el Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA) regulan la promoción de las dos clases de productos.

¿Qué otras disposiciones o normas rigen la promoción de productos médicos? (p.ej. códigos de conducta profesional)

La Ley 1480 de 2011 regula la promoción de productos médicos en asuntos relacionados a la protección del consumidor y Ley 256 de 1996 regula su promoción en asuntos relacionados a la competencia desleal. La Superintendencia de Industria y Comercio vigila tales asuntos.

Además, el Código de Ética Médica, Ley 23 de 1981, contiene provisiones relevantes a la promoción de tales productos.

La Ley 1438 de 2011, Artículo 106, modificado por la Ley 1474 de 2011, Artículo 133, prohíbe la promoción u otorgamiento de cualquier tipo de prebendas o dádivas, sean estas en dinero o en especie, a trabajadores

Colombia

Georgette Olga Otero

Introduction

In Colombia, the promotion of medical products must be done in conformity with national statutes, national decrees, and resolutions of government agencies that directly regulate the parameters within which such promotion may be performed. In addition, legal norms that address criminal conduct, consumer protection, unfair competition, contests/games of chance and physician conduct also affect how medical products may legally be promoted. Finally, non-binding ethical rules in Colombia should also be considered.

Regulatory Framework for the Promotion of Medical Products

Laws

In Colombia, the promotion of medical devices is governed essentially by Decree 4725 of 2005. The promotion of drugs is governed essentially by Decree 677 of 1995. In addition, the promotion of over-the-counter ("OTC") drugs is governed by Resolution 4320 of 2005 of the Ministry of Social Protection (now named the Ministry of Health and Social Protection). The Ministry of Health and Social Protection and the National Institute of Surveillance of Drugs and Food ("INVIMA") regulate the promotion of both types of products.

Rules, Regulations and Codes

Law 1480 of 2011 regulates the promotion of medical products in matters related to consumer protection, and Law 256 of 1996 regulates the promotion of these products in matters related to unfair competition. The Superintendency of Industry and Commerce oversees such matters.

In addition, the Physicians Code of Ethics, Law 23 of 1981, contains provisions relevant to the promotion of such products.

Law 1438 of 2011, Article 106, as modified by Law 1474 of 2011, Article 133, prohibits the promotion or giving of any type of perk or gift, either monetary or in kind, to workers (either employed or contracted) of the

(empleados o contratados) de las entidades del Sistema General de Seguridad Social en Salud y trabajadores independientes. Asimismo, el Código Disciplinario Único, Ley 734 de 2002, la cual se aplica a los funcionarios públicos y particulares con funciones públicas, tiene aplicación potencial.

Por último, la promoción indebida de productos médicos potencialmente implica ciertas leyes penales como el soborno, la concusión, el cohecho y el soborno transnacional,[1] y leyes contra la corrupción.[2]

¿Qué licencia de mercadeo se necesita para poner un producto médico en el mercado?

Para que un dispositivo médico o un medicamento puedan ser puestos en el mercado colombiano se necesita un registro sanitario. En el caso de los productos importados, este registro sanitario es verificado para dar un visto bueno de importación y nacionalizar las importaciones.

¿Quién otorga esa autorización? INVIMA.

¿Se permite poner productos médicos en el mercado sin esa autorización? No.

Prácticas permitidas y prohibidas

Publicidad de productos médicos

Si, tanto para dispositivos médicos como para medicamentos, se deben suministrar a los consumidores la información suficiente para que estos productos sean usados de forma segura.

La promoción y la publicidad de los medicamentos y dispositivos médicos deben ajustarse a la información autorizada en el registro sanitario y hacerse de conformidad con las disposiciones técnicas vigentes para estos asuntos. Tal información tiene que ser veraz y tener el respaldo científico correspondiente. En consecuencia, no se deben exagerar los beneficios de su uso.

[1] Ley 599 de 2000.
[2] Decreto 126 de 2010 (mediante el cual se dicta disposiciones sobre la corrupción en el Sistema General de Seguridad Social en Salud); Ley 970 de 2005 (por la cual se aprobó aprobó la Convención de las Naciones Unidas contra la Corrupción); Ley 190 de 1995 (mediante la cual se fijan disposiciones con el fin de erradicar la corrupción administrativa).

entities within the General System of Social Security for Health. Likewise, the Disciplinary Code, Law 437 of 2002, which applies to public servants and private entities exercising public functions, has potential application.

Finally, the wrongful promotion of medical products potentially implicates certain criminal laws,[1] including types of bribery and extortion, as well as anti-corruption laws.[2]

Marketing Authorization

In order for a medical device or drug to be put on the market in Colombia, a product registration must be obtained. In the case of imported products, their product registration is verified in order to be approved for importation and nationalization.

Market authorization is granted by INVIMA.

Medical products are prohibited from sale without such authorization.

Permitted and Prohibited Practices

Advertising Medical Products

With regard to both medical devices and drugs, consumers must be provided with information regarding the product's safe use.

The promotion and advertising of drugs and medical devices must conform with the information authorized in the product registration and conform to current applicable technical norms. The information must be truthful and there must be scientific support. As a consequence, the benefits of use may not be exaggerated.

For prescription drugs, information and publicity may only be directed at physicians (or dentists, if applicable) and should specify its instructions, effects, therapeutic uses, contraindications, side effects, risks of administration, risk of dependency, and other precautions and warnings, without omitting any items that are contained in scientific literature or were

[1] Law 599 of 2000.
[2] Decree 126 of 2010 (addressing corruption in the General System of Social Security for Health); Law 970 of 2005 (approving the United Nations Convention against Corruption); Law 190 of 1995 (addressing bureaucratic corruption).

Para medicamentos de prescripción, la información y propaganda solo puede ser dirigida al cuerpo médico (u odontológico, si aplica), y deberán especificarse las acciones, indicaciones, usos terapéuticos, contraindicaciones, efectos colaterales, riesgos de administración, los riesgos de farmacodependencia y las otras precauciones y advertencias, sin omitir ninguna de las que figuren en la literatura científica o fueren conocidas por los fabricantes. Igualmente, deberá siempre citarse la bibliografía sobre la cual se basa la información, e identificarse el principio activo con su nombre genérico, el cual, en el caso de medicamentos esenciales, irá en igual de caracteres a los del nombre o marca del medicamento.

En Resolution 4320 of 2005 se encuentre requisitos especiales que aplican a la promoción de medicamentos de venta libre.

Expresiones promocionales en la publicidad de un producto médico (y en la información científica y promocional) debe contar con el respaldo de la información científica. Además, se requiere que tales expresiones debe ser fiel a la verdad, ajustarse a lo autorizado en el registro sanitario y acorde a las normas técnicas y legales aplicables, y no se exagera las bondades que pueda ofrecer su uso. Ver la respuesta a la pregunta 4 para más información.

El suministro de datos científicos y la bibliografía por parte de la compañía que produce el producto médico se considera material publicitario. Por tanto el Decreto 677 de 1995 y Decreto 4725 de 2005 expresamente contemplan requisitos de material publicitario e incluyen la información científica con fines promocionales o publicitarios. Debe tenerse en cuenta también que la Ley 1480 de 2011 sobre la protección del consumidor define publicidad como toda forma y contenido de comunicación que tenga como finalidad influir en las decisiones de consumo.

Según la ley colombiana de derechos de autor es posible hacer referencia a una publicación científica sin autorización del autor, si se hace en un párrafo corto, que no suponga una copia de un aparte significativo o de todo el trabajo científico. Además, cuando se cita una publicación científica es preciso indicar el nombre del autor y el título de la publicación. Si la promoción afecta la integridad de la publicación o del experto profesional citado, el autor podría iniciar un proceso con base en la afectación del derecho moral a la integridad que se hace por el uso del trabajo en la promoción. En tal sentido, es recomendable, en la medida de lo posible, solicitar la autorización del autor de la publicación científica o del experto profesional citado.

known by the manufacturers. Likewise, the bibliography in which the information is based should be cited and the principal active agreement should be identified by its generic name (and, for essential drugs, the name and trademark of the drug should also be identified).

According to Colombian copyright law, it is possible to refer to a scientific publication without authorization from the author if it is just a short paragraph and not a significant part of, or the entirety of, the scientific work. Moreover, when citing a scientific publication, it is important to indicate the name of the author and the title of the publication. If the promotion affects the integrity of the publication or the professional expert cited, the author could initiate legal claims based on the rights violated by the use of the work in the promotion. Because of this, it is recommended to request the authorization of the author of the scientific publication or the professional expert cited.

Special requirements applicable to OTC drugs are found in Resolution 4320 of 2005.

The supply of scientific data and literature by a medical products device company is considered advertising material. Decree 677 of 1995 and Decree 4725 of 2005 expressly apply their advertising requirements to both scientific information as well as promotional and advertising information. Moreover, Law 1480 of 2011 regarding consumer protection defines advertising as communication of any form and content whose objective is to influence consumer decisions.

Approval

Promotional materials for OTC drugs must be submitted to INVIMA for prior approval. Pre-approval is not required for prescription drugs or for medical devices. However, even where pre-approval is not required, it is possible to present INVIMA with the material in question in advance in order to obtain an opinion of whether it would violate any applicable rules.

Advertising to End Consumers / Patients

OTC drugs and medical devices of class I can be advertised in mass media,[3] according to the specifications of the product registration. Mass

[3] Decree 4725 of 2005, Article 58 (medical devices); Decree 677 of 1995, Article 79 (drugs); Resolution 4320 of 2004 (OTC drugs).

Los materiales promocionales para los medicamentos de venta libre se deben someter a aprobación previa al INVIMA. No se necesita aprobación previa para medicamentos bajo formula médica y los dispositivos médicos. Sin embargo, aun cuando no se requiera aprobación previa, es posible presentar normas aplicables.

Publicidad dirigida al consumidor final / paciente: ¿Está permitido:

hacerle publicidad a los dispositivos médicos dirigida al consumidor final / paciente;

Medicamentos OTC y los dispositivos médicos de clase I se pueden anunciar en los medios masivos, conforme a las especificaciones del registro sanitario. Se entiende que los medios masivos incluyen al consumidor final/paciente, dado que los medios masivos van dirigidos al público en general.

Los medicamentos de venta libre pueden ser publicitados al consumidor final, siempre y cuando cuenten con la autorización del material publicitario otorgada por el INVIMA.

Los medicamentos bajo formula médica y los dispositivos médicos de clases IIa, IIb y III sólo se pueden anunciar o promover en publicaciones de carácter científico o técnico dirigido al cuerpo medico (o odontológico, si aplica) en el caso de medicamentos bajo formula médica y profesionales de la salud en el caso de los dispositivos médicos de clases IIa, IIb y III.

vender dispositivos médicos directamente al consumidor final / paciente?

Si bien no hay una disposición legal que expresamente diga que un producto médico no puede ser vendido directamente al consumidor final/paciente, las normas colombianas establecen que su uso no puede poner en peligro la salud del consumidor.

Los dispositivos médicos se comercializarán de tal manera que su utilización no pondrá en peligro la situación clínica, la salud o la seguridad de los pacientes o de quienes entran en contacto con ellos, cuando se usan en las condiciones adecuadas y de conformidad con la finalidad buscada.[3] Los medicamentos de venta libre podrán ser comercializados al consumidor final.

[3] Decreto 4725 de 2005, Artículo 1.

media is understood to include the end consumer / patients because mass media is directed to the general public.

OTC drugs may be promoted to end consumers provided that INVIMA has granted prior authorization of the promotional material.

Prescription drugs and class IIa, IIb, and III medical devices may only be advertised or promoted in publications of scientific or technical character directed to physicians (or dentists, if applicable) in the case of prescription drugs, and healthcare professionals in the case of class IIa, IIb, and III medical devices.

Direct Sales to End Consumers / Patients

Although there is no legal provision that expressly states that any medical device cannot be sold directly to end consumers / patients, Colombian legal norms establish that if done, their use must not endanger the health of the consumer.

A medical device may not be commercialized in a manner that would endanger the clinical status, health, or safety of patients or of those who are in contact with them when the medical device is used in adequate conditions and in accordance with its intended purpose.[4]

OTC drugs may be commercialized to end consumers.

Advertising Requirements

Medical product companies are permitted to use expert terminology in advertising to patients, if in conformity with the content of the product registration and as long as the information is true.

Generally, according to Colombian law regarding unfair competition,[5] comparative advertising is prohibited in any of the following circumstances:

- Incorrect or false statements or assertions are made.
- The truth is omitted.
- Reference is made to extremes that are neither analogous nor verifiable.

[4] Decree 4725 of 2005, Article 1.
[5] Law 256 of 1996.

¿Las compañías que producen productos médicos están autorizadas para usar terminología experta en la publicidad dirigida al consumidor final / paciente?

Sí, esto está permitido, siempre de conformidad con el registro sanitario siempre y cuando la información sea verdadera.

¿Las compañías que producen productos médicos están autorizadas para usar publicidad comparativa? ¿Cuáles son las normas?

Generalmente, según la legislación colombiana relativa a la competencia desleal,[4] se prohíbe la publicidad comparativa en las siguiente circunstancias: si se utiliza indicaciones o aseveraciones incorrectas o falsas; si se omiten las verdades; o si se refiere a extremos que no sean análogos ni comprobables

Además, normas legales con aplicación específica a los medicamentos y dispositivos médicos prohíben publicidad que impute, difame, cause perjuicios o comparación peyorativa para otras marcas, productos, servicios, empresas u organismos.[5]

Teniendo esto en cuenta, generalmente las compañías que producen productos médicos están autorizadas a usar publicidad comparativa de productos médicos si cumplen las anteriores condiciones. De lo contrario, la compañía puede ser demandada en un proceso de competencia desleal y/o enfrentar un proceso sancionatorio ante el INVIMA.

¿Están autorizadas las compañías que producen dispositivos médicos a usar imágenes "antes de" y "después de" en la publicidad?

En Colombia, el uso de imágenes "antes de" y "después de" no esta prohibido expresamente. El uso de dichas imágenes debe ser autorizado por el paciente y el médico que toman las imágenes. Cualquier use de imágenes "antes de" y "después de" deberá cumplir con los requisitos más generales que aplican los productos médicos, los cuales varían en base del tipo y categoría del producto.

[4] Ley 256 de 1996.
[5] Decreto 4725 de 2005, Artículo 58 (dispositivos médicos); Decreto 677 de 1995, Artículo 79 (medicamentos).

Furthermore, Colombian legal norms that specifically apply to drugs and medical devices prohibit publicity that attributes, defames, causes harm or makes a pejorative comparison with other trademarks, products or services of other businesses or organizations.[6]

With this in mind, medical product companies may generally use comparative advertising if they meet the above-stated conditions. Otherwise, the company could be subject to an unfair competition action or a sanctionatory proceeding before INVIMA.

Likewise, use of "before and after" images is not expressly prohibited. The patient and physician who took the images must authorize their use. Any use of such images must comply with the more general advertising rules affecting medical products, which vary based on the product type and category.

There is also no legal norm in Colombia that addresses whether medical product companies are permitted to advertise the price of medical devices or drugs. Advertisements may not be deceitful, misleading or cause confusion, nor may they discredit the competitor, violate any Colombian Unfair Competition Law,[7] or violate consumer protection laws.[8] The publicity must also comply with health laws in the sense that, among other requirements, class I medical devices and OTC drugs, but not other types of medical devices or drugs, may be advertised in mass media.[9]

- Mass media includes email, TV, radio, web pages, blogs, posters, videos, etc.
- Prescription drugs, as well as class IIa, IIb and III medical devices, may not be advertised in mass media.[10] Prescription drugs may be advertised only in scientific or technical publications directed to physicians (or dentists, if applicable). Class IIa, IIb and III medical devices may be advertised only in scientific or technical publications directed to healthcare professionals, but there is no further definition of specific types of professionals.

