Pharma Flash

January 2018

New EU medical devices regulations: expected impact on the market

As is already known, the final versions of two new EU regulations were published in the Official Journal of the European Union in May 2017. The regulations lay down new rules governing the medical devices sector, to wit (i) Regulation No. 2017/745 on medical devices, regulating general medical devices (including active implantable medical devices), and (ii) Regulation No. 2017/746 on in vitro diagnostic medical devices (IVD). The Regulations will only come into effect in 2020 (general medical devices) and 2022 (IVD) to allow sufficient time for the entities concerned to prepare for the implementation. However, some important players, such as MedTech Europe, the UK's regulatory agency MHRA and the Czech Ministry of Health, have recently published guides to the new regulations. As a result, it is appropriate to ask the question what impact the regulations will have on the market.

Major conceptual change in medical devices law

At the EU level, medical devices have so far been regulated by three directives[1], which have been implemented in individual Member States by national laws (particularly the Medical Devices Act and applicable government decrees in the Czech Republic, and the Medicinal Products and Medical Devices Act and relevant government decrees in Slovakia).

However, contrary to the existing directives, the new Regulations are directly binding and do not require (do not even allow) implementation at the national level. As a result, a large part of national laws regulating medical devices in the Czech Republic and Slovakia will have to be abrogated without compensation or fundamentally amended and adapted to the Regulations. However, this 'adaptation' legislation is still in its infancy in both countries.

New EU Regulations: examples of new developments and their impact

- The Regulations change in particular the requirements for **manufacture, conformity assessments, clinical trials and post-marketing surveillance**. This is expected to have effects mainly on medical devices manufacturers or their authorised representatives in the EU.

- The Regulations also set out **distributor obligations**. Nevertheless, a number of such obligations are already present in current Czech (and partly also Slovak) legislation. Therefore, the new Regulations will have a rather indirect effect on distributors (including Czech and Slovak branches of multinational manufacturers) via new requirements placed on the manufacturers.

- Under the new Regulations, medical devices will be considered to also include, without limitation, **products with an aesthetic or another non-medical purpose** but which are similar to medical devices in terms of function (such as contact lenses; facial, dermal, or mucous membrane filling substances and liposuction equipment). What used to be considered cosmetics or unregulated products could now be considered a medical device.

- A major change will affect **conformity assessments of IVDs**. Under currently applicable rules, only 20% of IVDs require the involvement of a notified body (testing laboratory) in the conformity assessment, while self-certification is sufficient for the remainder (the conformity is assessed by the manufacturer itself). It is estimated that, as a result of the Regulations, the ratio will be reversed and the intervention of a notified body will be required for up to 80% of IVDs. Again, this change will primarily affect manufacturers.

- **Eudamed, the European-wide database of medical devices**, will undergo a substantial makeover. Manufacturers and authorised representatives will register in the database, while distributors will still register in national databases. Also, medical devices will be entered in Eudamed. Consequently, the current Czech and Slovak laws regulating registration and notification of manufacturers and medical devices will have to be amended. Another important change is that the Eudamed database will become accessible to the public.

[1] *Council Directive 93/42/EEC of 14 June 1993 concerning medical devices; Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices; and Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices.*

Pharma Flash

January 2018

- The Regulations also deal with **parallel trade** in medical devices in the EU and the related issues of **repackaging** and **relabelling**. In recent years, especially Germany has seen several disputes related to the parallel import of glucose meters from other EU Member States.

- The **Unique Device Identification** ("UDI") system is introduced to enhance traceability of medical devices.

- The General Medical Devices Regulation will apply as of 26 May 2020, and the IVD Regulation will apply as of 26 May 2022. However, both Regulations contain complex **transitional provisions**, the purpose of which is to allow **certificates** issued by notified bodies in accordance with currently applicable legislation **to remain valid** for a certain period after the effective dates of the new Regulations.

New Regulations summarised in flowcharts and other responses

The new Regulations have been recently reflected by some major players. For example:

- **MedTech Europe**, the European-wide association of medical device manufacturers, published a comprehensive overview of both Regulations in the form of flowcharts[2] in December 2017;

- The UK's regulatory agency **Medicines and Healthcare products Regulatory Agency** (**MHRA**) has prepared interactive guidance on the legislation[3];

- The Czech **Ministry of Health** has provided a 'questions and answers' section on its website addressing the new Regulations[4].

In conclusion, we should add that both Regulations impose an obligation on the European Commission to issue a rather large number of implementing acts to specify the provisions of the Regulations in more detail. However, the Commission has only issued one implementing act[5] so far.

---

[2] *See http://www.medtecheurope.org/industry-themes/topic/130*
[3] *See https://www.gov.uk/guidance/medical-devices-eu-regulations-for-mdr-and-ivdr*
[4] *See http://www.mzcr.cz/Odbornik/dokumenty/evropske-narizeni-v-oblasti-zdravotnickych-prostredku-otazky-a-odpovedi_14034_2491_3.html*
[5] *Commission Implementing Regulation (EU) 2017/2185 of 23 November 2017 on the list of codes and corresponding types of devices for the purpose of specifying the scope of the designation as notified bodies in the field of medical devices*

Authors:
Václav Audes | *Partner*
František Neuwirth | *Associate*

HAVEL & PARTNERS

CONNECTED THROUGH SUCCESS

Our team

200 lawyers | **400** employees

Our clients

1,000 clients | **70** 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

OSTRAVA

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

BRATISLAVA

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