New rules for the advertising of medical devices in Poland from 1 January 2023

SK&S SOŁTYSIŃSKI KAWECKI SZLĘZAK

As of 1 January 2023, the rules governing the advertising of medical devices, systems, and treatment kits in Poland will change dramatically. On this date, some provisions of the Act of 7 April 2022 on medical devices will come into force.[1] Businesses may be subject to fines of up to PLN 5 million for failing to comply with the requirements of the new regulations.

Diametrical changes

Compared to current regulations, there will be significant changes. The Medical Devices Act ("Act on medical devices") implements the standards contained in EU regulations, including Regulation 2017/745 and Regulation 2017/746 on medical devices The preambles of which[2] also require EU Member States to regulate or clarify certain issues by law. Therefore, some of the new provisions on the advertising of medical devices have been introduced to counteract unethical advertising. As can be seen from the explanatory memorandum of the bill[3], it is justified by the overriding public interest in protecting life and public health.

In effect, as of 1 January 2023 the advertising of **a device** to the public in a way that is explained below will not be allowed:[4]

1) **using the image of persons engaged in the medical profession or claiming to be such persons, or depict persons presenting a product in a manner suggesting that they are engaged in such a profession**;
2) **containing a direct appeal** to **children** to purchase the advertised products or to **persuade parents** or other adults to buy advertised products; and
3) showing products **intended for use by users other than laypersons.**

In practice, this means a complete elimination of doctors, dentists, pharmacists, and other medical or health care professionals from advertising messages about medical devices or the services connected to them.

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[1] *Act on medical devices.*
[2] *Point 76 of Regulation 2017/745 and 2017/746.*
[3] *https://www.sejm.gov.pl/sejm9.nsf/druk.xsp?nr=1764*
[4] *Article 2 of the Act on medical devices.*

Definitions

The term layperson is used by the legislature to describe an individual who has no formal training in the relevant field of health care or medicine.[5] In turn, **a device should be understood as** 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 following specific medical purposes:

- the diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of a disease;
- the diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability;
- the investigation, replacement, or modification of the anatomy or of a physiological or pathological process or state; and
- providing information by means of in-vitro examination of specimens derived from the human body, including organ, blood, and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological, or metabolic means in or on the human body but which may be assisted in its function by such means.

The following products will also be considered medical devices:

- devices for the control or support of conception; and
- products specifically designed for cleaning, disinfecting, or sterilizing the devices referred to in Article 1, paragraph 4, and the devices referred to in the first paragraph of this point.

The new regulations' scope of application

The above regulations will have a very broad scope of application that will include, i.a.:[6]

- **the advertising of a business or professional activities in which the product will be used to provide services** (insofar as it relates to the services provided using the product), including services of lending, renting, or borrowing of products;
- **presenting products at meetings** whose purpose or effect is to encourage the purchase of products, or financing such meetings;
- directing **opinions** to the public **by product users if they receive benefits from doing so (i.e. influencers)**;
- visiting medical professionals to promote products;
- **the sponsorship of fairs, exhibitions, shows, presentations, conferences, conventions, and scientific congresses**, including for medical practitioners or product marketers, and the presentation of products at these events; and
- providing samples to promote products.

Supervisory authorities

The supervision of the advertising of business or professional activities will be exercised by the Minister in charge of health regarding entities performing medical activities, and - to the remaining extent - by the Chief Sanitary Inspector. In turn, in the other aforementioned cases, the supervisory authority will be the President of the Office for the Registration of Medicinal Products, Medical Devices, and Biocidal Products.[7]

[5] *Article 2(1)(38) of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance).*
[6] *Article 58 (1) of the Act on medical devices.*
[7] *Article 58 (2) and (3) in conjunction with Article 2 (1) (26) of the Act on medical devices.*

Obligatory elements of the advertising message

As of 1 January 2023, the advertising of a device will have to include **at least the name or trade name of the device and its intended use.** In addition, it will have to meet the requirements of the Regulation of the Minister of Health of 7 July 2022, amending the Regulation on the advertising of medicinal products.[8] Advertising the device will be allowed only by the business entity, and by other entities, only after its approval, in writing, by the business entity. Responsibility for the compliance of the advertisement with law will be borne by the economic entity approving the advertisement[9].