[6] Decree 4725 of 2005, Article 58 (medical devices); Decree 677 of 1995, Article 79 (drugs).
[7] Law 256 of 1996.
[8] Law 1480 of 2011.
[9] Decree 4725 of 2005, Article 58 (medical devices); Decree 677 of 1995, Article 79 (drugs).
[10] Decree 4725 of 2005, Article 58 (medical devices); Decree 677 of 1995, Article 79 (drugs).

¿Las compañías que producen productos médicos están autorizadas a anunciar los precios de los productos médicos?

No hay en Colombia una norma que regule si las compañías que producen productos médicos están autorizadas a anunciar los precios de productos médicos como tal. La publicidad comparativa está permitida siempre y cuando se haga bajo ciertas condiciones. No se permite la publicidad que sea engañosa o induzca a error. No puede causar confusión. No puede desacreditar al competidor, ni violar las normas colombianas de competencia desleal[6] ni las que regulan la protección del consumidor.[7] La publicidad también tiene que cumplir la norma sanitaria, en el sentido de que los dispositivos médicos de la clase I y los medicamentos de venta libre, pero no otras clases de dispositivos médicos y medicamentos, se pueden anunciar en los medios masivos, entre otros requisitos estipulados en esa norma.[8]

¿Alguno de los siguiente tipos de avisos se permiten para los dispositivos médicos: Correo electrónico; TV / radio?

Los medicamentos de venta libre y los dispositivos médicos de clase I se pueden anunciar en los medios masivos.[9] Medios masivos incluyen correo electrónico, TV, radio, páginas de internet, blogs, afiches, videos, etc.

Medicamentos bajo fórmula médica y los dispositivos médicos de clases IIa, IIb y III no se pueden anunciar en los medios masivos de comunicación.[10] Medicamentos bajo fórmula médica sólo se puede anunciar o promocionar en publicaciones científicas o técnicas dirigidas al cuerpo medico (o el cuerpo odontológico, si aplica). Los dispositivos médicos de clases IIa, IIb y III sólo podrán anunciarse o promocionarse en publicaciones de carácter científico o técnico destinados a los profesionales de la salud.

Las compañías que producen dispositivos médicos están autorizadas a usar testimonios para promover sus productos?

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[6] Ley 256 de 1996.
[7] Ley 1480 de 2011.
[8] Decreto 4725 de 2005, Artículo 58 (dispositivos médicos); Decreto 677 de 1995, Artículo 79 (medicamentos).
[9] Decreto 4725 de 2005, Artículo 58 (dispositivos médicos); Decreto 677 de 1995, Artículo 79 (medicamentos); Resolución 4320 de 2004 (medicamentos OTC).
[10] Decreto 4725 de 2005, Artículo 58 (dispositivos médicos); Decreto 677 de 1995, Artículo 79 (medicamentos).

According to Colombian legal norms (the unfair competition law and the consumer protection statute) regarding publicity, medical product companies are permitted to use testimonials to promote their products, testimonials are permitted if they are merely opinions and are not misleading.

If a medical product company offers any contest, raffle or other procedure where results are determined by chance the activity must be authorized by a Colombian authority called the Regional Business for Health ("ETESA"), or, the *Entidad Territorial para la Salud*.

Any such activity would need to respect provisions requiring that medical devices in classes IIa, IIb and III may only be offered in scientific or technical publications directed at healthcare professionals, and that prescription drugs can only be offered in scientific or technical publications directed at physicians (or dentists, if applicable). Likewise, any such activities must respect the prohibition against the promotion or giving of any type of perks or gifts to workers (either employed or contracted) of the entities within the General System of Social Security for Health.[11]

There are fewer restrictions on medical product companies advertising the company itself and not a particular medical product. A medical product company can advertise itself because it has a right as the owner of the commercial name of the company. Advertising of the medical product company's commercial name must not violate third parties' rights as stated in the Andean Community Law.[12]

Promotional Activities

Products

Only the information and usage authorized by the product registration granted by INVIMA can be promoted with regard to said medical product.

It is also worthy to note that patient information sessions about medical products, arranged by medical product companies, will be understood to be promotion of medical devices or drugs. In this sense, they are not permitted for prescription drugs or class IIa, IIb, or III medical devices, which may only be promoted directly to physicians (or dentists, if applicable) in the case of

[11] Law 1438 of 2011, Article 106, as modified by Law 1474 of 2011, Article 133.
[12] Andean Decision 486, 2000, Title X.

Según las normas colombianas (la ley de competencia desleal y el estatuto de protección al consumidor) que regulan la publicidad, se permiten los testimonios sin son meras opiniones y no constituyen publicidad engañosa.

¿Las compañías que producen dispositivos médicos están autorizadas a organizar concursos, rifas, u otros procedimientos en los cuales los resultados se dan por azar a los consumidores que compran sus dispositivos médicos? ¿O a los médicos que los prescriben?

Cualquier concurso, rifa u otro procedimiento cuyos resultados se den por azar tiene que estar autorizado por una autoridad colombiana llamada la Entidad Territorial para la Salud (ETESA).

Cualquiera de las actividades mencionadas deberán respectar las normas que requieren que los dispositivos médicos de clases IIa, IIb y III sólo podrán anunciarse o promocionarse en publicaciones de carácter científico o técnico destinados a los profesionales de la salud, y que los medicamentos bajo fórmula médica sólo se puede anunciar o promocionar en publicaciones científicas o técnicas dirigidas al cuerpo medico (o el cuerpo odontológico, si aplica). Asimismo, tales actividades deberán respetar la prohibición de la promoción u otorgamiento de cualquier tipo de prebendas o dádivas a trabajadores (empleados o contratados) de las entidades del Sistema General de Seguridad Social en Salud.[11]

¿Hay menos restricciones cuando sólo se anuncia la compañía productora de productos médicos (y no sus productos)?

La compañía que produce productos médicos puede ser anunciada con menos restricciones que el producto médico como tal. La compañía productora de productos médicos puede ser anunciada porque este es un derecho del propietario sobre el nombre comercial de la compañía. La publicidad del nombre comercial no podría violar los derechos de terceros protegidos por la Ley de la Comunidad Andina.[12]

Actividades promocionales

Sólo lo que sea autorizado por el registro sanitario otorgado por INVIMA puede ser anunciado en relación con los productos médicos.

[11] Ley 1438 de 2011, Artículo 106, modificado por el de Ley 1474 de 2011, Artículo 133.
[12] Decisión 486 de la Comunidad Andina, 2000, Título X.

drugs and healthcare professionals in the case of medical devices. Therefore, only OTC drugs and class I medical devices may be promoted in such sessions.

Disease

Similarly, prescription drugs and class IIa, IIb, or III medical devices may not be referenced in patient sessions arranged by medical product companies, in relation to a disease. The information in such sessions would have to concern the treatment without mentioning the drug or medical device and without having the objective of publicizing it.

Surgery

Additionally, prescription drugs and class IIa, IIb, or III medical devices may not be referenced in patient sessions arranged by medical product companies, in relation to a surgery. The information in such sessions would have to concern the surgery itself and post-operative treatments without mentioning the drug or medical device and without having the objective of publicizing it.

Gifts, Hospitality and Sponsorships

Medical product companies providing healthcare professionals or medical institutions with gifts, sample products, hospitality, entertainment, sponsorship for training, research, employee positions or events, and discounted products, must comply with the prohibitions on the promotion of drugs and medical devices described above, including the stricter requirements that apply to the promotion of prescription drugs and class IIa, IIb and III medical devices.

Moreover, the aforementioned activities must not violate the Physicians Ethics Code,[13] which prohibits physicians from receiving commercial benefits from pharmacies, laboratories, and other similar organizations in charge of objects that could be prescribed by them. In other words, if any of the these activities amount to commercial benefits to the physician, accepting such items would amount to a violation of the Ethics Code by the physician.

With respect to healthcare professionals that are public employees or contractors, generally, the crime of bribery amounts to the offering or giving of money, any benefit, or promise to give a benefit to a public official for the

[13] Law 23 of 1981, Article 40.

Productos;

Las sesiones arriba mencionadas podrían ser entendidas como promoción de dispositivos médicos o medicamentos. En tal sentido, estas sesiones no están permitidas para dispositivos médicos de las clases IIa, IIb y III los cuales sólo podrían ser promocionados en publicaciones científicas o técnicas dirigidas a los profesionales de la salud. Por consiguiente, en dichas sesiones sólo se podrían promocionar los dispositivos médicos de la clase I.

Una enfermedad;

No se puede referir a medicamentos bajo formula medica o dispositivos médicos de las clases IIa, IIb y III en sesiones informativas con pacientes con relación a una enfermedad. La información en tal sesión tiene que versar sobre el tratamiento de la enfermedad, y no anunciar el medicamento o el dispositivo médico ni tener fines publicitarios sobre ellos.

Cirugía

No se puede referir a medicamentos bajo formula medica o dispositivos médicos de las clases IIa, IIb y III en sesiones informativas con pacientes con relación a una cirugía. La información en tal sesión tiene que versar sobre el procedimiento quirúrgico y el tratamiento postoperatorio, y no anunciar el medicamento o el dispositivo médico ni tener fines publicitarios sobre ellos.

¿En relación con la promoción de dispositivos médicos, cuáles son las normas que rigen al hecho de que las compañías que producen dispositivos médicos ofrezcan a los profesionales de la salud o las instituciones médicas: obsequios; productos de muestra; atenciones; entretenimiento; patrocinio para entrenamiento, investigación, vinculación laboral o eventos; y productos con descuento?

Las anteriores actividades están autorizadas si cumplen lo siguiente:

Las anteriores actividades tienen que respectar las prohibiciones de la promoción de medicamentos y dispositivos médicos (ver pregunta 13), incluyendo los requisitos más estrictos que aplican a la promoción de los medicamentos bajo formula medica y de dispositivos médicos de las clases IIa, IIb y III.

purpose of inducing such officer to perform or expedite his public duties, not perform or delay such duties, or perform actions contrary to such duties.

Thus, the offering or giving, for example, of gifts, hospitality, entertainment, sponsorships, etc., to a physician employed or contracted by the government in exchange for the generation of business could constitute bribery.[14] In addition, the aforementioned activities must respect the prohibition against the promotion or giving of any type of perks or gifts to workers (either employed or contracted) of the entities within the General System of Social Security for Health.[15]

Some interpretations state that these activities (the giving of gifts, sample products, hospitality, entertainment, etc.) could be considered as acts of unfair competition when they are considered to contravene healthy commercial customs, good commercial faith, honest industrial and commercial uses, or when they are intended to affect the free decision of the consumer or to deceive clients. The unfair competition caused by those activities would have to be duly proven in an administrative or judicial process to be sanctioned.

Sample drug products may only be given to physician.[16]

Donations of drugs and medical devices that are not registered with INVIMA in Colombia may be made in accordance with the provisions of Decree 919 of 2004. An authorization from INVIMA is required in order to make such a donation. Specific requirements to be met include those relating to the product's active ingredients, the packaging and labeling that may be used, the product's useful life, compliance with the product's own specifications, and the product's storage and conservation. The donation of experimental products is prohibited, as is the commercialization, for-profit use, or other misuse of donated products.

Colombian law does not specifically regulate donations of medical products that are already registered with INVIMA. There is no express legal requirement to obtain an authorization from INVIMA in order to make this type of donation.

[14] Colombian Criminal Code, Articles 405, 406, and 407.
[15] Law 1438 of 2011, Article 106, as modified by Law 1474 of 2011, Article 133.
[16] Decree 677 of 1995, Article 76.

Las anteriores actividades no deberán violar el Código de Ética Médica[13] que estipula que está prohibido que los médicos reciban beneficios comerciales de farmacias, laboratorios farmacéuticos, y otras organizaciones similares a cambio de artículos que puedan ser prescritos por ellos. En otras palabras, si los obsequios, productos de muestra; atenciones; entretenimiento; patrocinio para entrenamiento, investigación, vinculación laboral o eventos así como productos con descuento constituyen beneficios comerciales para el médico, se estaría violando el Código de Ética.

En lo que respecta a los profesionales de la salud que son funcionarios públicos o trabajadores independientes, la norma general indica que el ofrecimiento o entrega de dinero, beneficios, o la promesa de dar un beneficio a un funcionario público con el propósito de inducir a dicho funcionario a (i) cumplir o agilizar los deberes de su cargo, (ii) no cumplir o demorar dichos deberes, o (iii) realizar acciones contrarias a dichos deberes, configura el delito de cohecho. Por tanto, ofrecer o dar, por ejemplo, obsequios, atenciones, entretenimiento, patrocinios etc., a un médico empleado del estado a cambio de la generación de negocios constituye cohecho.[14] En adición, las anteriores actividades deberán respetar la prohibición de la promoción u otorgamiento de cualquier tipo de prebendas o dádivas a trabajadores (empleados o contratados) de las entidades del Sistema General de Seguridad Social en Salud.[15]

Algunas interpretaciones sostienen que esas actividades (obsequios, productos de muestra; atenciones; entretenimiento, etc.) podrían ser consideradas como competencia desleal cuando se considera que obran contra las sanas costumbres comerciales, la buena fe comercial, los usos industriales y comerciales honestos, o cuando tienen por objeto afectar la libre decisión del consumidor. Dichas actividades también podrían considerarse como actos de competencia desleal cuando, obrando en contra de las sanas costumbres comerciales y los usos industriales y comerciales honestos, se usan para desviar la clientela. Para que la competencia desleal causada por dichas actividades pueda ser penalizada tiene que ser debidamente probada en un proceso administrativo o judicial.

[13] Ley 23 de 1981, Artículo 40.
[14] Código Penal Colombiano, Artículos 405, 406, y 407.
[15] Ley 1438 de 2011, Artículo 106, modificado por el de Ley 1474 de 2011, Artículo 133.

Special requirements apply with regard to the importation for donation of "biomedical equipment" (generally, medical devices that are neither implanted nor for one-time use).[17] Biomedical equipment imported into Colombia in order to be donated must be donated to a healthcare institution. The donation (as wells as importation and acquisition) of used class I and IIa biomedical equipment is expressly permitted under certain circumstances, but the donation (as well as importation and acquisition) of used class IIb and III biomedical equipment is expressly prohibited.

Laws regarding perks and gifts to health system workers, laws regarding the promotion of the medical products, and tax obligations should also be considered in making donation.

Contracts with Healthcare Professionals and Medical Institutions

Colombian law permits medical product companies to engage healthcare professionals in speaking arrangements for other services. However, such engagements must respect the prohibition against the promotion or giving of any type of perks or gifts to workers (employed or contracted) of the entities within the General System of Social Security for Health, and the norms regarding the promotion of medical products. Moreover, the information given by these healthcare professionals must comply with Colombian law.

Liability Under Criminal and Civil Law and Applicable Codes of Conduct

Medical product companies could be the subject of several complaints and sanctions if a law or provision regarding promotion of medical products is infringed. The procedures that could be initiated are the following:

- Sanction Proceeding: INVIMA could initiate a sanction proceeding if the company violates a heath law or regulation that regulates the advertising of medical products or another Colombian health law or regulation. Where the violation is proven sanctions include the following:
  - Warnings
  - Fines

[17] Decree 4725 of 2005, Article 37.

Productos de muestra sólo se puede proporcionar a los médicos.[16]

Se puede hacer donaciones de drogas y dispositivos médicos que no son registrados ante el INVIMA en Colombia según lo que prevé el Decreto 919 de 2004. Se requiere una autorización del INVIMA para poder hacer tal clase de donación. Dentro de los requerimientos específicos que se deben cumplir se incluye lo relacionado con los principios activos del producto, el envase, empaque, rótulo, y etiquetado del producto, la vida útil del producto, cumplimiento con las especificaciones del producto, y el almacenamiento y la conservación del producto. Se prohíbe la donación de productos experimentales, así como la comercialización, uso con fines lucrativos, o la desviación de los productos donados.

La ley colombiana no regula específicamente la donación de productos médicos que ya son registrados ante el INVIMA. No hay un requerimiento legal expreso en el cual sea necesaria una autorización del INVIMA para esta clase de donación.

