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Healthcare & Life Sciences
Tokyo

Client Alert

28 July 2023

Outline of new MHLW guidelines on the treatment of disease risk indicating software as a medical device

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Development and commercialization of innovative products/services — including smart technologies — have recently been accelerating rapidly in the healthcare industry. One example is the growing use of AI/machine learning technologies in medical devices that perform diagnosis and/or testing. Further, many software applications and wearable devices are being launched that enable ordinary consumers to collect health-related data, etc.

Commercializing innovative healthcare products/services must of course comply with healthcare regulations, including the Pharmaceuticals and Medical Devices Act of Japan. Whether a product constitutes a "medical device"[1] will materially impact a company's regulatory response, commercialization strategy and the time and resources required for commercialization. Although this analysis is essential, companies often have difficulty determining whether innovative products will be treated as medical devices due to a lack of relevant precedents. Accordingly, the Ministry of Health, Labour and Welfare (MHLW) issued the "Guidelines for determining whether a program is a medical device" to help companies assess whether software will be treated as a medical device.[2] The Guidelines were last updated on March 31, 2023 to provide further clarification and guidance (*Yakuseiki-hatsu* 0331-1, *Yakuseikanma-hatsu* 0331-4 on March 31, 2023).

The latest Guidelines provide updated explanations of factors that will be considered when assessing whether software constitutes a medical device, etc. One of these is whether software diagnoses disease or indicates the risk of disease — an expanding category of software products. Some products are intended for use in the diagnosis or prevention of disease, while others provide information on future disease risks merely for use in improving overall health and wellness. It is not easy to determine where the line is between software that does and does not constitute a medical device. The updated Guidelines clarify the factors to be used in making this assessment and include a flowchart for use in analyzing whether software "indicates a risk of disease" ("**Disease Risk Indicating Software**") and therefore constitutes a medical device.

The MHLW's position is that any software which delivers highly reliable, "publicly known" medical or pharmaceutical information or which merely provides quotations from existing medical literature to users does not constitute a medical device. This is true even where the software indicates that the user may have or be at risk of having a disease. The Guidelines further provide that information is "publicly known" when it is generally

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[1] Under the Pharmaceuticals and Medical Devices Act, a medical device is a device designated by Ministerial Order to be intended for use in the diagnosis, treatment or prevention of human/animal disease or to have an impact on the bodily structure or functions of humans/animals.

[2] Please see Baker McKenzie's, "Regulatory considerations for the development of healthcare products and services based on the new guidelines for determining whether a program is a medical device," issued on April 28, 2021.

recognized as scientifically substantiated from perspective of medical, pharmaceutical and/or nutritional science and where the mere fact of the information's provision by the software does not cause it to be "publicly known."[3] Software that only provides reliable, publicly known information to users does not constitute a medical device because it does not engage in any independent medical analysis. On the other hand, the Guidelines state that products that go beyond this — including those employing new, unique algorithms or features — may constitute medical devices.

The Guidelines go on to state that Disease Risk Indicating Software which targets a "specific individual" may constitute a medical device. In other words, if software indicates a specific individual's risk of disease, it could be considered to be performing disease diagnosis or prevention for this particular individual. However, software that only compares data provided by an individual with statistical disease risk data from a certain population group is not considered to constitute a medical devices because it is not considered to be targeting the individual[4].

Finally, the Guidelines provide that software that indicates that a user may currently be suffering from a disease likely constitutes a medical device. This is more likely to be the case where software determines possible diseases from which users may currently be suffering and/or their severity. On the other hand, the Guidelines provide that software that targets healthy individuals and indicates their future disease risks to "promote health by taking primary preventive measures" is unlikely to constitute a medical device. However, even software that only addresses future disease risk may constitute a medical device where it is found to be intended for use in the diagnosis, treatment or prevention of disease or where such a purpose is explicitly indicated.[5]

As stated above, the Guidelines updated in 2023 provide the latest practical guidance on whether healthcare-related software may constitute a medical device, including specific guidance on Disease Risk Indicating Software based on Japanese legal precedents. Companies pursuing the development and commercialization of new healthcare products and services should refer to these latest Guidelines when assessing whether their products will be treated as medical devices in Japan.

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[3] For example, the guidelines state that "publicly known" information may include (i) information pertaining to medical treatment recognized as standard care in medical text books / guidelines issued by competent Japanese medical societies and (ii) information pertaining to medical treatment referenced in therapeutic guidelines, etc. established by foreign medical societies and recognized by the competent Japanese medical societies as standard therapies applicable in Japan.

[4] Merely comparing statistical data and test results in connection with a multifactorial disease affected by genetic and environmental factors is not considered "diagnosis" and does not constitute medical practice. However, forecasting or assessing the risk of disease in a specific individual is considered to be diagnosis and constitutes the practice of medicine (Seventh meeting of Genomic Medical Practice Implementation Task Force on March 30, 2016). The same considerations seem to apply in evaluating whether a product constitutes a medical device.

[5] For example, the Guidelines provide that, "software which analyzes the test results of [healthy individuals'] cognitive functions or information collected from video of the movements of an examined individual and then indicates the risk that the individual may suffer from dementia or a mild cognitive impairment (MCI) in the future" constitutes a medical device where the software is expected to be used by physicians in diagnosis or by non-physicians to verify the existence of an abnormal condition.