SONDERHOFF EINSEL

[Law Practice Newsletter] 2019 Amendments to the Pharmaceuticals and Medical Devices Act and Their Impact on Companies

I. Introductory

On December 4, 2019, the "Act on Securing the Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices" (the "**Act**") was amended ("**Amended Act**"). The Amended Act is scheduled to be enforced on April 1, 2020, September 1, 2020, August 1, 2021 and December 1, 2022, depending on the item being amended under the Amended Act. We have set out below a brief summary of the four key amendments under the Amended Act, together with their impact on pharmaceutical companies.

II. Key amendments under the Amended Act

1. Improving a company's system to have a more secure, expedient, and efficient development of and post-marketing processes for pharmaceuticals and medical devices

In order to improve a company's system to implement the safety, speed, and efficiency of the development and marketing of pharmaceuticals and medical devices, the Amended Act includes the following amendments:

(1) An expedited approval procedure for innovative pharmaceuticals and medical devices (***Sakigake* Examination System**) (enforcement date: September 1, 2020)

As a matter of practice under the current Act, certain pharmaceuticals and medical devices are subject to priority examination for approval by the Ministry of Health, Labour and Welfare (**MHLW**). The Amended Act puts this practice into statutory form by providing the conditions under which certain pharmaceuticals and medical devices would fall under the *Sakigake* Examination System (i.e., the "*Sakigake* Pharmaceuticals" (*sakigaketeki iyakuhintou*) and the "Specific Usage Pharmaceuticals" (*tokutei youto iyakuhintou*)).

(2) A conditional approval system for pharmaceuticals and medical devices which require a long clinical trial period (**Conditional Early Approval System**) (enforcement date: September 1, 2020)

The same as (1) above, the Amended Act puts the current practice into statutory form by clarifying that approval applications for certain pharmaceuticals and medical devices can be submitted without validating clinical study data.

(3) Introduction of a notification procedure for the change in manufacturing methods pursuant to a post-approval change management protocol (PACMP) (enforcement date: August 1, 2021)

The new procedure enables companies to implement certain changes pursuant to PACMP without waiting for standard longer examination by MHLW and therefore is expected to shorten the authorization process for such changes.

(4) Introduction of an approval examination system for high-tech medical devices (enforcement date: September 1, 2020)

This amendment enables the continued and frequent improvement of high-tech medical devices (e.g. medical devices using artificial intelligence (AI)) without obtaining authorization from MHLW for individual improvements.

(5) Change the principle way of providing "package inserts" so that they should be provided by electronic methods (enforcement date: August 1, 2021)

(6) New obligation to display bar codes on the packaging of pharmaceuticals (enforcement date: December 1, 2022)

(7) Change to (i) GMP/GCTP and (ii) QMS examination system to relax companies' obligations in certain cases (enforcement date for (i) August 1, 2021 and for (ii): September 1, 2020)

Pharmaceutical companies, medical device companies and regenerative medicine manufacture companies should be able to take advantage of these amendments in their business strategy for their development/approval processes and post-marketing changes to their products. Further, companies should establish a new operation system to comply with (5) and (6) above prior to the enforcement of the Amended Act.

2. Amendments in respect of the operations of pharmacists and pharmacies

The Amended Act includes the following amendments. These amendments should be noted by companies which operate a pharmacy business as part of their operations.

(1) New obligations on pharmacists and pharmacy operators (enforcement date: September 1, 2020)

Obligations are newly imposed on pharmacists to: (i) understand the patient's usage status of medicine; (ii) provide instructions on the use of drugs to patients; and (iii) make efforts to provide information on patients' drug use to doctors at other medical facilities (please note that, depending on the status of the patient's decease, pharmacists need to perform these obligations on a continuous basis, not only at the time of filling a prescription). Pharmacy operators are obliged to ensure their pharmacists comply with the above obligations.

(2) Introduction of an approval system for pharmacies cooperating with the regional community and specialized medical institutions (enforcement date: August 1, 2021)

(3) Introduction of providing instructions on the use of drugs through a video call (enforcement date: September 1, 2020)

It will be important to follow the MHLW ministerial ordinances which will be established, in order to understand the detailed requirements for this new video instruction by pharmacists.

