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Regulatory implications of the new guidelines for determining whether software constitutes a medical device

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Healthcare has not been left out amid rapid technological growth and the accelerating digital transformation of the economy in recent years. Active development in this field has resulted in a flurry of releases of new products and services, including medical care, health and exercise apps for smartphones and other devices, support services for online medical examinations and treatment and insurance products linked to healthcare services.

Introducing new healthcare-related products and services in Japan requires an awareness of regulations under the Pharmaceuticals and Medical Devices Act (the "**PMD Act**"). Under the PMD Act, in addition to hardware, software installed on a general-purpose computer, smartphone or other information device, depending on its intended purpose and features may itself constitute a medical device. In particular, programs used to diagnose, treat or prevent disease[1] are treated as medical devices[2] and subject to strict regulation under the PMD Act. Accordingly, whether healthcare-related hardware or software will be treated as a medical device is an extremely significant issue.

In view of this situation, the Ministry of Health, Labour and Welfare (MHLW) issued "Guidelines for determining whether software is a medical device"[3] (the "**Medical Software Guidelines**") on March 31, 2021. These Guidelines supplant the MHLW's "Basic policy for determining whether software is a medical device"[4] (the "**Basic Policy**"), further clarifying and refining the treatment of software and providing important practical guidelines for business operators.

First, the Guidelines identify types of software that will generally not be considered to constitute medical devices under the PMD Act. Excluded from the definition of a medical device under the PMD Act is software (1) intended to provide explanations to patients; (2) intended for in-hospital business support and maintenance; (3) intended to enable users to view their own medical and health-related information; and (4) believed to pose a low risk to human health and life. Typical examples of excluded software have been organized by type in terms of their intended use with the goal of clarifying the determination of whether software is a medical device. "Software that stores, manages and displays the health records of individuals" and "software intended for any purpose other than medical or health purposes, such as

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[1] Excluding those that pose almost no risk to human health or life even in the event of side effects or functional impairments.
[2] PMD Act, Art. 2(2)(iv); Order for Enforcement of the PMD Act, Art. 1 and Appendix 1
[3] Pharmaceutical Safety and Environmental Health Bureau, Medical Device Evaluation Division Notification 0331 No. 1, Pharmaceutical Safety and Environmental Health Bureau, Compliance and Narcotics Division Notification 0331 No. 15
[4] Pharmaceutical Safety and Environmental Health Bureau, Compliance and Narcotics Division Notification 1228 No. 2, December 28, 2018; repealed upon the issuance of the Medical Softw are Guidelines.

exercise management" are listed as examples in item (3). This is helpful when offering apps and other programs that target non-healthcare workers.

The first step in determining whether software is a medical device is a search for it under its generic name in a specialized database[5]. Based on its specifications, intended use and other attributes, an initial determination is made as to whether similar products are treated as medical devices. If it is found that no equivalent medical device exists, the process proceeds according to a newly released flowchart. The first question is whether the software in question is intended to be used in the diagnosis, treatment or prevention of disease. If not, the software is then categorized according to whether it is used by individuals or medical institutions. Software that does not constitute a medical device based on its specifications, uses and the details of how it processes data is then screened out and excluded. The GHTF classification rules[6] are then used to identify software falling under the general medical device (Class I) category, which is not subject to regulation under the PMD Act. If it is difficult to make a determination under the GHFT rules, the company should consider: (1) the extent to which the software contributes to disease treatment and diagnosis in view of the importance of the results it produces; and (2) the overall risk the software would pose to human health and life in the event of a functional impairment.

