Pharma Flash

October 2019

Proposal of New Medical Devices Legislation in the Czech Republic: Adaptation of the EU Medical Devices Regulations, and a Brand New Regulation of Advertising

In the context of adaptation of the new EU Medical Devices Regulations,[1] two drafts have been published: a brand new draft bill on medical devices which is intended to apply to general medical devices; and a draft amendment to the existing act on medical devices which should be renamed and should hereafter only apply to in vitro diagnostic medical devices. Beyond the scope of the requirements laid down in the EU regulations, specific national regulation of advertising of medical devices is underway. The drafts referred to above are currently undergoing the inter-ministerial reflection process. Based on the proposed wording, they should enter into force as of 26 May 2020.

Act on (general) medical devices

Given the direct applicability of the Regulation on Medical Devices, the draft bill only regulates those aspects of medical devices which the Regulation allows to be regulated at the national level, or which it does not regulate at all. The bill only applies to general medical devices, not to in vitro diagnostic medical devices.

The bill concerns, among other issues, certain aspects of clinical trials, notification duty of distributors and service providers, as well as prescription, supply, use (including training of healthcare professionals) and service of medical devices. In some of these areas, the bill introduces certain changes as compared to the legislation currently in force. The bill also proposes prohibition of reprocessing of single-use medical devices in the Czech Republic.

Act on in vitro diagnostic medical devices

It is proposed that the existing act on medical devices should – for the period preceding the entry into force of the Regulation on In Vitro Medical Devices, i.e. until 26 May 2022 – change its title and only apply to in vitro diagnostic medical devices. The reason behind the proposal is that the existing national legislation concerning in vitro diagnostic medical devices based on EU Directive 98/79/EC[2] needs to remain in place until the above Regulation enters into force.

The draft amendment also incorporates some of the changes contained in the proposed bill on (general) medical devices.

Amendment to the act on the regulation of advertising

Completely new, specific regulation of advertising of medical devices (including both general medical devices and in vitro diagnostic medical devices) is significantly inspired by the regulation of advertising of medicinal products.

---

[1] *Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2015 on medical devices, in force as of 26 May 2020 (the "**Regulation 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, in force as of 26 May 2022 (the "**Regulation on In Vitro Medical Devices**").*

[2] *Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.*

Pharma Flash

October 2019

The draft proposes in particular the following:

- special rules for **advertising targeting healthcare professionals**:
  - specific requirements concerning the contents of advertisements are set out;
  - advertising can only be disseminated via communication channels intended primarily for healthcare professionals;
  - provision of gifts to healthcare professionals in connection with advertising is prohibited; and
  - hospitality and accommodation provided to healthcare professionals in connection with professional gatherings or congresses must be proportionate;
- special rules for **advertising targeting the general public**:
  - specific requirements concerning the contents of advertisements are set out;
  - recommendations with reference to recommendation by scientists, healthcare professionals or celebrities is prohibited;
  - promotion (including the distribution of samples) of medical devices intended for use by healthcare professionals and of prescription-only medical devices is prohibited; and
  - a number of additional prohibitions are introduced in this area in line with the rules governing advertising of medicinal products;
- **comparative advertising** of medical devices is permissible solely if aimed at persons authorised to prescribe and/or supply medical devices; and
- **prohibition of advertising of reimbursed medical devices** in the form of a **contest, lottery or any other similar game** based on the quantity of medical devices prescribed, supplied or used.

The **State Institute for Drug Control** should newly become the authority competent for the **enforcement** of rules governing advertising of medical devices.

Authors:
Václav Audes | *Partner*
František Neuwirth | *Associate*
Vladěka Laštůvková | *Junior Associate*



HAVEL & PARTNERS

CONNECTED THROUGH SUCCESS

Our team

220 lawyers | **400** employees

Our clients

1,500 clients | **100** of the Fortune 500 global companies
50 companies in the Czech Top 100 league | **7** companies in the Czech Top 10 league

International approach

Legal advice
in more than **80** countries of the world
in **12** world languages
up to **70**% of cases involve an international element

www.havelpartners.cz

PRAGUE
Florentinum, Reception A
Na Florenci 2116/15
110 00 Prague 1
Czech Republic
Tel.: +420 255 000 111

BRNO
Titanium Business Complex
Nové sady 996/25
602 00 Brno
Czech Republic
Tel.: +420 545 423 420

BRATISLAVA
Zuckermandel Centre
Žižkova 7803/9
811 02 Bratislava
Slovak Republic
Tel.: +421 232 113 900

PILSEN
Nepomucká 144
326 00 Plzeň
Czech Republic
Tel.: +420 371 005 320

OLOMOUC
Salm Palace
Horní náměstí 371/1
779 00 Olomouc
Czech Republic
Tel.: +420 581 000 310

OSTRAVA
Poděbradova 2738/16
702 00 Ostrava
Czech Republic
Tel.: +420 596 110 300