Dentons Prague Newsletter - New legislation on advertising of medical devices in the Czech Republic

May 27, 2021

As of May 26, 2021, the legal regulation of medical devices in the Czech Republic is being comprehensively recodified in response to the European Union's Medical Device Regulation (MDR) and In Vitro Diagnostic Medical Device Regulation (IVDR).[1]

Until now, the advertising of medical devices did not have a special legal regulation (unlike medicinal products) and was thus subject to general rules. It will now be reflected in the legal system in a completely new way. Given the specifics of the sale and promotion of medical devices, we see the adoption of an independent legal framework for advertising as a positive step towards a comprehensive approach to the regulation of advertising in the healthcare sector.

Below we summarize some of the most important points of the new legislation and practical insights from our practice.

The new legislation applies to both general medical devices and in vitro medical devices, and differs primarily according to whether the advertising is aimed at professionals or the general public. It also regulates the advertising of health-related products that are neither medicinal products nor medical devices. The State Institute for Drug Control, which has been responsible for supervising the compliance with medicines' advertising regulation will now also monitor the advertising of medical devices alongside the Council for Radio and Television Broadcasting.

Advertising aimed at professionals may only be promoted through communication media primarily intended for such professionals, such as professional publications and videos, and its content is severely restricted. Any gifts or other benefits offered to professionals, unless they are of negligible value and related to the professional activity carried out, are strictly prohibited. This does not apply to the provision of samples, as long as they are only the necessary quantity and the samples are properly labelled. Restrictions, similar to the regulation of advertising of medicinal products, also apply to congresses and other meetings. At such events, the sponsor may provide free hospitality, accommodation and transport only in proportion to the purpose of the meeting and only to relevant experts.

With regard to advertising aimed at the general public, the promotion of medical devices intended only for use by healthcare professionals or of medicines available only by prescription is strictly prohibited. Where advertising is permitted, it is subject to a number of restrictions. In addition to general requirements such as the prohibition of misleading or comparative advertising, advertising of medical devices must not, for example, downplay the need to consult a doctor, imply that clinical efficacy is guaranteed, or suggest that non-use of a medical device may adversely affect health. The new law also prohibits advertising practices such as recommendations by experts or celebrities or misleading illustrations of changes to the body as a result of the use of a medical device (eg. 'before' and 'after' photographs). Provision of samples to the general public is also unacceptable.

In addition, the Czech legislator has decided to extend the rules on advertising to include products that are not medical devices or medicinal products, but whose promotion is aimed at human health. According to the legislator, the

purpose of the new provision is to prevent fraudulent claims that a product can improve health, when such a claim is unsubstantiated. Firstly, it is strictly prohibited to advertise a health-targeted product as a medicinal product or medical device, if it is not one.

Furthermore, the law extends the restriction on advertising, in a vague manner, to all other products that are not medicinal products and medical devices, and states that such advertising:

- may not imply that the use of the products will improve or maintain health;
- may not imply that by not using the product, health may be adversely affected; and
- may not use medical experts or public figures to recommend the product.

This provision was inserted into the new law by a last-minute amendment of several Members of Parliament. The extensive potential interpretation of this new regulation may affect a large number of products that are more or less related to a healthy lifestyle and whose use is recommended in practice by health experts or celebrities. Thus, for example, well-known advertisements for toothbrushes, food, or sports equipment may be affected. Only administrative or judicial practice is likely to show whether or not the application of the unfortunately worded provision goes beyond its originally intended purpose.

We will keep you informed about legislative developments in this area. If you have any questions, please do not hesitate to contact us.

Read the Newsletter

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1. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices.

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