En adición, con relación a la realización de una donación, se deben considerar aspectos relacionadas a leyes con relación a prebendas o dádivas a trabajadores en el sistema de salud, leyes relacionadas con la promoción de los productos médicos, y las obligaciones tributarias.

Requisitos especiales aplican con relación a la importación a la donación de "equipos biomédicos" (generalmente, dispositivos médicos que ni son implantados ni destinados para un solo uso).[17] Equipos biomédicos importados a Colombia para donación deberán ser deberán ser destinados única y exclusivamente a una institución prestadora de servicios de salud. La donación (e importación y adquisición) de equipos biomédicos de clase I y IIa está explícitamente permitido bajo ciertos condiciones, pero la donación (e importación y adquisición) de equipos biomédicos de clase IIb o III quedó explícitamente prohibido.

Además, cuando se haga una donación, se debe considerar asuntos relacionados a normas con respecto a prebendas o dádivas para trabajadores en el sistema de salud, la promoción de los productos médicos, y obligaciones tributarios.

[16] Decreto 677 de 1995, Artículo 76.
[17] Decreto 4725 de 2005, Artículo 37.

  - Seizures
  - Suspension or cancellation of product registrations or permits
  - Temporary or permanent shutdown of the establishment, laboratory or building.[18]

- Unfair competition action: This kind of action could be initiated by a competitor if a medical product company engages in misleading publicity or unfair comparative advertising. The action would be initiated before a civil judge or before an administrative authority (the Superintendency of Industry and Commerce). In this type of action, the plaintiff mainly requests the cessation of the act of misleading publicity or unfair comparative advertising, and compensation for the damages caused.
- Consumer protection action: This action is initiated before the Superintendency of Industry and Commerce by a consumer who considers the promotion or advertising of a medical product company misleading or because the same induces consumer error. Possible sanctions resulting from such an action include:

  - fines
  - permanent or temporary closures of commercial establishments
  - permanent or temporary prohibition on production, distribution or offering the product to the public
  - or destruction of the product, if it is dangerous to consumer health or security. Moreover, mayors may, within their respective jurisdictions, exercise the same administrative powers of control and vigilance exercised by the Superintendency of Industry and Commerce, including the imposition of fines. Decisions by mayors may be appealed before the Superintendency of Industry and Commerce.[19]

- Criminal action: A criminal action could be initiated against a person who, in the promotion of a medical product, allegedly commits an act of aggression that could be considered as defamation or slander against another person or company. This act, according to Colombian criminal law, is an offense and is penalized by criminal law. Moreover, the wrongful promotion of medical products potentially implicates certain

[18] Decree 4725 of 2005, Article 80 (medical devices); Decree 677 of 1995, Article 125 (drugs).
[19] Law 1480 of 2011, Articles 61 and 62.

Contratos con profesionales de la salud e instituciones médicas

La ley colombiana permite que las compañías productoras de productos médicos contraten profesionales de la salud en calidad de conferencistas o para que les presten otros servicios. No obstante, tales contrataciones deberán respetar la prohibición de la promoción u otorgamiento de cualquier tipo de prebendas o dádivas a trabajadores (empleados o contratados) de las entidades del Sistema General de Seguridad Social en Salud y las normas de promoción de los productos médicos. Además, la información que den estos profesionales de la salud deberá cumplir con la ley.

Responsabilidad penal y civil y códigos de conducta pertinentes

Las compañías que producen productos médicos podrían ser objeto de varias reclamaciones y sanciones si infringen una ley o norma sobre la promoción de productos médicos. Los siguientes son los procesos que se podrían iniciar:

- Proceso sancionatorio: El INVIMA podría iniciar un proceso sancionatorio si la compañía viola una norma sanitaria que regula la promoción de productos médicos u otra norma sanitaria colombiana. Las sanciones que resultan de un proceso sancionatorio en el curso del cual se pruebe la violación son los siguientes: a) Amonestación; b) Multa; c) Embargo; d) Suspensión o cancelación de registros sanitarios o permisos; d) Cierre temporal o definitivo del establecimiento, laboratorio o edificación.[18]
- Proceso de competencia desleal: Este tipo de acción puede ser iniciado por un competidor si la compañía que produce productos médicos comete un acto de publicidad engañosa o publicidad comparativa tendenciosa. Este proceso podría iniciarse ante un juzgado civil o ante una autoridad administrativa como la Superintendencia de Industria y Comercio. En este tipo de acción el demandante solicita principalmente la cesación del acto de publicidad engañosa o publicidad comparativa tendenciosa, y reclama los daños y perjuicios sufridos.

[18] Decreto 4725 de, 2005, Artículo 80 (dispositivos médicos); Decreto 677 de 1995, Artículo 125 (medicamentos).

criminal laws,[20] including types of bribery and extortion (as well as anti-corruption laws).[21]

- Gifts and perks: Administrative agencies charged with inspection, monitoring and control may impose fines from 100 to 500 legal monthly minimum salaries for the promotion or giving of any type of perks or gifts, either monetary or in kind, to workers (either employed or contracted) of the entities within the General System of Social Security for Health.[22]

Recommendations

The following are among the strategies that a medical product company could adopt to minimize the risk of violating legal norms regarding the promotion of medical products in Colombia:

- Scrutinize gifts, payments or donations to be made to medical professionals and institutions beforehand to ensure they may be made in conformity with applicable legal norms, especially when being made to government entities, employees, and contractors.
- Promote prescription medical products to physicians (or dentists, if applicable) only, and do not promote such products to the general public and/or via mass media.
- Obtain agency approvals for promotions of medical products, where applicable.
- Be aware of rules and guidance related to the promotion of medical products given by the Ministry of Health and Social Protection, INVIMA, the Ministry of Industry and Commerce, and other applicable agencies.
- Be aware of rules and guidance related to the promotion of medical products given by the Ministry of Health and Social Protection, INVIMA, the Ministry of Industry and Commerce, and other applicable agencies.
- Implement policies and procedures directed at ensuring proper promotion practices.

[20] Law 599 of 2000.
[21] Decree 126 of 2010 (addressing corruption in the General System of Social Security for Health); Law 970 of 2005 (approving the United Nations Convention against Corruption); Law 190 of 1995 (addressing bureaucratic corruption).
[22] Law 1438 of 2011, Article 106, as modified by Law 1474 of 2011, Article 133.

- Acción de protección del consumidor: Esta acción es interpuesta por un consumidor ante la Superintendencia de Industria y Comercio si considera que la promoción o publicidad de una compañía productora de productos médicos es engañosa o ha inducido a error al consumidor. Posibles sanciones resultantes de una acción así incluyen los siguientes: a) Multas; b) Cierre temporal o definitivo del establecimiento de comercio; c) Prohibición temporal o definitiva de producir, distribuir u ofrecer al público los productos; o d) Destrucción de un determinado producto, que sea perjudicial para la salud y seguridad de los consumidores. Además, los alcaldes también pueden, en sus respectivas jurisdicciones, ejercer las mismas facultades administrativas de control y vigilancia que la Superintendencia de Industria y Comercio, incluyendo la imposición de multas. Contra la decisión de los alcaldes procede el recurso de apelación que será resuelto por la Superintendencia de Industria y Comercio.[19]
  Proceso penal: Se puede iniciar un proceso penal en contra de la persona que presuntamente ha cometido el delito, si la promoción de un producto médico supone una agresión contra una persona natural o jurídica que pueda ser considerada como una calumnia o difamación de su buen nombre. Este acto según la ley penal colombiana constituye una injuria que está penalizada por la ley penal. Además, la promoción indebida de productos médicos potencialmente implica ciertas leyes penales como el soborno, la concusión, el cohecho y el soborno transnacional,[20] (y leyes contra la corrupción).[21]
  Prebendas y dádivas: Las entidades del estado de inspección, vigilancia y control pueden imponer multas de 100 a 500 salarios mínimos legales mensuales vigentes por la promoción u otorgamiento de cualquier tipo de prebendas o dádivas, sean estas en dinero o en especie, a trabajadores de las entidades del Sistema General de Seguridad Social en Salud y trabajadores independientes.[22]

[19] Ley 1480 de 2011, Artículos 61 y 62.
[20] Ley 599 de 2000.
[21] Decreto 126 de 2010 (mediante el cual se dicta disposiciones sobre la corrupción en el Sistema General de Seguridad Social en Salud); Ley 970 de 2005 (por la cual se aprobó aprobó la Convención de las Naciones Unidas contra la Corrupción); Ley 190 de 1995 (mediante la cual se fijan disposiciones con el fin de erradicar la corrupción administrativa).
[22] Ley 1438 de 2011, Artículo 106, modificado por el de Ley 1474 de 2011, Artículo 133.

Recomendaciones

Las siguientes son entre las estrategias que una compañía de productos médicos podrían adoptar para minimizar el riesgo de violar normas legales que restringen la promoción de los productos médicos en Colombia:

- Escudriñar regalos, pagos o donaciones que se harán a los profesionales médicos e instituciones de antemano para asegurarse que puede hacerse de conformidad con las normas jurídicas vigentes, especialmente cuando se están realizando a las entidades gubernamentales o sus empleados o contratistas.
- Promocionar productos médicos sólo a los médicos (o los odontólogos, si aplica), y no los promocione al público en general ni por medio de medios masivos.
- Obtener aprobaciones para promociones de los órganos del estado, si aplica.
- Conocer la reglamentación y los conceptos relacionados a la promoción de los productos médicos dado por el Ministerio de Salud y Protección Social, INVIMA, el Ministerio de Industria y Comercio, y otros órganos del estado indicados.
- Implementar política y procedimientos dirigidos a asegurar prácticas la promoción apropiadas.

Mexico

Adriana Ibarra-Fernandez, José Hoyos Robles, Pedro Tapia Juárez

Introducción

El propósito de las disposiciones legales mexicanas en materia de publicidad de Productos Médicos consiste en evitar que los profesionales de la salud y los consumidores reciban información engañosa sobre productos médicos que podrían representar un riesgo para la salud de la población mexicana.

Las disposiciones de publicidad de productos médicos son acordes con la obligación de las autoridades mexicanas en materia de salud (la Secretaría de Salud a través de la Comisión Federal para la Protección contra Riesgos Sanitarios "COFEPRIS"), de ejercer el control sanitario de Productos Médicos que se comercializan en México y que pudieran representar un riesgo sanitario.

Para determinar los Productos Médicos que están sujetos a requisitos de publicidad específica es importante definir lo que se entiende de acuerdo a la legislación mexicana como Dispositivo Médico y Medicamento o Producto Farmacéutico.

De conformidad con la Farmacopea de los Estados Unidos Mexicanos[1] y sus suplementos ("Farmacopea"), las siguientes definiciones resultan aplicables:

Dispositivo Médico.- Sustancia, mezcla de sustancias, material, aparato o instrumento (incluyendo el programa de informática necesario para su apropiado uso o aplicación), empleado solo o en combinación en el diagnostico, monitoreo o prevención de enfermedades en humanos o auxiliares en el tratamiento de las mismas y de la discapacidad, así como los empleados en el reemplazo, corrección, restauración o modificación de la anatomía o procesos fisiológicos humanos. Los dispositivos médicos incluyen a los productos de las siguientes categorías: equipo médico, prótesis, órtesis, ayudas funcionales, agentes de diagnostico, insumos de uso odontológico, materiales quirúrgicos y de curación y productos higiénicos.

Medicamento.- Toda sustancia, o mezcla de sustancias de origen natural o sintético que tenga efecto terapéutico, preventivo o rehabilitatorio, que se presente en forma farmacéutica y se identifique como tal por su actividad

[1] *Farmacopea de los Estados Unidos Mexicanos y sus Suplementos.*

Mexico

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Introduction

Mexican legal provisions on advertising of medical products prevent healthcare professionals and consumers from receiving misleading information about medical products which could lead to health risks for the Mexican population.

The provisions on advertising of medical products are in accordance with the obligation of the Mexican health authorities (the Ministry of Health through the Federal Commission for the Prevention of Health Risks or "COFEPRIS") to exercise sanitary control of medical products that are commercialized in Mexico and which may represent sanitary risks.

To determine the medical products that are subject to specific advertising requirements, it is important to define what is understood under Mexican legislation as a medical device and as a medication or pharmaceutical product.

In terms of the Pharmacopeia of the United Mexican States and its Supplements[1] ("Pharmacopeia"), the following definitions apply:

- Medical Device

Substance, mixture of substances, material, apparatus or instruments (including the computer program necessary for its appropriate use or application), used solely or in combination in the diagnosis, monitoring or prevention of diseases in humans, or auxiliary in the treatment of diseases and disabilities. Additionally, those used in the substitution, correction, restoring or modification of the anatomy or physiological human processes. Medical devices include products of the following categories: medical equipment, prostheses, orthoses, functional aids, diagnosis agents, dental materials, surgical and healing materials and hygienic products.

- Pharmaceutical Product

Any substance or mixture of substances of natural or synthetic origin which has therapeutic, preventive or rehabilitative effect, which is presented in pharmaceutical form and is identified as such due to its pharmacologic

[1] *Farmacopea de los Estados Unidos Mexicanos y sus Suplementos.*

farmacológica, características físicas y biológicas. Cuando un producto contenga nutrimentos, será considerado como medicamento, siempre que se trate de un preparado que contenga de manera individual o asociada: vitaminas, minerales, electrolitos, aminoácidos o ácidos grasos, en concentraciones superiores a las de los alimentos naturales y además se presente en alguna forma farmacéutica definida y la indicación de uso contemple efectos terapéuticos preventivos o rehabilitatorios.

Marco Regulatorio

Legislación de la Industria Farmacéutica en Materia de Publicidad

La publicidad de Medicamentos y Dispositivos Médicos en México se rige principalmente por los siguientes ordenamientos legales:

- Ley General de Salud;[2]
- Reglamento de Insumos para la Salud[3] ("RIS");
- Reglamento de la Ley General de Salud en material de Publicidad[4] ("Reglamento de Publicidad");
- Farmacopea; y
- Ley Federal de Protección al Consumidor[5] ("LFCP") y su Reglamento.
- Ley de Adquisiciones, Arrendamientos y Servicios del Sector Público y su Reglamento.

Asimismo, las actividades de promoción relacionadas con ventas o arrendamientos de Medicamentos y dispositivos médicos a entidades gubernamentales se rigen por las siguientes leyes y reglamentos:

- Ley de Adquisiciones, Arrendamientos y Servicios del Sector Público y su Reglamento.[6]

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[2] *Ley General de Salud*, publicada en el Diario Oficial de la Federación el 7 de febrero, 1984, con sus modificaciones.
[3] *Reglamento de Insumos para la Salud*, publicada en el Diario Oficial de la Federación el 3 de febrero, 1998, con sus modificaciones.
[4] *Reglamento de la Ley General de Salud en material de Publicidad*, publicada en el Diario Oficial de la Federación el 2 de mayo, 2000, con sus modificaciones.
[5] *Ley Federal de Protección al Consumidor y su Reglamento*, publicada en el Diario Oficial de la Federación el 24 de diciembre, 1992 y 2 de agosto 2006, con sus modificaciones.
[6] *Ley de Adquisiciones, Arrendamientos y Servicios del Sector Público y su Reglamento*, publicada en el Diario Oficial de la Federación el 4 de enero, 2000 y 28 de julio, 2010, con sus modificaciones.

activity and its physical and biological characteristics. When a product has nutrients, it will be considered as a pharmaceutical product, so long as it is a preparation that contains, individually or in associated form: vitamins, minerals, electrolytes, amino acids or fatty acids, in concentrations higher than those in natural food and which is also presented in a defined pharmaceutical form, and the instructions for use indicate preventive or rehabilitating therapeutic effects.

