New version of the Bill on Medical Devices
The Minister of Health has published another version of the bill on medical devices. It is no longer as surprising as the first version from October 2019, as most of the modifications are ordering changes. As for a law that technically implements directly applicable EU regulations, it is still an extremely elaborate document.

Advertising

In the first version of the bill, there already were provisions on the advertising of medical devices. In the new version, they have been modified to some extent. Among others, the new version rightly no longer includes provisions from the regulation on some of the detailed provisions on advertising, including those on mandatory warnings.

The originally broad catalogue of advertising bans has been limited to prohibiting the use of the image of HCPs or suggesting the use of such image, as well as directing advertising only to children. Also, advertising that is misleading with regard to the terms and conditions of maintenance and other activities related to, inter alia, servicing, maintenance, software updates or safety checks, will be prohibited. The catalogue of entities that may conduct advertising has been extended to all “business entities” and other entities with the consent of such entity.

The new version of the bill includes a catalogue of the following activities, subject to advertising provisions:

1. advertising of activities in which a device is used to provide services;
2. presentation of a device during promotional meetings;
3. paid public opinions of users;
4. visiting HCPs for promotional purposes;
5. sponsoring various types of events and presenting devices at them.

Originally, the supervision over the advertising of the devices indicated in point 1 was to be exercised by the President of the Office for Competition and Consumer Protection, whereas according to the new version, the Minister of Health will be supervising in the scope of medical entities, and the Chief Sanitary Inspectorate (Główny Inspektorat Sanitarny, “GIS”) in the remaining scope. Activities under points 2-5 will be supervised by the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych, “URPL”).

It has been extended that the provisions on advertising in pharmacies and medicinal entities will apply accordingly to, inter alia, medical practices and pharmacy outlets. Rules corresponding to those applicable to the promotion of medicines were introduced for the visiting of HCPs in places where services are provided. Advertisements that do not comply with the new provisions will be allowed to be distributed for 6 months from the date of entry into force of the proposed regulation.

Administrative fines

Apart from a few changes, the new version still contains a very broad catalogue of administrative fines. In some cases, a fine may amount to as much as PLN 5 million, e.g. for illegal marketing or use of medical devices, or the introduction of devices that do not meet safety and performance requirements, or the use of, inter alia, texts, names or trademarks that may mislead the user as to the intended use, safety and performance of the device.
With the exception of the fine for misleading advertising of an activity in which the device is used to provide services, which will be imposed by the GIS, the President of the URPL will impose all fines on the basis of an administrative decision.

**List of distributors and products**

The original version of the bill included the creation of a public list of medical devices. The new version additionally foresees the creation of a list of distributors who, having obtained an access code and password to this list, will enter the Basic UDI-DI code of the device, its type and trade name, as well as information about each device imported for the first time in Poland. Failure to comply with these obligations will be subject to a fine of up to PLN 200,000.

Additionally, manufacturers of custom-made devices and their authorised representatives based in Poland will be obliged to submit an application to the President of the URPL for registration of the activity before the first marketing or submission for evaluation of the activity. Failure to do so will also be subject to a fine of up to PLN 200,000.

**Reprocessing**

The new version maintains the acceptability of reprocessing single use medical devices while prohibiting their disclosure or further use. Violation of this prohibition will be subject to a fine of up to PLN 500,000.

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