

# Poland: key changes in the advertising of medical devices and medicinal products

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## Regulatory changes

- On 26 May 2021, the provisions of the Regulation on medical devices ("**Regulation 2017/745**") came into force
- In 2022, also on 26 May, the provisions of the second Regulation, also directly applicable, on in vitro diagnostic medical devices ("**Regulation 2017/746**") enter into force
- At the same time, the new Medical Devices Act of 7 April 2022 in Poland enters into force on 26 May 2022 (the "**Act**"), bringing the Polish medical device market in line with both EU regulations and repealing the provisions of the Medical Devices Act of 20 May 2010
- Work is also underway to tighten the regulations on advertising of medicinal products under a draft Regulation of the Minister of Health dated 5 April 2022 amending the Regulation on advertising of medicinal products (the "**Regulation**")

## Which "medical devices" will be affected by the changes introduced by the Act?

According to the EU definition to which the provisions of the Act refer, a medical device means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific medical purposes listed in Regulation 2017/745. In vitro diagnostic medical devices or, in broad terms, devices intended for the examination of specimens derived from the human body, have their own, appropriately modified definition in Regulation 2017/746. In addition to the instruments or appliances traditionally regarded as medical devices in the broader public perception, increasingly the term medical device also applies to capsules, tablets and syrups.

In order for a product to be considered a medical device, it must not achieve its principal intended action by pharmacological, immunological or metabolic means (but assisting the function of the product by such means is already allowed). Consequently, if a product does not contain substances with a pharmacological action in its composition, but only has a coating effect (e.g. by creating a "mechanical" barrier it relieves a sore throat), it can be classified as a medical device. This classification of the product was advantageous for manufacturers due to the minimal provisions on advertising in the previously applicable Act on Medical Devices. **As a result, many preparations, e.g. cough syrups, sore throat tablets or indigestion capsules with the "medical device" designation, could be advertised under much less restrictive rules than medicines. This is set to change from 1 January 2023, when the new rules for advertising medical devices introduced by the Act come into force.**

## What is meant by the advertising of a medical device?

**While medical devices are clearly defined, neither the EU regulations nor the Act define the concept of advertising.** As a result of doubts raised by manufacturers and suppliers of medical devices on this topic, the Minister of Health agreed to issue an interpretation that distinguishes between advertising and informational activities. Currently, determining how the notion of advertising of medical devices should be understood requires reading the entire chapter of the Act that is devoted to advertising. For example, in accordance with the Act, commercial catalogues or price lists containing only the trade name, the price of the device or the technical specification, as well as information placed on and attached to packages of devices, as required by the Act and EU regulations, are not considered to be advertising of a device.

## Advertising of a medical device in compliance with the new legislation

The regulations introduced by the Act apply to advertising conducted in audio-visual, audio and visual form. In accordance with the Act, the basic standards for the advertising of medical devices are determined by the prohibitions contained in Article 7 of Regulation 2017/745 and Regulation 2017/746, respectively. In both Regulations, the wording of Article 7 is identical and stipulates that in the labelling, instructions for use, making available, putting into service and advertising of devices, it shall be prohibited to use text, names, trademarks, pictures and figurative or other signs that may mislead the user or the patient with regard to the device's intended purpose, safety and performance.

In addition, advertising of a device to the public must be formulated in a way that is readily understood by a lay person, i.e. an individual who does not have formal education in a relevant field of healthcare or medical discipline.

**As in the case of medicine advertising, the advertising of medical devices will no longer be allowed to use the image of persons exercising or claiming to exercise a medical profession or to depict persons presenting a device in a manner suggesting that they do so.** This means the end of the advertising of medical devices with actors dressed as doctors, in pharmacies, dentists' surgeries or doctors' surgeries, readily used to advertise medical devices in the form of the aforementioned capsules, tablets and syrups.

All of the above-mentioned prohibitions also apply to other areas of advertising activities specified in the six points of Article 58 of the Act, such as the presentation of devices during meetings, the purpose or effect of which is to encourage the purchase of devices, or the financing of such meetings, or the communication of opinions to the public by users of devices if they receive benefits therefrom. The explanatory memorandum to the Act expressly emphasises that such a broad definition of advertising will make it possible to "eliminate the currently encountered unfavourable phenomena". One cannot help thinking that this is a reference to, among other things, the growing influence of the influencer industry on the medical device sector and advertising based on so-called personal experience.

**Failure to comply with regulations on the advertising of medical devices can cost a significant amount – the penalties, although mitigated at the Senate stage, are still very severe.** For example, advertising in a manner contrary to the prohibitions set out in Article 7 of each of the EU regulations may expose a business entity to an administrative fine of up to PLN 2,000,000 (approximately EUR 426,000).

## Changes to the advertising of medicinal products

The draft Regulation provides for changes in three areas: the content of warnings on the safety of medicinal products, the contraindications to the use of medicinal products in advertising to the public, and the updating of nomenclature.

As the Minister of Health points out in the explanatory memorandum to the Regulation, current messages and warnings appearing in advertisements for medicinal products are often incomprehensible and unclear to the recipient. Changing their content would ensure their better reception by patients, which in turn should result in more sensible use of advertised medicinal products. As acknowledged in the explanatory memorandum to the draft, ignoring the content of warnings heard and read repeatedly may encourage the spread of the phenomenon of "self-medication" among Poles, i.e. taking medicinal products without medical supervision. In order to change this, **the draft includes warnings in three different versions, with the main message "This is a medicine. For your safety, use it in accordance with the package leaflet."**

The Regulation also provides for **an exemption from the obligation to include contraindications to the use of a medicinal product in advertising.** As the Minister of Health noted in the explanatory memorandum, the text referring to contraindications in advertising should not replace the package leaflet, which should be the main source of information on the use of the medicine, its action, indications and contraindications.

In view of the comments received, the entry into force of the provisions has been extended to 6 months from the date of publication. The transitional provisions also stipulate that advertising, the dissemination of which began before the date of entry into force of the regulation, which does not meet the requirements contained therein, may be disseminated after the date of its entry into force, but no longer than for 6 months from the date of entry into force of the regulation. Although the **new warnings will not appear in advertisements before next year**, the progress of work on the draft should certainly not escape the notice of pharmaceutical companies, but also producers of selected FMCG. Currently, the draft has been subject to the consultation process and has been submitted to 36 institutions for opinions and public consultations, and it is likely that further changes will be made.

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