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Amendments to the Medical Devices Act Introduces Private Review System for Medical Device Advertisements

Beginning on June 24, 2021, the Ministry of Food and Drug Safety (the "**MFDS**") will no longer preview medical device advertisements and instead, this will be delegated to private review bodies which will also monitor compliance with such reviews and report the results of such monitoring to the MFDS. This follows an August 28, 2020 Constitutional Court decision that the rules on preliminary review of medical device advertisements by the MFDS were unconstitutional. As a result of that decision, the Medical Devices Act, including its Enforcement Decree and Enforcement Rules (collectively the "**MDA**"), was amended earlier this year to provide for the "Private Review System" for medical device advertisements. Of note, the Enforcement Decree was most recently amended on June 15, 2021.

Qualifications for Private Review Bodies

A "Private Review Body" must be a medical device-related institution or organization established in accordance with the Civil Act, the Framework Act on Cooperatives, or the Small and Medium Enterprise Cooperatives Act, or a consumer organization registered with the Korea Fair Trade Commission in accordance with the Consumer Framework Act, and the scope of its business or the purpose of its establishment is required to include medical devices or related items.

Currently, the only organization that has been registered as a Private Review Body is the Korea Medical Device Industry Association.

Operation of the Review Committee

The Private Review Bodies are required to establish a review committee to review medical device advertisements, and the review committee must consist of between 10 to 20 members, including one chairperson and one vice-chairperson. Such review committee is to be composed of members of the medical device industry including, doctors, dentists, oriental medicine doctors, and lawyers.

Expanded Scope of Review for Advertisements

Currently, the advertisements subject to review include medical device advertisements made through TV and radio broadcasts, newspapers, Internet newspapers and magazines, and the Internet. This scope will be expanded to include outside advertisements displayed on placards, posters, or flyers, and advertisements displayed on transportation facilities and electronic signboards. Also subject to review are medical device advertisements made on Internet news services, Internet homepages operated by broadcasting companies, Internet media operated by mail order retailers and distributors, and large social network services (i.e., with daily average users of 100,000 or more for the three months immediately preceding the end of the previous year).

Standards of Review

A Private Review Body is required to establish the standards of review that will apply to its screening of medical device advertisements, and if there are two or more Private Review Bodies, common standards will be prepared by mutual consultation.

The standards of review adopted by the Private Review Bodies must comply with the MDA, especially requirements under Article 24 of the MDA which prohibit the following types of medical device advertisements:

- false or exaggerated advertisements regarding the name of a medical device, its manufacturing methods, performance, efficacy or effectiveness, or principles of operation;
- advertisements claiming that doctors, dentists, oriental medicine doctors, veterinarians or other persons who guarantee, recommend, certify, instruct use of, or recognize the performance, efficacy or effectiveness of, the medical device, or that such medical professionals use the device;
- advertisements using articles, photographs, designs or drawings or other materials suggesting the performance, efficacy or effectiveness of a medical device or use other implied methods;
- advertisements suggesting abortion or using obscene text or images;
- advertisements referring to the name, manufacturing methods, performance, efficacy or effectiveness of a medical device that have not been approved under Article 6 (2) or Article 15 (2) of the MDA, or are different from those reported; or
- advertisements that have not been reviewed by the Private Review Bodies or advertisements with contents different from those reviewed.

Appeals Process

If there is an objection to the review decision by a Private Review Body, a request may be made for a second review by the same Private Review Body within 30 days from the date of notification of the initial review decision. The result of this second review can then be appealed to the MFDS within 30 days of the notification of such result.

Compliance Monitoring

The relevant Private Review Body must monitor the advertisements to ensure compliance by medical device companies with the relevant decisions with respect to the subject advertisements, and must submit a report of their monitoring results to the MFDS.

Penalties

Penalties for violations (i.e., advertising without review by a Private Review Body or with content that is different from the reviewed content) include:

- Cancellation of product permits or licenses;
- Business closure;
- Prohibition on the manufacturing, import, and distribution of the relevant product; or
- Suspension of business, in whole or in part, up to one year.

Please do not hesitate to contact us at any time if you have any questions on the above. The Healthcare Team at Shin & Kim provides a wide range of legal services and advice relating to medical devices and the healthcare industry, and we would be happy to assist you with any legal issues that impact the industry and/or your business.

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