3. Establishment of a legal compliance system

For the establishment of a legal compliance system, the Amended Act includes the following amendments:

(1) New obligation on license holders to establish a legal compliance system relating to pharmaceutical affairs ("**Pharmaceutical Compliance System Obligation**") (enforcement date: August 1, 2021)

The introduction of the Pharmaceutical Compliance System Obligation would have an impact on the governance system of: (i) companies which market, manufacture or sell pharmaceuticals, medical devices, regenerative medicine products, quasi-pharmaceutical products and cosmetics (collectively, the "**Healthcare Products**"); (ii) pharmacies; (iii) store retailers, non-store retailers, and wholesale sellers of Healthcare Products; (iv) blood drawing business operators; and (v) sellers, lease operators and repairers of specially-controlled medical devices. For detailed information on this new obligation, please refer to our newsletter on the draft guidelines to the Amended Act published on August 11, 2020.[1]

(2) Introduction of new penalties against false or misleading advertising (enforcement date: August 1, 2021)

Under the Amended Act, if a company advertises their Healthcare Products by a false or misleading advertisement in terms of its name, manufacturing method, efficacy, effect or performance, a penalty will be imposed based on the following calculation formula:

Period of false/misleading advertisement	×	Total sales amount of Healthcare Products on such advertisement	×	4.5%

This penalty system is unique in that, unlike under the Antitrust Law and the Financial Instruments and Exchange Act, the Amended Act provides cases where the penalty is not imposed on the violator, such as the case where their business license has been revoked. The Amended Act also provides: (i) a reduction of the penalty for self-reported cases; and (ii) an exemption for cases where (a) five years have passed since the company stopped its false or misleading advertising or (b) the total sales amount is less than 50 million JPY.

Advertising regulations and monitoring by authorities in the health care industry are becoming increasingly strict year by year, and therefore, companies need to establish a monitoring system for advertising to ensure that they do not violate the strict regulations.

4. Other

Furthermore, the Amended Act includes the following amendments:

[1] "Publication of Amended Pharmaceuticals and Medical Devices Act – Draft Guidelines Regarding Legal Compliance by MAH and Manufactures"(https://se1910.com/newsletters/20200817en/#_ftn1)

(1) Establishment of an MHLW official committee for the evaluation and monitoring of Healthcare Products (enforcement date: September 1, 2020)

MHLW will establish a committee to: (i) ensure the safety of Healthcare Products; and (ii) evaluate and monitor the implementation status of measures to prevent harmful side effects of Healthcare Products.

(2) Relaxation of statutory restrictions on blood drawing (enforcement date: September 1, 2020)

The Amended Act, together with the amendments to the act on a stable supply of safe blood products (the "**Blood Law**"), expands the scope of legitimate blood drawing by allowing blood drawing for the purpose of using for "items to be used for the research and development of Healthcare Products, and other items which will contribute to the improvement of the quality of medical care or health and hygiene" (collectively, the "**R&D Items**"). Currently, this expansion would legalize the creation of iPS cardiomyocytes from blood for the purpose of research and development of medicines. The detailed requirements to fall under the R&D Items will be set out in the MHLW ministerial ordinances in the future, which would have an impact on a pharmaceutical company's business strategy. Furthermore, it should be noted that the revised Blood Law newly requires manufacturers of blood products and the plasma of blood products to provide safety information to marketing authorization holders of blood products.

III. Conclusion

The Amended Act includes a wide range of amendments that will have much impact on the governance system and business strategy of pharmaceutical companies. It would also be important to understand the details to be provided in the future MHLW ministerial ordinances and other regulations.

(28 November 2019 as updated on 9 December 2019, 11 March and 11 May 2020)

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Sonderhoff & Einsel provides legal advice for Pharmaceuticals and Medical Devices Act (PMD Act) including advising on healthcare-related regulations, contracts, negotiations with MHLW, internal training, and dispute resolution.

The information in this newsletter is provided as general information and is not meant to be provided as specific professional advice. If you have any specific questions, please contact Ayuko Nemoto（a-nemoto@se1910.com）.

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