The Regulatory Framework

Advertising Legislation

Advertising of pharmaceutical products and medical devices in Mexico is mainly governed by the following legal bodies:

- General Health Law[2]
- Regulations to the General Health Law on Sanitary Inputs[3] ("RSI")
- Regulations to the General Health Law on Marketing Activities[4] ("Marketing Regulations")
- Pharmacopeia
- Federal Law on Consumer's Protection[5] and its Regulations

Promotional activities related to sales or leases of pharmaceutical products and medical devices to governmental entities are governed by the following laws and regulations:

- Law on Acquisitions, Leases and Services of the Public Sector and its Regulations[6]
- Federal Law of Responsibilities of Public Officials.[7]

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[2] *Ley General de Salud*, published in the Federal Official Gazette on 7 February 1984, as amended.
[3] *Reglamento de Insumos para la Salud*, published in the Federal Official Gazette on 3 February 1998, as amended.
[4] *Reglamento de la Ley General de Salud en material de Publicidad*, published in the Federal Official Gazette on 2 May 2000, as amended.
[5] *Ley Federal de Protección al Consumidor y su Reglamento*, published in the Federal Official Gazette on 24 December 1992 and 2 August 2006, as amended.
[6] *Ley de Adquisiciones, Arrendamientos y Servicios del Sector Público y su Reglamento*, published in the Federal Official Gazette on 4 January 2000 and 28 July 2010, as amended.
[7] *Ley Federal de Responsabilidades de los Servidores Públicos*, published in the Federal Official Gazette on 13 March 2002, as amended.

- Ley Federal de Responsabilidades de los Servidores Públicos.[7]

En adición a lo anterior, ciertas sanciones y compensaciones pueden estar incluidas en los Códigos Civiles y Penales de los Estados donde se promueven los Medicamentos y Dispositivos Médicos.

Códigos de Conducta

Los artículos 99 y 100 del Reglamento de Publicidad establecen que la Secretaría de Salud promoverá que los consejos y asociaciones, grupos de personas e instituciones de gobierno participen en la promoción de Medicamentos y dispositivos médicos y elaboren Códigos de Ética que regulen las acciones relacionadas con la producción y difusión de materiales promocionales.

En este sentido, los códigos de conducta más relevantes que están actualmente en vigor y regulan las actividades de promoción son los siguientes:

- Código de Ética y Transparencia de la Industria Farmacéutica del Consejo de Ética y Transparencia de la Industria Farmacéutica[8] (Código de Ética de CETIFARMA);
- Código de Buenas Prácticas de Promoción del Consejo de Ética y Transparencia de la Industria Farmacéutica[9] (Código de Buenas Prácticas de Promoción); y
- Código de Ética Publicitaria de la Asociación de Fabricantes de Medicamentos de Libre Acceso, A.C.[10] (Código de Ética Publicitaria de AFAMELA).

[7] *Ley Federal de Responsabilidades de los Servidores Públicos*, publicada en el Diario Oficial de la Federación el 13 de marzo, 2002, con sus modificaciones.
[8] *Código de Ética y Transparencia de la Industria Farmacéutica del Consejo de Ética y Transparencia de la Industria Farmacéutica.*
[9] *Código de Buenas Prácticas de Promoción del Consejo de Ética y Transparencia de la Industria Farmacéutica.*
[10] *Código de Ética Publicitaria de la Asociación de Fabricantes de Medicamentos de Libre Acceso, A.C.*

In addition to the above, certain sanctions and indemnities may be included in the Civil and Criminal Codes of the states where the pharmaceutical products and medical devices are promoted.

Professional Codes of Conduct

Articles 99 and 100 of the Marketing Regulations set forth that the Ministry of Health will encourage councils and associations engaged in promoting pharmaceutical products to develop codes of ethics for the production and broadcasting of promotional materials.

In this regard, the most relevant professional codes of conduct that are currently in force and regulate promotional activities are the following:

- The Code of Ethics and Transparency of the Pharmaceutical Industry of the Council of Ethics and Transparency of the Pharmaceutical Industry[8] ("CETIFARMA Code of Ethics")
- The Code of Good Promotional Practices for the Pharmaceutical Industry of the Council of Ethics and Transparency of the Pharmaceutical Industry[9] ("Code of Good Promotional Practices")
- The Code of Marketing Ethics of the Association of Manufacturers of Over the Counter Pharmaceutical Products[10] ("AFAMELA Code of Marketing Ethics")

Advertising Pharmaceutical Products and Medical Devices

General Provisions

General Health Law and Regulations

Pursuant to the provisions of the General Health Law, all promotional materials that refer to pharmaceutical products and medical devices must comply with the following requirements:

[8] *Código de Ética y Transparencia de la Industria Farmacéutica del Consejo de Ética y Transparencia de la Industria Farmacéutica.*
[9] *Código de Buenas Prácticas de Promoción del Consejo de Ética y Transparencia de la Industria Farmacéutica.*
[10] *Código de Ética Publicitaria de la Asociación de Fabricantes de Medicamentos de Libre Acceso, A.C.*

Publicidad de Productos Farmacéuticos y Dispositivos Médicos.

Disposiciones Generales

Ley General de Salud y sus Reglamentos

Conforme a las disposiciones de la Ley General de Salud, todos los materiales promocionales que hacen referencia a Medicamentos y Dispositivos Médicos deben cumplir los siguientes requisitos:

- La información que se refiere a la calidad, origen, pureza, conservación, propiedades nutrimentales y beneficios de los productos debe ser verificable;
- El contenido del mensaje debe corresponder a las características de la correspondiente autorización sanitaria (no se permite promoción "off-label");
- El mensaje no puede conducir a conductas, prácticas o hábitos que pueden resultar perjudiciales para la salud física o mental o atente contra la integridad física o la seguridad o la dignidad de toda persona, especialmente de las mujeres;
- El mensaje no puede distorsionar o contravenir los principios, disposiciones y reglamentos emitidos por la Secretaría de Salud en relación con la prevención, rehabilitación o tratamiento de enfermedades; y,
- Los mensajes de promoción deben hacerse de conformidad con las leyes y reglamentos aplicables.

El material promocional de Medicamentos y Dispositivos Médicos se clasifica en:

- Las actividades promocionales y materiales dirigidos al público en general; y,
- Las actividades promocionales y material dirigido a Profesionales de la Salud.

En términos generales, los materiales dirigidos al público en general son los que se refieren a los Medicamentos que no requieren receta médica, y las actividades promocionales y materiales dirigidos a Profesionales de la Salud son los que se refieren a la información y las características y uso de Medicamentos (incluyendo la información científica y médica).

- The information that refers to the quality, origin, purity, conservation, nutrimental properties and benefits of the products must be verifiable.
- The content of the message must be instructive and educational.
- The content of the message must correspond to the characteristics of the corresponding sanitary authorization (i.e. off-label promotion is not allowed).
- The message cannot lead to conduct, practices or habits that may be harmful to physical or mental health, or that endanger the physical integrity or safety or the dignity of any person, particularly of women.
- The message cannot distort or contravene the principles, provisions and regulations issued by the Ministry of Health with regards to the prevention, rehabilitation or treatment of diseases.
- The promotional message must be made in accordance with the applicable laws and regulations.

Promotional materials of pharmaceutical products and medical devices are classified as:

- promotional activities and materials addressed to the general public; and
- promotional activities and materials addressed to healthcare professionals.

In general terms, promotional activities and materials addressed to the general public are those covering pharmaceutical products that do not require medical prescription.

Promotional activities and materials addressed to healthcare professionals are those that refer to the information, characteristics and use of pharmaceutical products (including medical and scientific information).

For medical devices, the Ministry of Health, at the time of issuing or reviewing the corresponding sanitary registration, will specify whether the promotional and marketing materials corresponding to the specific product may be addressed to the general public or only to healthcare professionals.

Federal Law on Consumer Protection ("FLCP")

Under Article 32 of the FLCP, all information and promotional materials covering goods, products or services which are broadcast by any means must be truthful, verifiable and free of text, dialogue, sounds, images or any other description that may be misleading or confusing.

Ley Federal de Protección al Consumidor ("LFPC")

En términos del artículo 32 de la LFPC toda información y material promocional sobre bienes, productos o servicios que se difundan por cualquier medio, debe ser veraz, comprobable y libre de textos, diálogos, sonidos, imágenes o cualquier otra descripción que pueda ser engañosa o confusa.

La información o materiales que comparen productos o servicios de publicidad no pueden ser engañosos o abusivos.

La Procuraduría Federal de Protección al Consumidor ("PROFECO") podrá emitir lineamientos para el análisis y verificación del material de publicidad para evitar que se induzca al consumidor a engaños, tomando en consideración el momento en que es transmitido en relación con otros contenidos transmitidos en los mismos medios y las condiciones económicas específicas del mercado.

Autorizaciones y Avisos

De conformidad con el Reglamento de Publicidad, los materiales promocionales dirigidos al público en general están sujetos a la obtención de una autorización expedida por la COFEPRIS, mientras que aquellos dirigidos a Profesionales de la Salud están sujetos a la presentación de avisos ante dicha autoridad.

Cabe señalar que en ambos casos, la información contenida en el material promocional debe hacer referencia a los propósitos y las indicaciones contempladas en el Registro Sanitario correspondiente expedido por la autoridad sanitaria.

Prácticas Permitidas y Prohibidas

Actividades Promocionales Destinadas al Público en General.

Los materiales promocionales para Medicamentos que están dirigidos al público en general pueden incluir la descripción de las enfermedades y su tratamiento, diagnóstico, prevención o rehabilitación, siempre que estén referidos en el registro sanitario correspondiente y el lenguaje utilizado sea adecuado al público al que se dirige. Este tipo de mensajes debe identificar al que emita la información de publicidad con su nombre corporativo o con la marca de su producto.

Information or advertising materials which compare products or services should not be misleading or abusive.

The Federal Consumer Protection Bureau ("PROFECO") may issue guidelines for the analysis and verification of said advertising materials to prevent the consumer from being misled, taking into consideration the time when it is transmitted with regard to other contents transmitted in the same media and the specific economic conditions of the market.

Authorizations and Notices

Pursuant to the Marketing Regulations, promotional materials addressed to the general public require a marketing authorization issued by COFEPRIS, while those addressed to healthcare professionals are subject to filing a notice with such authority.

It should be noted that in both cases, the information contained in the promotional materials must refer to the purposes and indications referred to in the corresponding sanitary registration issued by the sanitary authority.

Permitted and Prohibited Practices

Promotional Activities Addressed to the General Public

Promotional materials for pharmaceutical products that are addressed to the general public may include the description of diseases and their treatment, diagnosis, prevention or rehabilitation, provided that they are referred to in the corresponding sanitary registration and that the language used is appropriate for the public to which it is addressed. Such messages must identify the issuer of the marketing information with its corporate name or with the trademark of the product.

This type of promotional materials must include, in visual form for printed materials, auditory for radio messages, and visual and auditory for films and television, the following:

- The legend "Consult your Physician" (*Consulte a su medico*)
- The corresponding warning legend when the use of the pharmaceutical product represents a risk under the presence of a coexistent pathological or clinical condition.[11]

[11] For films and television, one of the legends can be included in a visual and the other one in an auditory manner.

Los materiales promocionales deben incluir de manera visual para materiales impresos, de manera auditiva para los mensajes de radio y de forma visual y auditiva para cine y televisión, lo siguiente:

- La leyenda "Consulte a su médico"; y
- La correspondiente leyenda precautoria cuando el uso del producto farmacéutico represente un riesgo ante la presencia de una condición patológica o clínica coexistente.[11]

Los materiales promocionales para Medicamentos que están dirigidos al público en general no serán autorizados cuando:

- Los presente como solución definitiva en el tratamiento preventivo, curativo o rehabilitatorio de una determinada enfermedad;
- Indique o sugiera su uso en relación con sintomatologías distintas a las expresadas en la autorización sanitaria del producto;
- Altere la información sobre dosis que haya autorizado la Secretaría;
- Promueva su consumo a través de sorteos, rifas, concursos, coleccionables u otros eventos en los que intervenga el azar;

Promueva el consumo ofreciendo a cambio cualquier otro producto o servicio;

- Haga uso de declaraciones o testimoniales que puedan confundir al público o no estén debidamente sustentados;
- Emplee técnicas de caricaturización que puedan confundir e inducir a los menores de edad al consumo de los productos, y
- No incluya las leyendas mencionadas en los párrafos anteriores.

La comparación de productos podrá llevarse a cabo, siempre y cuando, tengan la misma indicación terapéutica, tomando como referencia idénticos elementos objetivos de comparación.

Los puntos de comparación deben basarse en hechos comprobables y fehacientes, no deben ser seleccionados de manera injusta o parcial y, en general, deben evitar que la comparación pueda engañar al consumidor.

[11] For films and television, one of the legends can be included in a visual and the other one in an auditory manner.

Promotional materials for medical devices that are addressed to the general public must include: messages that discourage self-treatment, when due to the characteristics of the product such legends are required; must be clear, concise and easily understandable; and must contribute to the hygienic education and express in the warning message, as applicable, that the product may represent a health risk.

Promotional materials for pharmaceutical products that are addressed to the general public will not be authorized when they:

- display the product as a definitive solution for the prevention, treatment or rehabilitation of a determined disease;
- indicate or suggest use for symptoms different than those contained in the corresponding sanitary registration;
- alter the doses authorized by the Ministry of Health;
- promote consumption through lotteries, raffles, contests or other similar activities;
- promote consumption of the product by means of offering other products or services in exchange;
- use declarations or testimonies that are misleading or that are not duly supported;
- use cartoons that could confuse children in the consumption of the products; or
- fail to include the warning legends referred to in the paragraphs above.

Comparing products is allowed, provided that they have the same therapeutic indication, considering identical objective elements of comparison.

The points of comparison must be based on verifiable facts, cannot be unfairly or partially selected and, in general, must avoid any comparison that may mislead the consumer.

Promotional Activities Addressed to Healthcare Professionals

Promotional materials addressed to healthcare professionals may be broadcast in media oriented to such sector, including specialized dictionaries and guides of pharmaceutical products, and must be based on the information to prescribe such pharmaceutical products. At all times, these materials must incorporate the code of the sanitary registration corresponding to the product.

Actividades Promocionales Destinadas a los Profesionales de la Salud

Los materiales de promoción dirigidos a los Profesionales de la Salud pueden ser emitidos en medios de comunicación orientados a tal sector, incluidos los diccionarios especializados, guías de Medicamentos y deben basarse en la información para prescribir esos Medicamentos. En todo momento, estos materiales deben incorporar el código del registro sanitario correspondiente al producto.

Por lo que hace al material promocional de Medicamentos y Dispositivos Médicos no estarán sujetos a autorización o leyendas precautorias cuando sólo incluyan la marca o el nombre del producto.

Invitaciones, Regalos y Hospitalidad al Sector Privado

No existen disposiciones legales que rigen las invitaciones a los médicos del sector privado para eventos organizados por la industria farmacéutica. Sin embargo, la Cámara Nacional de la Industria Farmacéutica ("CANIFARMA") ha desarrollado Códigos de Ética que establecen principios que deben cumplirse por las empresas que estén afiliadas a dicha Cámara, es decir Código de Ética de CETIFARMA y el Código de Buenas Prácticas Promocionales.[12]

No hay ningún límite o importe específico que no puede ser superado. Los códigos simplemente señalan que los gastos de hospitalidad no excederá el costo que los profesionales médicos estarían dispuestos a pagar por sí mismos en circunstancias similares. No deben ser lujosos y pueden incluir los gastos de viaje redondo, alojamiento, comidas y eventual inscripción (no se pueden ofrecer boletos de primera clase o suites en hoteles de 5 estrellas). Estos apoyos podrán proporcionarse a los profesionales de la salud, pero no se extenderán bajo ninguna circunstancia a acompañantes.

Los laboratorios farmacéuticos o los terceros que organicen o patrocinen eventos científicos y educativos, deberán notificar a CETIFARMA formalmente, por lo menos dos meses antes del evento mediante el formato que para tal efecto establezca CETIFARMA.

[12] Esta información se puede encontrar en inglés siguiendo el siguiente enlace: http://www.cetifarma.org.mx/descargables/04_cetifarma/03_CODES_OF_THE_PHARMACEUTICAL_INDUSTRY-2010.pdf

Promotional materials referring to pharmaceutical products and medical devices will not be subject to authorization or precautionary legends when they only indicate the trademark or name of the product.