Further, the Guidelines expand on and better organize the examples given in the Basic Policy of software that does and does not constitute a medical device. Examples of software that does not constitute a medical device have been divided in accordance with whether it is intended for personal use or for use by healthcare workers. Some specific examples given of software that is not a medical device in light of new products that have recently been released include "programs that actively monitor daily exercise, track exercise trends and propose actions"; "programs intended to provide advice regarding a healthy diet, exercise, weight management and the like to maintain and promote the general health of individuals"; and "programs that indicate the risk for developing multifactorial diseases such as diabetes based on test results from a model developed through statistical processing based on data on a specific population (limited to programs that do not mislead users into believing it is diagnosis)." By contrast, software that constitutes a medical device is divided into the following categories: (1) software that displays potential diseases and disease risks based on entered information; (2) software intended for use in the diagnosis, treatment or prevention of disease; and (3) software used in combination with a tangible medical device. Item (2) is further divided into the following three subcategories for which specific examples are provided: (i) software that

[5] The database maintained pursuant to the "Enforcement of specially-controlled medical devices, controlled medical devices, and general medical devices designated by the Minister of Health, Labour and Welfare pursuant to the provisions of Articles 2(5) through 2(7) of the Act on Ensuring Quality, Efficacy, and Safety of Pharmaceuticals and Medical Devices, Etc. (Notice) and specially-designated medical devices requiring maintenance designated by the Minister of Health, Labour and Welfare pursuant to the provisions of Article 2(8) of the Act on Ensuring Quality, Efficacy, and Safety of Pharmaceuticals and Medical Devices, Etc. (Notice)" (July 20, 2004, Pharmaceutical and Food Safety Bureau Notification No. 0720022 by the Ministry of Health, Labour and Welfare, Director of the Pharmaceutical and Food Safety Bureau).

[6] An international classification based on the Global Harmonization Task Force. The following shall be used as a reference when determining the classification: "Amendment of Classification Rules for Specially-Controlled Medical Devices, Controlled Medical Devices, and General Medical Devices" (May 10, 2013, Pharmaceutical and Food Safety Bureau Notification 0510 No. 8 by the Ministry of Health, Labour and Welfare, Director of the Pharmaceutical and Food Safety Bureau).

processes data (including images) obtained from medical devices to create indices, images, graphs and the like to be used in the diagnosis or treatment of disease; (ii) software that assists in the determination of treatment plans and methods (including simulations); and (iii) software that controls or enhances the features of medical devices by analyzing medical device data. Various examples are given that have been organized in a useful and systematic manner.

Lastly, as a practical consideration, the Medical Software Guidelines state that, where software is found not to constitute a medical device through the use of the flowchart, it is desirable to include a statement or notice to the effect that, "this software is not intended for use in the diagnosis, treatment or prevention of disease" in order to prevent user confusion[7]. The Guidelines also state that, in order to ensure that software users do not use software for any purpose unforeseen by the business operator (developer), it is important for business operators to conduct awareness-raising and educational activities targeting intended users appropriate in method (eg, self-learning, online training, face-to-face training, etc.) and given the level of risk posed by misuse of the software. The Guidelines further state that it is important for business operators engaged in the development of healthcare-related products to take initiatives to prevent use of their software for unforeseen purposes.

Companies engaged in the development and commercialization of new healthcare-related products and services should carefully analyze their software in accordance with the new Medical Software Guidelines to determine whether it constitutes a medical device and is therefore subject to strict regulatory requirements under the PMD Act.

[7] Whether a product constitutes a medical device is determined based on whether it has the purpose of a medical device in accordance with generally accepted social norms in view of the notice included, structure and shape of the product. For example, the MHLW states that a product will be found to constitute a medical device where "the purpose of the product is specified to be a medical device in a statement on the package insert, container, or the like, or by oral explanation, and even if this is not specified, where the structure and shape of the product itself, according to generally accepted social norms, gives the impression that it has the purpose provided for in Article 2(4) of the Pharmaceutical Affairs Act" (December 26, 1968, Pharmaceutical Affairs No. 239). Displaying a notice stating that a product is "not intended for the purpose of disease diagnosis, treatment or prevention" does not by itself exclude a product from the definition of a medical device. However, the Guidelines recommend that a statement or notice be displayed to prevent user confusion where a product is found not to constitute a medical device.