Exclusions

The above restrictions **will not apply to trade catalogues or price lists** which contain **only the trade name, product price, or technical specifications** as well as information placed on the packaging and attached to the packaging of the products as required by law and Regulation 2017/745 or Regulation 2017/746.[10]

Additional obligations of advertisers and multimedia service providers

Business entities advertising a product directed to the public **will be obliged to keep specimens of advertisements and information about the places where they are distributed for a period of 2 years from the end of the calendar year** in which the advertisement was distributed, and to make the specimen available at the request of the President of the Office, together with information about the manner and period of its distribution. Also, a media service provider or publisher will be obliged to make available, upon request of the President of the Office for Medicinal Products, Medical Devices, and Biocidal Products, the names and addresses of businesses or individuals in their possession who place paid advertisements or advertisements and any other materials related to advertising. In addition, media service providers or publishers will be required to keep the aforementioned information and materials for a period of not less than one year.[11]

Transition period

The advertising of products which distribution began before 1 January 2023 that does not meet the requirements specified above **will not be allowed to be distributed after 30 June 2023**.[12]

[8] OJ 2022 item 1554, enters into force on 26 January 2023.
[9] Article 56 of the Act on medical devices.
[10] Article 59 of the Act on medical devices.
[11] Article 61 of the Act on medical devices.
[12] Article 143 of the Act on medical devices.

Sanctions

If the President of the Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products finds a violation of Article 7 of Regulation 2017/745 or Article 7 of Regulation 2017/746 concerning advertising, or Articles 55 or 56 of the Law on medical devices, the President will issue a decision ordering the removal of the violations found or the cessation of the publication, appearance, or conduct of the advertising in question, or the publication of the decision issued in the places or mass media in which the advertising in question appeared. Decisions will be subject to immediate enforcement.[13] Violations will also result in the imposition of a fine. Depending on the case, this could range from several thousand złoty to PLN 5,000,000:

- for the use of texts, names, trademarks, images, and symbols or other signs that may mislead the user or patient as to the intended use, safety, and performance of the device - up to PLN 5,000,000;
- for advertising devices in a manner contrary to Article 7 of Regulation 2017/745, Article 7 of Regulation 2017/746, or Articles 54-60 of the Act on medical devices - up to PLN 2,000,000;
- for failing to store or make available advertisements, information, or materials under the terms of Article 61 (1)-(4) of the Act on medical devices - up to PLN 50,000;
- for violating Article 21(3) of Regulation 2017/745 or Article 19(3) of Regulation 2017/746 by presenting products in a manner other than specified in these regulations or for failing to provide the information referred to in these regulations - up to PLN 1,00,000; and
- for failing to comply with information obligations related to the labeling and packaging of products, instructions for use - up to PLN 5,000,000.

dr hab. Ewa Skrzydło-Tefelska
Senior Partner, attorney-at-law
✆ +48 608 420 802
✉ ewa.skrzydlo-tefelska@skslegal.pl

Marta Kowalczuk-Kędzierska
Associate
✆ +48 883 391 699
✉ marta.kowalczuk-kedzierska@skslegal.pl

[13] *Article 57 of the Act on medical devices.*
[14] *Article 103 of the Act on medical devices.*

Warszawa
Jasna 26, 00-054 Warszawa
T +48 22 608 70 00
F +48 22 608 70 70
E office@skslegal.pl

Katowice
Wojewódzka 10, 40-026 Katowice
T +48 32 731 59 86
F +48 32 731 59 90
E office.katowice@skslegal.pl

Poznań
Mickiewicza 35, 60-837 Poznań
T +48 61 856 04 20
F +48 61 856 05 67
E office.poznan@skslegal.pl

Wrocław
Plac Solny 16, 50-062 Wrocław
T +48 71 346 77 00
E office.wroclaw@skslegal.pl

www.skslegal.pl