Invitations, Gifts, Hospitality to Private Sector

There are no legal provisions governing inviting doctors of the private sector to events organized by the industry. However, the National Chamber of the Pharmaceutical Industry ("CANIFARMA") has developed the CETIFARMA Code of Ethics and the Code of Good Promotional Practices, that set forth principles that must be met by companies affiliated with this chamber.[12]

There is no threshold or specific amount that gifts or hospitality cannot exceed. The codes simply indicate that hospitality expenses shall not exceed the cost that healthcare professionals would be willing to absorb themselves in similar circumstances. They shall not be luxurious and may include round-trip travel expenses, lodging, meals, and eventual registration fees (no first class tickets or suites in 5-star hotels). These aids may be provided to healthcare professionals, but shall not be extended, under any circumstance, to accompanying persons.

Pharmaceutical laboratories or third parties that organize or sponsor scientific and/or educational events must inform CETIFARMA about the event at least two months prior to the event, using the prescribed form issued by CETIFARMA for this effect.

CETIFARMA may verify that the organization of an event complies with the provisions of the code. Non-fulfillment of this stipulation will be considered as a breach of the abovementioned codes.

Additionally, the health authority, healthcare consumers, or any pharmaceutical company, may file a complaint with the Council of Ethics against a pharmaceutical company established in Mexico for breaching the provisions of the CETIFARMA Code of Ethics and the Code of Good Promotional Practices. The Council may proceed to investigate *ex-officio* any possible breach, when it deems appropriate.

[12] You may find information in English in the following link: http://www.cetifarma.org.mx/descargables/04_cetifarma/03_CODES_OF_THE_PHARMACEUTICAL_INDUSTRY-2010.pdf

El Consejo de CETIFARMA podrá verificar que el desarrollo del evento cumpla con las disposiciones del Código. El incumplimiento de estas disposiciones se considerará como una violación a los Códigos antes mencionados.

Adicionalmente, cualquier empresa farmacéutica, la autoridad sanitaria, profesionales de la salud y los consumidores pueden presentar ante el Consejo de Ética una denuncia en contra de una empresa farmacéutica que este establecida en México cuando esta haya incumplido las disposiciones del Código de Ética de CEFIFARMA y el Código de Buenas Prácticas Promocionales. El Consejo podrá investigar de oficio cualquier posible violación, cuando lo considere pertinente.

Los regalos consistentes en libros o materiales visuales, en medios magnéticos o electrónicos, así como material científico, se podrá aceptar cuando su valor comercial no exceda en conjunto el equivalente a cincuenta veces el salario mínimo diario (US$ 250).

Invitaciones, Regalos y Hospitalidades al Sector Público

De acuerdo a la legislación mexicana, todas las entidades, departamentos y oficinas del Sector Público, así como todos los trabajadores de esas instituciones son considerados funcionarios públicos. Asimismo, cualquier persona que administre recursos económicos del Gobierno también será considerado funcionario público.

Los regalos o donaciones de una sola persona o de una entidad a un funcionario público no pueden superar los 10 salarios mínimos diario del Distrito Federal[13] (alrededor de US$50 o £30), por año. Cualquier funcionario público que reciba cualquier donación o regalo de la misma persona que supere esta cantidad, deberá informar de esta situación a la Secretaría de la Función Pública con la finalidad de devolver los bienes o ponerlos a disposición de dicha autoridad.

Por lo tanto, en México los regalos, bonificaciones, remuneraciones económicas, las prestaciones en especie, o cualquier tipo de incentivo podrá ser ofrecido o prometido a profesionales de la salud, personal administrativo o cualquier otro funcionario público involucrado en el proceso de prescripción, compra, distribución, dispensación y administración de

[13] Actualmente el salario mínimo general vigente en el Distrito Federal es de $62.33 pesos equivalentes a $4.79 dólares a un tipo de cambio de $13 pesos por dólar.

Gifts consisting of books or materials in optical, magnetic or electronic format, as well as scientific material, are acceptable provided their total commercial value does not exceed the equivalent of fifty times the minimum daily wage (USD250).

Invitations, Gifts, Hospitality to Public Sector

Under Mexican legislation, all entities, departments and offices of the public sector as well as all of the officials within these organizations are considered public officials. Additionally, any person administrating government monetary resources is also considered a public official.

Gifts or donations from a single person or entity to a public official cannot exceed 10 times the daily minimum wage for the Federal District[13] (which is approximately equivalent to USD50 or GBP30) per year. Any public official receiving any gift or donation which exceeds this amount from the same person should report such occurrence to the authority appointed by the Ministry of Public Function, to facilitate the return of the goods or to be able to put them at the disposition of this authority.

Hence, no gifts, bonuses, pecuniary advantages, benefits in kind, or any sort of incentive may be offered or promised to healthcare professionals, administrative staff or any other public official involved in the cycle of prescription, purchase, distribution, dispensing and administration of medicines (except inexpensive promotional aids related to the practice of medicine or pharmaceutical activities that do not exceed the threshold).

Nothing may be offered or provided under conditions that may influence healthcare professionals' prescription practices.

All payments, including those characterized as facilitation payments under the Foreign Corrupt Practices Act ("FCPA"), are considered illegal under Mexican Law.

Donations to charitable organizations may be questionable when the institution is somehow related to a public official who is a decision maker in deals where the company participates. In these cases, a conflict of interest may arise. Moreover, a donation under these circumstances may be considered a bribe. As a general rule, in order to contract with any

[13] Current daily minimum wage is MXN62.33 as of 1 January 2012, equivalent to USD4.79 at an exchange rate of MXN13 per USD.

medicamentos (excepto las promociones gratuitas relacionadas con el tratamiento de enfermedades, la práctica de la medicina o actividades farmacéuticas que no superen el límite antes mencionado). Nada podrá ser ofrecido o proporcionado en condiciones que puedan influir en las prácticas de prescripción de los profesionales de la salud.

Todos los pagos, incluyendo los que se utilicen para agilizar un trámite, serán considerados ilegales en términos de las Leyes Mexicanas.

Las donaciones a organizaciones de beneficencia podrán ser cuestionables cuando la institución esté relacionada de alguna manera con un funcionario público y este sea el encargado de resolver los asuntos o negocios donde participa la empresa. En estos casos puede surgir un conflicto de intereses. Asimismo, una donación en estas circunstancias puede considerarse un soborno. Como regla general, para poder celebrar un contrato con cualquier entidad gubernamental es necesario previamente entrar en un proceso de licitación pública, aunque en algunos casos específicos se permite la contratación directa.

Los funcionarios públicos involucrados en estos procesos tienen prohibido participar en transacciones donde podría presentarse un conflicto de intereses. Por otra parte, un funcionario público tiene prohibido participar en cualquier negocio donde los ofertantes involucrados u otros funcionarios públicos que participen, estén relacionados con dicho funcionario público de cualquier manera (es decir, si existe una relación académica, empresarial o familiar). Esta prohibición incluye las relaciones que pudieran resultar en un beneficio para el funcionario público; su esposa o esposo; sus parientes; u otras personas que tuvieran una relación profesional, laboral o de negocio con el funcionario público; o esas empresas o accionistas de estas empresas en las que el funcionario público haya participado en los dos años previos al proceso de contratación.

Lineamientos para la Selección de Oradores, Capacitación y Utilización

Los empleados del Gobierno o funcionarios de los organismos reguladores no deberán ser asignados para servicios de consultoría cuando exista un conflicto de intereses.

En caso de que el orador sea considerado para ocupar un cargo como funcionario público, o reciba una invitación para participar en un Congreso no resultará aplicable el límite antes mencionado de US$ 50 para regalos. Sin

governmental entity, it is a requirement for a company to previously enter into a public bidding process. However, direct contracting is permitted in specific cases.

Public officials involved in these processes are prohibited from participating in dealings where a conflict of interest might be present. Furthermore, a public official is prohibited from participating in any deal where the involved bidders, or other public officials that participate, are related to that public official in any way (i.e., if an academic, business or family relation exists).

This prohibition includes dealings which may result in a benefit to the public official; his or her wife or husband; his or her relatives; other individuals having a professional, labor or business relationship with the public official; or companies or shareholders of companies in which the public official had participated within two years prior to the contracting process.

Guidelines for Speakers Selection, Training and Utilization

Government employees or staff from regulatory bodies may not be assigned consultancy services if a conflict of interest may exist.

If the speaker is considered to be a public official, an invitation to participate in a congress would not fall in the abovementioned USD50 cap for gifts. However, the invitation should not have the intention of obtaining a benefit for the company, closing deals with public hospitals that would otherwise not take place, or influence doctors to use the company's products only.

While there are no legal provisions governing invitations to doctors in the private sector, the CETIFARMA Code of Ethics and the Code of Good Promotional Practices hospitality expenses shall not exceed the cost that healthcare professionals would be willing to absorb themselves in similar circumstances.

Medical Samples

Applicable Legislation

Under Article 49 of the Marketing Regulations, it is not necessary to secure an authorization for samples of pharmaceutical products which are given out free of charge in order for healthcare professionals to learn about the product in question, and which meet the requirements and specifications applicable to products to be retailed to the general public but which contain a lower amount of units.

embargo, la invitación no deberá tener la intención de obtener un beneficio para la empresa, cerrar cualquier contrato con hospitales públicos que de lo contrario no tendría lugar, o influenciar a médicos para que utilicen los productos de la empresa.

Aunque no hay disposiciones legales que rijan las invitaciones a los médicos del sector privado, con base en el Código de Ética de CEFIFARMA y Código de Buenas Prácticas de Promoción, los gastos de hospitalidad no deben exceder el costo que los Profesionales de la Salud estarían dispuestos a absorber por sí mismos en circunstancias similares.

Muestras Médicas

(i) Legislación aplicable

En términos del artículo 49 del Reglamento de Publicidad, no es necesario obtener una autorización para las muestras que se dan de forma gratuita, con el objeto de que los Profesionales de la Salud obtengan información sobre el producto en cuestión y que cumplan los requisitos y especificaciones aplicables a los productos que se venden al público en general, pero que contienen una cantidad menor de unidades.

Las muestras de medicamentos sujetas a receta médica que se suministran gratuitamente no se podrán dar al público en general. Las muestras de estos productos y de productos farmacéuticos de libre venta no podrán ser distribuidos a menores de edad.

(ii) Códigos de Conducta

De acuerdo a los Códigos de Buenas Prácticas de Promoción las muestras médicas son presentaciones de productos farmacéuticos apegadas a lo dispuesto en la ley y el reglamento correspondientes, y serán proporcionadas directa y gratuitamente en cantidades razonables a los Profesionales de la Salud, con el único fin de que puedan conocer y familiarizarse con dichos medicamentos y/o iniciar tratamiento, no debiendo comercializarse de ninguna forma.

Por lo tanto, además de cumplir con lo establecido en la Ley General de Salud y sus reglamentos, habrán de apegarse a lo siguiente:

- Las muestras de productos no pueden ser ofertadas o dadas para solicitar o recompensar prácticas de prescripción.

Free samples of pharmaceutical products subject to medical prescription cannot be given out to the general public. Samples of these products and over-the-counter ("OTC") pharmaceutical products cannot be distributed to children.

Codes of Conduct

To comply with the Code of Good Promotional Practices, medical samples should be presentations of pharmaceutical products, provided directly, in fair amounts and without cost to healthcare professionals, so that they may get to know and be familiar with the products and/or initiate a treatment. Commercialization of medical samples is prohibited.

Companies must comply with the provisions of the General Health Law and its regulations, as well as with the guidelines of the Code of Good Promotional Practices:

- Samples of a product may not be offered or supplied with the purpose of seeking or rewarding prescription practices.
- Samples may not be sold, purchased or commercialized in any form and, therefore, must have a "not for sale" label clearly displayed. Non-compliance with the aforementioned conditions will be reported to CETIFARMA, who will proceed in accordance with the provisions of the Code of Good Promotional Practices. Samples must not be used as gifts or provided to healthcare professionals for other purposes than for free provision to their patients.
- In accordance with the provisions defined in international agreements and determined by the national health authorities, provision of medical samples containing psychotropic or narcotic substances is forbidden.
- Companies must have thorough and up-to-date control of their samples, including their manufacture, storage, delivery to regional coordinators or others, and provision to medical representatives and physicians. Adopted measures on this matter will be reported to CETIFARMA who will proceed, in due time, with the corresponding evaluation and verification. Any deviation identified by the company must be reported to CETIFARMA in order to be informed, in due time, of possible misuses.
- Mailing lists for the delivery of promotional material must be regularly updated. Requests by healthcare professionals to be removed from such lists must be complied with.

- Las muestras no deben ser vendidas, compradas ni comercializadas de ninguna forma, para lo cual llevarán impresa una leyenda visible que diga "prohibida su venta". Cualquier incumplimiento a lo antes señalado se hará del conocimiento de CETIFARMA para que proceda de acuerdo con lo establecido en el Código de Ética. No pueden ser usadas como regalos ni proporcionadas a Profesionales de la Salud para algún propósito que no sea su distribución gratuita a los pacientes.
- Con arreglo a lo definido en los convenios internacionales y lo que determine la autoridad sanitaria nacional, está prohibida la entrega de muestras de medicamentos que contengan sustancias psicotrópicas o estupefacientes.
- Las empresas llevarán un control escrupuloso y actualizado de las muestras médicas desde su producción, almacenamiento, entrega a los coordinadores regionales o figuras equivalentes, distribución a los representantes médicos y a los médicos. Las medidas que adopten para cumplir lo anterior deberán informarlas a CETIFARMA, que en su momento y oportunidad hará la evaluación y constatación correspondientes.

Cualquier desviación identificada por la empresa deberá reportarse a CETIFARMA con el propósito de conocer con oportunidad los casos en que se pueda dar mal uso.

- Las listas de direcciones para la remisión de material promocional habrán de mantenerse actualizadas. Cuando los profesionales de la salud soliciten ser excluidos de esas listas, deberá atenderse su petición.
- Cada empresa farmacéutica designará a una persona profesionalmente calificada que supervisará el cumplimiento de lo establecido en este capítulo.

Publicidad de usos no autorizados ("off-label")

En términos de la Ley General de Salud, los dispositivos médicos registrados sólo pueden ser anunciados para utilizarse de acuerdo a las indicaciones especificadas en el registro sanitario correspondiente. De lo contrario, se podrá imponer una multa de hasta 10,000 veces el salario mínimo diario del Distrito Federal.[14]

[14] Aproximadamente MXN $623,300, equivalentes a $47,946 dólares a un tipo de cambio de $13 pesos por dólar.

- Pharmaceutical companies must appoint a professionally qualified person to supervise compliance with these provisions.

Off-Label Promotion

Under the General Health Law, registered medical devices can only be advertised to be used for the indication specified in the corresponding sanitary registration. Otherwise, a fine up to 10,000 times the daily minimum wage for the Federal District[14] may be imposed.

Any advertisements indicating a use different from that contained in the sanitary registration would be removed from the media and, in certain cases, the sanitary registration of the product could be revoked.

Consequences of Breach

Consequences of Breach for the Public Sector

Offering gifts to public officials, where the value exceeds the mentioned threshold, may be considered a bribe. Under the Federal Criminal Code, individuals found guilty of committing the offense, may face up to 14 years of imprisonment and an administrative fine of up to 1,000 times the Daily Minimum Wage for the Federal District (approximately USD5,000). If the perpetrator is a public official, he/she would be removed from office and disqualified from any public position for up to 14 years, in addition to the abovementioned administrative fine.

In addition, even when receiving of a gift is not considered a crime, if the amount exceeds the threshold, such public officials may face the following administrative sanctions under the Federal Law of Responsibilities of Public Officials:

- Public reprimand
- Temporary removal from office for a term between three days and one year
- Removal from office
- Monetary fine
- Temporary disqualification from public service (up to 20 years).

[14] Approximately MXN623,300, equivalent to USD47,946 at an exchange rate of MXN13 per USD.

Los anuncios que indiquen un uso distinto al autorizado en el registro sanitario se eliminarán de los medios de comunicación y, en ciertos casos, el registro sanitario del producto podría ser revocado.

Consecuencias de Incumplimiento

Consecuencias de incumplimiento en el Sector Público.

El ofrecimiento y recepción de regalos a funcionarios públicos, cuyo valor supere el límite mencionado de $50 dólares por año se considera soborno. En términos del Código Penal Federal quienes resulten culpables de cometer este delito, pueden enfrentar hasta 14 años de prisión y una multa administrativa de hasta 1.000 veces el salario mínimo diario del Distrito Federal (alrededor de US$ 5.000) y si el autor del delito es un funcionario público, además sería destituido de su cargo y privado de ocupar cualquier cargo público hasta por 14 años.

Asimismo, incluso cuando el recibir un regalo no se considera un delito, si el monto supera el límite, en términos de la Federal Ley de Responsabilidades de Servidores Públicos, pueden enfrentar las siguientes sanciones administrativas:

- Amonestación pública.
- Separación temporal del cargo por un período de entre 3 días hasta 1 año.
- Remoción del cargo.
- Multas
- Descalificación temporal del servicio público (hasta 20 años)

Estas sanciones administrativas son aplicables también para conductas que impliquen un conflicto de intereses.

Al momento en que fue redactado este documento, está pendiente de publicación en el Diario Oficial de la Federación una nueva Ley sobre Contratación con Entidades Públicas (ya ha sido aprobada por la Cámara de Diputados y por el Senado). Dicha ley sancionará la concesión u oferta de algún beneficio material o no material u otro beneficio destinado a influir en forma, una licitación pública o proceso de contratación pública.

These administrative sanctions also apply to conduct involving conflicts of interest.

At the time this document was drafted, a new law on contracting with public entities is pending to be published in the Federal Official Gazette to become effective (already approved by the Chamber of Deputies and by the Senate). This new Anti-corruption Law will sanction the granting or offering of any material or non-material benefit or other advantage aimed at influencing any public bidding, tender or invitation contracting processes.

Consequences of Breach for the Private Sector

FLCP

In accordance with the FLCP, one of the functions of PROFECO is to coordinate the corresponding federal, state and municipal authorities in order to ensure the effective protection of consumers against deceitful information or promotional materials.

In order to meet the foregoing, PROFECO has authority to order the suspension of any information or marketing materials that breach the provisions of the FLCP, order the amendment of the marketing materials, and impose the monetary sanctions set in the FLCP.

Marketing Regulations

The Ministry of Health may order the media to suspend broadcasting of marketing materials for herbal remedies, food supplements or cosmetic products which are publicized or are retailed as pharmaceutical products or goods to which therapeutic effects were attributed for preventive treatment, rehabilitation or healing of one or more diseases. Media shall suspend broadcasting the marketing materials within 24 hours following serving of the notice issued to that effect by the Ministry of Health.

In the event that manufacturers, distributors or retailers refrain from or impede the seizure of products, the sanitary authority can request the support of the police force.

The Ministry of Health may also impose fines ranging between 2,000[15] and 16,000 times the minimum daily wage, among others, in the following cases:

[15] Fine ranging between MXN124,660 (which is equivalent to USD8,968.00 at an exchange rate of MXN13 pesos per USD) and MXN997,280 (equivalent to USD71,747).

Consecuencias de Incumplimiento en el Sector Privado.

LFPC

De conformidad con la LFPC una de las funciones de la PROFECO es coordinar a las autoridades municipales, estatales y federales, a fin de garantizar la protección efectiva de los consumidores contra información engañosa en materiales promocionales.

A fin de cumplir con lo anterior, PROFECO tiene la facultad para ordenar la suspensión de cualquier información o materiales de publicidad que infrinjan las disposiciones de la LFPC; ordenar la revisión de los materiales de publicidad e imponer sanciones establecidas en la LFPC.

Reglamento de Publicidad

La Secretaría de Salud tiene la facultad de ordenar a los medios de comunicación que suspendan la difusión de materiales de publicidad para remedios herbolarios, suplementos alimenticios o productos cosméticos que sean publicitados o sean vendidos como productos farmacéuticos o productos que se atribuyen efectos terapéuticos para tratamiento preventivo, rehabilitación o curación de una o más enfermedades. Los medios de comunicación suspenderán la transmisión de los materiales de publicidad dentro de 24 horas siguientes a ser debidamente notificados de la orden por parte la Secretaría de Salud.

En caso de que los fabricantes, distribuidores se abstengan o impidan el aseguramiento de productos, la autoridad sanitaria podrá solicitar el apoyo de la fuerza pública.

La Secretaría de Salud también podrá imponer multas que oscilarán entre dos mil[15] y dieciséis mil veces el salario mínimo diario, en los siguientes casos entre otros: (i) cuando la comercialización pueda amenazar la integridad física o mental de la población; (ii) cuando leyendas precautorias no aparezcan en los materiales de publicidad previstos en el Reglamento de Publicidad; (iii) cuando la comercialización de materiales de productos farmacéuticos destinados al público en general se muestren como solución definitiva en el tratamiento preventivo, curativo o rehabilitación de una determinada enfermedad.

[15] Multa de entre $124,660 pesos (equivalentes a $8,968.00 dólares a un tipo de cambio de $13 pesos por dólar) y $997,280 (equivalentes a $71,747 dólares).

- for marketing that may threaten the physical or mental integrity of the population; when warning legends do not appear in marketing materials as provided for in the Marketing Regulations;
- or when marketing materials of pharmaceutical products addressed to the general public are displayed as definitive solution in the prevention, healing or rehabilitation treatment of a determined illness.

Codes of Conduct

In terms of the Code of Good Promotional Practices, infractions are classified as minor, serious or very serious based on the following criteria:

- If the nature of the breach harms the relationship between associates of CANIFARMA
- If the nature of the breach implies a potential risk for the patients' health
- If the breach has an impact on the medical profession and the scientific credibility of the resulting practice
- If the reputation of the pharmaceutical industry is affected
- If it leads to unfair competition

Once the sanction has been determined, the following aggravating and attenuating circumstances must be taken into account:

Aggravating circumstances: degree of intentionality:

- disregard to previous warnings;
- recidivism;
- concurrence of several breaches in the same act of infringement;
- financial benefits for the laboratory derived from the breach;
- damage to another laboratory;
- analogous practices to the ones denounced, failing to follow the principles of honesty and truth.

Attenuating circumstances:

- adoption of corrective measures prior to the complaint or during the examination procedures;
- opportunity in the collection of evidence; Prompt response to CETIFARMA's requirements

En términos del Código de Buenas Prácticas Promocionales las infracciones se calificarán como leves, graves y muy graves en función de los siguientes criterios:

- Si la característica de la infracción perjudica la relación entre asociados y/o adherentes.
- Si la característica de la infracción implica un posible riesgo para la salud de los pacientes.
- Si la infracción afecta la profesión médica y la credibilidad científica del hecho que genera.
- Si perjudica la imagen de la Industria Farmacéutica.
- Si propicia prácticas de competencia desleal.

Una vez calificada la infracción, habrán de considerarse las siguientes agravantes y atenuantes:

Agravantes:

(a) Grado de intencionalidad.
(b) Incumplimiento de las exhortaciones previas.
(c) Reincidencia.
(d) Concurrencia de varias infracciones en el mismo hecho.
(e) Beneficio económico para el laboratorio derivado de la infracción.
(f) Perjuicio a otro laboratorio competidor.
(g) Realización de prácticas análogas a las denunciadas, faltando a los principios de honestidad y apego a la verdad.

Atenuantes:

(h) Adopción de medidas correctivas aplicadas previo a la queja o durante el proceso de desahogo de la denuncia.
(i) Oportunidad en la aportación de pruebas.
(j) Respuesta expedita a los requerimientos del CETIFARMA.

El CETIFARMA podrá acordar desde la imposición de amonestaciones hasta sanciones pecuniarias correspondientes a la gravedad de la infracción.

La CANIFARMA ejecutará las sanciones impuestas y se abstendrá de participar en las deliberaciones que para tal propósito realice el CETIFARMA.

According to the seriousness of the infringement, CETIFARMA will decide between issuing a warning or imposing a monetary sanction.

CANIFARMA will execute the sanction determined by CETIFARMA and will refrain from participating in the proceedings undertaken by CETIFARMA for this purpose.

CANIFARMA may decide, if appropriate, to notify the health authorities about a member's recurring serious or very serious infringements. This will be decided by CANIFARMA's Directive Council. In case of contempt to a resolution, CETIFARMA will notify CANIFARMA´s Directive Council, which will proceed according to its regulations. Expulsion of a member from CANIFARMA will be decided in the General Associates' Meeting.

Criminal and Civil Liability

According to the criminal codes of the different Mexican states and the Federal District, when a product does not deliver the offered results or effects, the affected party may initiate criminal action for fraud. This offense is subject to imprisonment for a term that varies depending on the economic loss caused.

Regarding civil liability, in the event that a medical device or pharmaceutical product causes health injury, the affected individual is entitled to sue the manufacturer or the distributor, in order to claim payment for damages. In addition, please note that Mexican legislation has been recently amended to implement class actions. Hence, a group of individuals who are injured as a result of the consumption of a pharmaceutical product or the use of a medical device may file for class action.

Recommendations

When granting a sanitary registration for a medical device, COFEPRIS will indicate whether marketing may be addressed to the general public or only to healthcare professionals.

Determining if pharmaceutical products may be promoted to the general public or to healthcare professionals depends on whether they are OTC medications or pharmaceutical products subject to a medical prescription.

Marketing materials for medical products share with the general marketing requirements the aim of avoiding consumers receiving deceptive information. However, and because medical products may represent a higher risk to the

Ante la reiteración de infracciones graves o muy graves por parte de un asociado, el Consejo Directivo de la CANIFARMA determinará el hacerlo o no del conocimiento de la autoridad sanitaria. Ante el desacato de una resolución del CETIFARMA, este lo notificará al Consejo Directivo de la CANIFARMA que procederá conforme a sus estatutos. La separación de ese asociado a la CANIFARMA será resolución de su Asamblea General.

Responsabilidad Civil y Penal

De acuerdo al Código Penal de los distintos Estados y del Distrito Federal, cuando un producto no proporcione los resultados o efectos ofrecidos, la parte afectada podrá iniciar acción penal por fraude. Este delito está sujeto a una pena de prisión cuyo término depende del monto de las pérdidas económicas causadas.

En cuanto a responsabilidad civil, en caso de que un Medicamento o Dispositivo Médico cause un daño en la salud, los individuos afectados tienen derecho a demandar al fabricante o distribuidor, a fin de reclamar el pago de daños. Adicionalmente, tenga en cuenta que la legislación mexicana ha sido modificada recientemente para implementar Acciones Colectivas. En caso de que un Dispositivo Médico o Medicamento provoque daños de salud, las personas afectadas pueden ejercer una acción colectiva contra el fabricante o el distribuidor, a fin de reclamar el pago de daños y perjuicios.

Recomendaciones

Al otorgar un registro sanitario para un Dispositivo México, COFEPRIS indicará si los materiales promocionales pueden ir dirigidos al público en general o únicamente puede dirigirse a los Profesionales dela Salud.

Tratándose de Medicamentos, que la publicidad pueda destinarse al público en general o a Profesionales de la Salud dependerá de si se trata de Medicamentos de venta libre o si son Medicamentos sujetos a receta médica.

Los materiales promocionales para Productos Médicos comparten con los requisitos de la publicidad aplicable a todos los productos, la finalidad de evitar que los consumidores reciban información engañosa. Sin embargo, y toda ves que los Productos Médicos pueden representar un riesgo mayor a la salud y las vidas de la población mexicana, las disposiciones que regulan la publicidad de estos productos establecen requisitos adicionales y las autoridades sanitarias mexicanas monitorean de manera muy cercana, cualquier material promocional de estos tipos de productos.

health and lives of the Mexican population, the provisions that govern these products set forth additional requirements, and Mexican health authorities closely monitor any promotional materials of these types of products.

Before investing in any promotional materials for medical products, it is advisable to contact COFEPRIS and PROFECO to ensure that all applicable provisions are met. Otherwise, a company faces the risk of seizure of its medical products, suspension or termination of broadcast of its marketing materials, as well as imposition of stiff fines.

Antes de invertir en cualquier material promocional para Productos Médicos es recomendable entrar en contacto con las autoridades de COFEPRIS y PROFECO para asegurarse de que se está dando cabal cumplimiento a todos los requisitos aplicables. De lo contrario, podría existir un riesgo de aseguramiento de Productos Médicos, una orden de suspensión de transmisión de los materiales promocionales así como la imposición de elevadas multas.

Venezuela

María Fernanda Zajía, Dianne Phoebus, Martha Cohen

Publicidad de productos farmacéuticos y equipos médicos

Marco Normativo

La publicidad y promoción de productos farmacéuticos está regulada por las siguientes leyes y reglamentos;

- Las Normas para Promoción y Publicidad de los Medicamentos, publicada en Gaceta oficial No. 37.966 de fecha 23 de junio de 2004 ("Las Normas de Promoción");
- La Ley de Medicamentos, publicada en Gaceta Oficial No. 37.006 de fecha 3 de agosto de 2000 (la "Ley");
- Las Normas de la Junta Revisora de Productos Farmacéuticos del Instituto Nacional de Higiene Rafael Rangel (la "Junta Revisora de Productos Farmacéuticos") en materia de Publicidad y Promoción de Productos Farmacéuticos (Las "Normas de la Junta Revisora");
- Ley para la Defensa de las Personas en el Acceso a los Bienes y Servicios publicada en Gaceta Oficial No. 39.358 de fecha 1 de febrero de 2010, ("La Ley de Defensa al Acceso");
- Ley de Responsabilidad Social en Radio, Televisión y Medios Electrónicos, publicada en Gaceta Oficial No. 39.610 de fecha 7 de febrero de 2011;
- El Reglamento Parcial sobre Transmisiones de Televisión, publicado en Gaceta Oficial No. 35.096 de fecha 20 de noviembre de 1992;
- Las Normas Técnicas sobre Definiciones, Tiempo y Condiciones de la Publicidad, Propaganda y Promociones en los Servicios de Radio, Televisión y Difusión por Suscripción publicadas en la Gaceta Oficial No. 38.352 de fecha 6 de enero de 2006; y
- El Código de Ética de la Asociación Nacional de Anunciantes y la Federación Venezolana de Agencias Publicitarias de fecha 26 de julio de 2007 (el "Código de Ética ANDA").

No existen disposiciones expresas en lo que respecta a la publicidad y promoción de equipos médicos. la Resolución No. DM-0010-99 emitida por el Ministerio del Poder Popular para la Salud ("Ministerio de la Salud"), de fecha 3 de diciembre de 1999, regula específicamente la elaboración, importación, mercadeo y distribución de equipos en Venezuela. No obstante, dicha Resolución no incluye disposiciones con relación a la publicidad de los

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Introduction

Health-related products and services are highly regulated in Venezuela. The People's Ministry of Health and the corresponding divisions are the motors behind the regulation. In addition, health-related products and services are also subject to increased regulation and restrictions through the equivalent of the Consumer Protection Agency. Eventually, health-related products and services will most likely be subject to the price control legislation recently enacted in Venezuela.

Regulatory Framework

The advertising and promotion of pharmaceutical products is governed by the following laws and regulations:

- Rules for the Promotion and Advertising of Medicines, published in Official Gazette No. 37.966 dated 23 June 2004 ("Promotion Rules")
- Law on Medicines, published in Official Gazette No. 37.006 dated 3 August 2000 ("Law")
- Rules of the Pharmaceutical Products Review Board of the Rafael Rangel National Institute of Hygiene ("Pharmaceutical Review Board") relating to Advertising and Promotion of Pharmaceutical Products ("Review Board Rules")
- Law for the Defense of Persons in Accessing Goods and Services published in Official Gazette No. 39.358 dated 1 February 2010 ("Access Defense Law")
- Law Governing Social Responsibility in Radio, Television and Electronic Media published in Official Gazette No. 39.610 dated 7 February 2011
- Partial Regulations on Television Transmissions published in Official Gazette No. 35.096 dated 20 November 1992
- Technical Rules on Definitions, Time and Conditions of Advertising, Propaganda and Promotion in the Services of Radio, Television and Subscription Transmission published in Official Gazette No. 38.352 dated 6 January 2006

mismos. Como asunto práctico, las autoridades sanitarias aplican a los equipos médicos la normativa aplicable a la promoción y publicidad de productos farmacéuticos.

Prácticas Permitidas y Prácticas Prohibidas

Toda promoción y/o publicidad de medicamentos debe ser autorizada por el Ministerio de la Salud, oída la opinión de la Junta Revisora de Productos Farmacéuticos. Sólo aquellos medicamentos aprobados y registrados en Venezuela pueden ser objeto de promoción y publicidad. Toda promoción y publicidad relacionada con productos farmacéuticos debe cumplir con las disposiciones específicas relacionadas con dicha publicidad y promoción. Esto se aplica a todas las secciones que siguen relacionadas con la publicidad y promoción, en adición a la información suministrada en cada una de dichas secciones.

Adicionalmente, la Ley de Defensa al Acceso establece que las promociones de bienes y servicios deben ser autorizadas por el Instituto para la Defensa de las Personas en el Acceso a los Bienes y Servicios ("Instituto para la Defensa del Acceso"). No está del todo claro si este régimen es aplicable a los productos farmacéuticos. Sin embargo, atendiendo a lo gravoso de las sanciones aplicables previstas en la Ley de Defensa al Acceso la solicitud de autorización debe ser considerada

Prácticas Permitidas:

La promoción y publicidad de medicamentos debe ser de contenido informativo, educativo, veraz, actualizado, susceptible de comprobación y expresado en idioma castellano. En ningún caso el contenido oral, escrito o gráfico de la promoción y publicidad de un medicamento podrá contrariar las condiciones y restricciones de uso oficialmente aprobadas.

Las condiciones de uso son:

- la (s) indicación (es) del medicamento;
- la posología y el grupo etario a quien va dirigida la administración del medicamento; y
- la (s) vía (s) de administración y modo de uso.

Las restricciones de uso son:

- Las advertencias y precauciones;
- Las contraindicaciones;

- Code of Ethics of the National Association of Announcers and the Venezuelan Federation of Advertising Agencies dated 26 July 2007 ("ANDA Code of Ethics")

There are no express legal provisions regarding advertising and promotion of medical devices. Resolution No. DM-0010-99 issued by the People's Ministry of Health ("Ministry of Health") on 3 December 1999, regulates the manufacture, importation, marketing and distribution of medical equipment in Venezuela. It does not, however, include provisions relating to advertising of medical equipment. As a matter of practice, health authorities apply the provisions regarding the promotion and advertising of pharmaceutical products to medical devices.

Permitted and Prohibited Practices

All advertising and promotion of pharmaceutical products must be authorized by the Ministry of Health, taking into consideration the opinion of the Pharmaceutical Review Board. Only pharmaceutical products which have been approved and registered in Venezuela can be promoted and advertised. Furthermore, all promotion and advertising dealing with pharmaceutical products must comply with the specific, applicable provisions dealing with the advertising and promotion of these products. This applies to all sections below dealing with advertising and promotion, in addition to the specific information provided under each heading.

In addition, the Access Defense Law provides that promotions must be authorized by the Access Defense Institute. It is not clear whether or not these provisions apply to pharmaceutical products. However, taking into account the severe sanctions for violations, authorization should be considered.

Permitted Practices

The advertising and promotion of pharmaceutical products should be informative, educational, true, up-to-date, able to be proven and should be in Spanish. Under no circumstances can spoken, written or graphic publicity and promotion contradict the officially-approved use conditions and restrictions.

The use conditions are:

- instructions for the pharmaceutical product;
- dosage and age group which is the target of the product; and

- Las reacciones adversas e interacciones; y
- Las establecidas para grupos especiales de pacientes (tales como aquellos que sufren de insuficiencia renal, hepática, cardíaca).

La promoción y publicidad de los medicamentos no debe inducir a la automedicación irracional ni al abuso de los medicamentos.

La promoción y publicidad de productos farmacéuticos podrá estar basada en la comparación de precios, siempre que dicha comparación sea fidedigna.

Las empresas farmacéuticas podrán promocionar su nombre a través de los medios de comunicación social, identificándose como patrocinantes de mensajes o como compañías de divulgación sanitaria dirigida al uso racional de medicamentos o a los cuidados de la salud. Sólo los productos "sin prescripción facultativa" pueden mencionarse en dicha promoción.

Los medicamentos de venta sin prescripción facultativa pueden ser objeto de publicidad y promoción por todos los medios de comunicación social, previa autorización del Ministerio de la Salud, acatando los textos, las condiciones y restricciones de uso oficialmente aprobadas.

La promoción y publicidad de medicamentos de venta con prescripción facultativa debe estar dirigida exclusivamente a los profesionales de la salud, quedando prohibido dirigir éstas al público en general. La única excepción a esta disposición, son los avisos de prensa relacionados con la disponibilidad de medicamentos en el mercado.

La información científica y tecnológica contenida en la publicidad o promoción de los medicamentos, deberá estar respaldada por la correspondiente bibliografía, la cual debe ser debidamente aprobada por el Director o Asesor Científico de la Empresa y el Farmacéutico Patrocinante del producto. Las comparaciones entre diferentes medicamentos sólo podrán hacerse usando las correspondientes denominaciones genéricas y nunca los nombres del producto que se promociona.

Cualquier patrocinio a profesionales de la salud por parte de las compañías farmacéuticas para que participen en eventos de carácter científico-educativo, sean nacionales o internacionales, no debe estar condicionado a la obligación de promocionar o anunciar ningún medicamento.

- means of administration and use.

The use restrictions are:

- warnings and precautions;
- contraindications;
- adverse reactions and interactions; and
- those that deal with special types of patients (such as those suffering from kidney, liver or heart problems).

Advertising and promotion of pharmaceutical products should not promote unreasonable self-medication or abuse.

Such advertising and promotion can include price comparisons as long as such comparisons are reliable.

Pharmaceutical companies can promote their company's name through the media, identifying themselves as sponsors of a message or as companies which provide health information aimed at the rational use of medicine or healthcare. Only non-prescription drugs can be mentioned in such promotion.

Non-prescription drugs can be advertised and promoted through all types of media once the advertising and promotion has been approved by the Ministry of Health and the approved texts, conditions and use restrictions have been complied with.

Prescription drugs can only be advertised to medical professionals, and not to the general public. The only exception to this prohibition are notices published in newspapers which advises the general public that a certain medicine is available.

Scientific and technological information included in advertising and promotion must be supported by bibliographies, which must be approved by the company's scientific director or consultant as well as the sponsoring pharmacist. Only generic names can be used in the comparison of pharmaceutical products; product names cannot be used.

A pharmaceutical company's sponsoring of health professionals for scientific educational events, either national or international, cannot be conditioned on the promotion of any pharmaceutical product.

Los artículos de promoción y publicidad ofrecidos gratuitamente o por debajo de su valor real, sólo se permiten cuando éstos estén relacionados con el trabajo del profesional de la salud y ofrezcan un beneficio para el paciente.

Prácticas Prohibidas

En Venezuela está prohibido:

La promoción y/o publicidad de medicamentos sin registro sanitario;

- Utilizar información y material promocional en el texto de las etiquetas, empaques o prospectos internos que acompañen al medicamento. Las etiquetas, empaques o prospectos internos deben ceñirse estrictamente al texto aprobado por el Ministerio de la Salud;
- La promoción y publicidad de medicamentos en forma de beneficios financieros o materiales a favor de los profesionales de la salud o de cualquier otra persona natural o jurídica encargada de prescribir y dispensar medicamentos; y
- La distribución de muestras gratis de los medicamentos con o sin prescripción facultativa entre el público en general, como medio de promoción. Se exceptúa la distribución gratuita realizada por los organismos o instituciones sanitarias oficiales en campañas sanitarias.

Adicionalmente, en la promoción y publicidad de los medicamentos queda prohibido:

- La competencia desleal;
- Preconizar bondades sobre la base de lo que un producto no es, o lo que no contiene;
- Utilizar calificativos tales como “inocuo” en relación al uso del medicamento; y
- Utilizar calificativos sobre calidad en relación a las características y propiedades del medicamento.

Afirmaciones Promocionales

Todas las afirmaciones hechas en la promoción y publicidad deben estar respaldadas. Si las afirmaciones son falsas, el Instituto para la Defensa del Acceso podría sancionar a la compañía responsable por haber incurrido en publicidad falsa o engañosa (Art. 58, 59, 131 de la Ley de Defensa al Acceso). En caso de controversias surgidas como consecuencia de lo dispuesto en dicha Ley, el anunciante deberá probar la veracidad de las

Free (or under-priced) promotional and advertising items are permitted only when they are related to the health professional's work and they benefit the patient.

Prohibited practices

The following are prohibited in Venezuela:

- The promotion and/or advertising of unregistered pharmaceutical products.
- The use of promotional information and material in the text of the labels, packages or patient information leaflets of medicines; labels, packages or patient information leaflets must strictly abide by the text approved by the Ministry of Health.
- The promotion and advertising of medicines by offering or granting economic or material benefits to the health professional or any other person or company responsible for prescribing and supplying medicines.
- The distribution of free samples of prescription or non-prescription medicines to the general public as a means of promotion, with the exception of free distribution by official health entities or institutions during health campaigns.

In addition, the following are prohibited in the promotion and advertising of pharmaceutical products:

- Unfair competition
- Preaching of benefits based on what a product is not or does not contain
- Use of qualifiers such as "harmless" regarding the use of the medicine
- Use of quality claims in connection with the medicine's characteristics and properties

Promotional Claims

Claims made in advertising must be supported. If the claims are false, the Access Defense Institute could sanction the responsible company for false or misleading advertising (Articles 58, 59 and 131 of the Access Defense Law). If controversies arise out of the application of this law, the announcer should prove the accuracy of the claims made in the advertising. The announcer is understood to be the supplier of the goods that was responsible for the advertising.

afirmaciones contenidas en el mensaje publicitario. Se entenderá por anunciante al proveedor de bienes que ha encargado la difusión del mensaje publicitario.

De conformidad con la Ley de Defensa al Acceso, se deberá tener especial cuidado en la publicidad dirigida a los niños, ancianos, enfermos de gravedad y otras personas que no están en capacidad de entender plenamente la información que se les está presentando.

Uso de Publicaciones Científicas y/o Cita de Expertos Profesionales

En Venezuela, no existe regulación alguna sobre referencias a publicaciones científicas o citas de expertos profesionales en relación con la promoción de productos farmacéuticos.

El ordenamiento jurídico venezolano tampoco prohíbe el uso de terminología experta cuando se promocionan productos farmacéuticos a consumidores finales/pacientes. Sin embargo, la Ley de Defensa al Acceso exige que la información sobre los bienes puestos a la disposición de los consumidores finales sea veraz, precisa, comprensible y en idioma castellano.

Publicidad Comparativa

Las compañías farmacéuticas podrán utilizar publicidad comparativa, siempre y cuando no incluyan en dicha publicidad declaraciones falsas o concernientes a desventajas o riesgos de cualquier producto de los competidores, ya que dicha conducta podría considerarse "competencia desleal". Esta conducta está prohibida de conformidad con el artículo 6 de la Ley para Promover y Proteger el Ejercicio de la Libre Competencia, publicada en la Gaceta Oficial No. 34.880 de fecha 13 de enero de 1992 ("Ley para la Libre Competencia"). Por otra parte, dicha conducta podría ser considerada una infracción a la normativa sobre promoción y publicidad de medicamentos. Adicionalmente, el Código de Ética ANDA establece algunos lineamientos generales para la utilización de publicidad comparativa de productos.

Fotografías de "Antes y Después"

No existe normativa alguna que regule el uso de fotografías de "Antes y Después" en la publicidad de productos farmacéuticos. Sin embargo, debe tenerse en cuenta que conforme a lo dispuesto en el Artículo 57 de la Ley de Defensa al Acceso, es falsa y engañosa todo tipo de información o comunicación de carácter comercial en que se utilicen textos, diálogos,

Pursuant to the Access Defense Law, special care must be taken in connection with advertising targeting children, the elderly and the gravely ill, as well as other persons who are not capable of fully understanding the information being presented.

Use of Scientific Publications and/or Expert Opinion

In Venezuela, there are no provisions regarding references to scientific publications or expert opinions in connection with the promotion of pharmaceutical products. Venezuelan law does not prohibit the use of expert terminology when promoting pharmaceutical products to consumers/patients. However, the Access Defense Law requires that the information regarding goods sold to consumers be truthful, precise, understandable and in Spanish.

Comparative Advertising

Pharmaceutical companies can use comparative advertising as long as such advertising does not include false declarations or disadvantages or risks of competitors' products since this would be deemed unfair competition, which is prohibited in Article 6 of the Law to Promote and Protect Free Competition, published in Official Gazette No. 34.880 dated 13 January 1992 ("Unfair Competition Law"). Furthermore, this type of advertising could be considered a violation of the Rules for the Promotion and Advertising of Medicines. ANDA's Code of Ethics also provides certain general guidelines for comparative advertising.

"Before and After" Photographs

There are no specific legal provisions regarding the use of "before and after" photographs in advertising. However, any such advertising must consider Article 57 of the Access Defense Law which indicates as false and misleading any type of information or communication which uses texts, dialogues, sounds, images or descriptions which, directly, indirectly or by omission, could mislead, confuse or induce errors. The Access Defense Law provides sanctions for false or misleading advertising.

Advertising via Electronic Means

Pursuant to the general provisions regarding advertising in the Access Defense Law, advertising of pharmaceutical products through email is permitted as long as it complies with the provisions of this law. Moreover, email advertising must be suspended within 24 hours of notification by the addressee that they do not want to receive such mails. We emphasize again

sonidos, imágenes o descripciones que directa o indirectamente, e incluso por omisión, puedan inducir a engaño, error o confusión de las personas. La publicidad falsa o engañosa está sancionada por la Ley de Defensa al Acceso.

Publicidad vía medios electrónicos

De conformidad con el régimen general sobre promoción de bienes previsto en la Ley de Defensa al Acceso, la publicidad de productos farmacéuticos a través de correo electrónico está permitida, siempre que se ajuste a las disposiciones previstas en esta Ley. Según la Ley de Defensa al Acceso, cuando una persona indique que no desea recibir correos electrónicos, el proveedor del servicio debe suspenderlos en un lapso no mayor de veinticuatro (24) horas. Una vez más enfatizamos que toda publicidad y promoción de productos farmacéuticos deben cumplir igualmente con las demás disposiciones legales pertinentes a este asunto.

Uso de Testimoniales

Las compañías que comercialicen productos farmacéuticos pueden utilizar testimonios de personas en las promociones, siempre y cuando la información sea veraz.

Concursos, rifas y otros

No existen disposiciones que prohíban a las compañías farmacéuticas ofrecer concursos, rifas u otros procedimientos como métodos asociados con la oferta, promoción o venta de tales productos. Tampoco existe una prohibición dirigida a los profesionales de la salud para intervenir en este tipo de concursos.

Conforme a lo anterior, las compañías podrían utilizar concursos, sorteos, regalos, vales, premios, o similares, como métodos relacionados con la oferta, promoción o venta de los productos, siempre que cumplan con el régimen de promoción y oferta previsto en la Ley de Defensa al Acceso, y el Reglamento Parcial de la Ley de Protección al Consumidor, publicado en la Gaceta Oficial N. 35.139 de fecha 26 de enero de 1993, y en las normas sobre esta materia dictadas por el Ministerio del Poder Popular para el Comercio.

Actividades Promocionales para Profesionales de la Salud incluyendo aquellos que sean empleados Públicos

- Regalos - Los regalos no están permitidos, exceptuando aquellos de valor nominal, comúnmente entregados durante celebraciones tradicionales (Por ejemplo, Navidad).

that all advertising and promotion of medical products must also comply with the legal provisions dealing specifically with this subject.

Use of Testimonials

Companies that sell pharmaceutical products can use personal testimonials as long as the information is true.

Contests, Raffles, etc.

There are no provisions that prohibit pharmaceutical companies from offering contests, raffles or other mechanisms in connection with the offer, promotion or sale of such products, nor are there express prohibitions regarding the participation of health professionals in this type of activities.

Based on the above, companies could use contests, drawings, gifts, vouchers, prizes or similar methods associated with the offer, promotion or sale of products as long as the activities comply with the provisions of the Access Defense Law and the Partial Regulations on the Consumer Protection Law published in Official Gazette No. 35.139 dated 26 January 1993, and with the regulations issued by the Ministry of Commerce on these activities.

Promotional Activities to Health Professionals Including Those Who are Public Employees

- Gifts - Gifts are not permitted except those of nominal value which are normally given during traditional celebrations (e.g., Christmas).
- Gimmicks - Free (or under-priced) promotional and advertising items are permitted only when they are related to the health professional's work and they benefit the patient.
- Hospitality - A meal or reception of reasonable value provided as a courtesy and without corrupt connotations would most likely be considered legal by a judge. Meals and receptions offered by pharmaceutical companies (related to seminars, for example) are permitted as long as there is no connection between the meal and reception on the one hand, and the duties of a public employee or the obligations of the host on the other.
- Sponsorship of training, investigations, employment or events - There are no specific legal provisions regarding these activities. However, the Rules for the Promotion and Advertising of Medicines indicate: hospitality provided by a pharmaceutical manufacturer or supplier in a scientific educational event must be moderate; and a pharmaceutical company's support of health professionals for scientific

- Trucos publicitarios - Los artículos promocionales o publicitarios gratis (o por debajo de su precio) están permitidos solamente cuando están relacionados con el trabajo del profesional de la salud y benefician al paciente.
- Hospitalidad - Una comida o recepción de valor razonable y de cortesía, sin connotaciones corruptas, es probable que sea considerada legal por un juez venezolano. Las comidas y recepciones ofrecidas por empresas farmacéuticas (por ejemplo, con ocasión de seminarios) están permitidas, siempre y cuando no haya relación alguna entre las comidas y recepciones, por una parte y por la otra, los deberes del funcionario público o las obligaciones de su anfitrión.
- Patrocinio de entrenamiento, investigación, empleo o eventos - No existe una regulación específica en Venezuela con respecto a este asunto. Sin embargo, de acuerdo con las Reglas para Promoción y Publicidad de Medicamentos: La hospitalidad proporcionada por un fabricante o un proveedor de productos farmacéuticos en eventos científicos educativos debe mantenerse a nivel moderado, y el apoyo individual a los profesionales de la salud por la industria farmacéutica que le permita al médico participar en eventos científicos educativos a nivel nacional o internacional, no debe estar sujeto a la promoción o publicidad de un medicamento.
- Descuento en Productos - Como se dijo anteriormente dar artículos promocionales o publicitarios gratis o por debajo de su precio a profesionales de la salud, sólo se permite cuando dichos artículos están relacionados con el trabajo del profesional de la salud y beneficien a los pacientes. Asimismo, en lo que respecta a la legislación venezolana, los funcionarios públicos no pueden recibir o aceptar regalos ni ningún otro beneficio bajo la promesa de tomar determinada acción o abstenerse de tomarla.

Sanciones por incumplimiento de la normativa sobre promoción y publicidad de medicamentos.

La Ley de Medicamentos y otras normas legales establecen sanciones por el incumplimiento de las normas relativas a la promoción y publicidad de medicamentos, sin perjuicio de que sean aplicadas las sanciones civiles y penales previstas en otras leyes. Igualmente, en la medida que la promoción o publicidad de medicamentos viole alguna disposición de la Ley de Defensa al Acceso podrán ser aplicables las sanciones previstas en dicha Ley.

educational events, either national or international, cannot be conditioned on the promotion of any pharmaceutical product.

- Product discounts - As indicated above, free (or under-priced) promotional and advertising items are permitted only when they are related to the health professional's work, and they benefit the patient. By the same token, pursuant to Venezuelan legislation, a public employee cannot accept gifts or any other benefit based on the promise to take or abstain from taking a certain action.

Consequences of Breach

The Law on Medicines and other legal instruments contain sanctions for failure to comply with the legal provisions on the promotion and advertising of pharmaceutical products, without prejudice to the civil and criminal sanctions provided in other laws. Furthermore, the sanctions in the Access Defense Law could also be applied to the extent that the promotion and advertising of pharmaceutical products violate this law.

Professional Codes of Conduct

Law on the Exercise of Medicine (Official Gazette No. 39.823 dated 19 December 2011)

The exercise of medicine is understood to be the offering of preventive-curative medical attention to the population by medical professionals through actions geared at the promotion of health, the prevention of illness, the reduction of risk factors, preventive diagnosis, early treatment and restoration of health, among other activities. Pursuant to the Law on the Exercise of Medicine, a health professional violates this code when, while providing professional services, he/she covers up for or sponsors individuals or companies which illegally exercise medicine.

Deontological Code

Pursuant to this code, the respect for the life and integrity of the human being as well as the promotion and preservation of health as elements of social well-being should always be a priority to medical doctors. It is, therefore, considered contrary to medical ethics for a doctor exercising the profession to act as a commission agent on behalf of companies which manufacture or sell pharmaceutical or biological products.

Códigos de Conducta Profesional

Ley de Ejercicio de la Medicina (G.O. No. 39.823, del 19 de diciembre de 2011)

Se entiende por ejercicio de la medicina la prestación de atención médica preventivo-curativa a la población por parte de los profesionales de la salud mediante acciones encaminadas a la promoción de la salud, prevención de enfermedades, reducción de los factores de riesgo, diagnóstico precoz, tratamiento oportuno, restitución de la salud, entre otras actividades. De conformidad con la Ley de Ejercicio de la Medicina, el hecho de que los profesionales de la salud que presten su concurso profesional, encubran o patrocinen a personas naturales o jurídicas o a establecimientos donde se ejerza ilegalmente la medicina violan esta Ley.

Código Deontológico Médico

De conformidad con este código, el respeto a la vida y a la integridad de la persona humana, el fomento y la preservación de la salud, como componentes del bienestar social, constituyen en todas las circunstancias el deber primordial del médico. Por ende, se considera contraria a la moral médica la participación del médico como comisionista en compañías encargadas de la elaboración o venta de productos farmacéuticos o biológicos, mientras esté en ejercicio activo de su profesión.

Código de Ética para el Funcionario Público (G.O. No. 36.268, del 23 de agosto de 1997)

Si un profesional de la salud lleva a cabo funciones públicas y califica como funcionario público bajo la legislación venezolana, estará sujeto a determinadas limitaciones derivadas del marco normativo aplicable a dichos funcionarios.

De conformidad con el Código de Ética para el Funcionario Público, los funcionarios en cuestión deben rechazar en cualquier caso y circunstancia y no solicitar jamás, ni para sí ni para terceros, pagos, beneficios o privilegios con ocasión del los servicios que deban prestar.

Ley Contra la Corrupción (G.O. Ext. 5.637, del 7 de abril de 2003)

El funcionario público que por algún acto de sus funciones reciba para sí mismo o para otro, retribuciones u otra utilidad que no se le deban o cuya promesa acepte, será penado con prisión y multa.

Public Employees Code of Ethics (Official Gazette No. 36.268 dated 23 August 1997)

If a health professional carries out public functions and qualifies as a public employee pursuant to Venezuelan legislation, this professional would be subject to certain limitations arising out of the legal provisions which apply to public employees. Pursuant to the Public Employees Code of Ethics, such employees must refuse under any circumstances and never ask for themselves or for others, payments, benefits or privileges arising out of their responsibilities.

Law Against Corruption (Official Gazette No. 5.637 dated 7 April 2003)

Public employees who, through their work, receive for themselves or for others, payouts or other benefits that are not to them, or accept a promise to that effect, shall be punished with imprisonment and a fine.

Law on the Statutes of the Public Employee (Official Gazette No. 37.522 dated 6 September 2002)

Soliciting or receiving money or any other benefit due to their condition as a public employee is cause for dismissal.

Code of Conduct for the Public Servant (Official Gazette No. 36.496 dated 15 July 1998)

The following are guiding principles of duty and conduct of public servants regarding ethical values which must govern public service: honesty, equality, decorum, loyalty, vocation for service, discipline, effectiveness, responsibility, punctuality, transparency and neatness.

Specifically regarding honesty, public servants should, in the course of their duties, refuse gifts, invitations, favors, handouts, payment for trips, use of transportation or any type of praise, or material or immaterial benefits offered by groups or persons interested in obtaining any type of favorable decisions.

Criminal and Civil Responsibility

False or Misleading Advertising, Under the Access Defense Law

If the company uses false or misleading advertising, it will be sanctioned with a fine of between 100 and 5000 tax units, or temporary closure for 90

Ley del Estatuto de la Función Pública (G.O. No. 37.522, del 6 de septiembre de 2002)

Es una causal de destitución del funcionario público, el solicitar o recibir dinero o cualquier otro beneficio, valiéndose de su condición de funcionario público.

Código de Conducta de los Servidores Públicos (G.O. 36.496, del 15 de julio de 1998)

Son principios rectores de los deberes y conductas de los servidores públicos respecto a los valores éticos que han de regir la función pública: la honestidad, la equidad, el decoro, la lealtad, la vocación de servicio, la disciplina, la eficacia, la responsabilidad, la puntualidad, la transparencia y la pulcritud.

Específicamente en lo que respecta a la honestidad, los servidores públicos deberán rechazar en el ejercicio de sus funciones los regalos, invitaciones, favores, dádivas, pago de viajes, uso de medios de transporte o cualquier clase de halagos, beneficios materiales o inmateriales, ofrecidos por personas o grupos interesados en obtener decisiones favorables o de cualquier tipo.

Responsabilidad Penal y Civil

Publicidad falsa o engañosa bajo la Ley de Defensa al Acceso

Si la compañía usa publicidad falsa o engañosa, será sancionada con una multa de 100 a 5.000 Unidades Tributarias (UT), o clausura temporal por noventa días. Al 5 de junio 2012, una unidad tributaria es equivalente a aproximadamente US$21 (Artículo 131).

Falta de Registro bajo la Ley Orgánica de la Salud

El mercadeo de productos farmacéuticos sin haberse cumplido con el registro correspondiente será sancionado con multa, decomiso o destrucción de los productos y/o clausura permanente o temporal del establecimiento, según el caso (Artículos 65, 66, 67).

Competencia Desleal Bajo la Ley de Libre Competencia

Las empresas que incurran en competencia desleal, podrán ser sancionadas con multa del 10 al 40 por ciento del valor de sus ventas (Artículo 49).

days. The value of a tax unit as of 5 June 2012 is approximately USD21 (Article 131).

Failure to Register a Product, Under the Organic Health Law

The marketing of pharmaceutical products without the corresponding registration shall be sanctioned with a fine, confiscation or destruction of the products, and/or permanent or temporary closure of the establishment, depending on the circumstances (Articles 65, 66 and 67).

Unfair Competition, Under the Unfair Competition Law

Companies who commit unfair competition are subject to a fine of between 10 percent and 40 percent of the value of their sales (Article 49).

Contracts with Healthcare Professionals and Medical Institutions

Contracts between pharmaceutical companies and health professionals are permitted depending on the nature of the contract, and are subject to certain limitations:

- Pursuant to Article 19 of the Law on the Exercise of Medicine, no person authorized to exercise medicine can offer for sale medicines or other products of therapeutic use, or suggest to patients that they acquire products in certain pharmacies or establishments.
- It is considered professionally immoral for an active medical professional to work as a commission agent on behalf of companies which manufacture or sell pharmaceutical or biological products.
- Under no circumstance can a health professional accept limits imposed by their employer on his or her professional independence; health professionals should give priority to providing physical and spiritual health to the patients that they examine and treat.
- A contract between a health professional and a public or private entity is considered a violation of the law and ethical principles if such contract means that the health professional would be working in two different entities during the same working hours (for example, a health professional that is hired to work at a public hospital and a private clinic during the same hours).
- Health professionals should notify the Ministry of Health and the Medical Board when they accept or resign from a position as a health professional.

Contratos con profesionales de la salud e instituciones médicas.

Los contratos entre las compañías farmacéuticas y los profesionales de la salud estarán permitidos dependiendo de la naturaleza del contrato y sujeto a determinadas limitaciones:

- De conformidad con el Artículo 19 de la Ley de Ejercicio de la Medicina, ninguna persona autorizada para ejercer la medicina podrá ofrecer en venta medicamentos u otros productos de uso terapéutico o sugerir a sus pacientes que los adquieran en determinadas farmacias o establecimientos;
- Se considera contrario a la moral médica que los profesionales de la salud actúen como comisionistas de compañías encargadas de la elaboración o venta de productos farmacéuticos o biológicos, mientras estén en el ejercicio activo de su profesión;
- Bajo ninguna circunstancia puede un profesional de la salud aceptar limitaciones sobre su independencia profesional, impuestas por su empleador; los profesionales de la salud deben dar prioridad a la provisión de salud física y espiritual a los pacientes que examinen y traten.;
- Un contrato entre un profesional de la salud y entidades públicas o privadas es considerado violatorio de la Ley y de los principios éticos cuando el profesional de la salud está trabajando en dos entidades diferentes durante las mismas horas de trabajo (por ejemplo, un profesional de la salud que contrate para trabajar en un hospital público y en una clínica privada durante las mismas horas de trabajo); y
- Los profesionales de la salud deben notificar al Ministerio de Salud y la Junta de Médicos la aceptación o renuncia de un cargo como profesionales de la salud.

Como mencionamos anteriormente si el profesional de la salud ejerce funciones públicas y califica como un funcionario público bajo la legislación venezolana, estará sujeto a determinadas limitaciones derivadas de la normativa aplicable a dichos funcionarios. En tal sentido, un contrato no puede ser utilizado por una compañía de productos farmacéuticos para obtener beneficios que deriven del ejercicio del cargo por parte de un profesional de la salud que, a su vez, es funcionario público.

As mentioned above, if the health professional exercises public functions and qualifies as a public employee pursuant to Venezuelan law, the professional would be subject to certain limitations arising out of the applicable legislation. Under these circumstances, a contract could not be used by a pharmaceutical company to obtain benefits that arise out of the health professional's position as a public employee.

Recommendations

As evidenced, health-related products and services are heavily regulated in Venezuela, and the promotion and advertising of pharmaceuticals and medical devices does not escape from this regulation. Furthermore, the trend is moving toward increased rather than decreased regulation in this area and in this regard, the legal panorama changes rapidly. Based on this, recommendations regarding the promotion of pharmaceutical and medical devices include the following:

- Assure that you are aware of the latest regulatory developments.
- Assure that any products to be promoted are registered with the Ministry of Health and that the registrations are current.
- Assure that all dealings with government officials and employees (including doctors who work part-time in public institutions), are transparent and well-documented.
- Provide training to the entire chain of employees and representatives who could be involved in the promotion of the products.

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This third edition of *"Promoting Medical Products Globally. Handbook of Pharma and MedTech Compliance"* is intended to provide an overview of the applicable compliance laws governing the cooperation between the medical industry and physicians in Europe, North America, Latin America and the Asia Pacific region. It highlights the legal framework within which medical device and pharmaceutical companies cooperate with health care professionals. It deals with common sponsoring practices such as invitations, conferences and financial grants for research, personnel and equipment as well as other promotional activities such as the giving of gifts, samples and other items and services which are of interest to health professionals. We trust that the third edition is a useful resource for lawyers, compliance officers, managing directors and managers in marketing and medical departments of the medical industry to assess the legal impact on their promotion and marketing activities involving healthcare professionals or medical institutions.

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