Temporary changes to legal rules on medical devices

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On 26 May 2020, an amendment[1] to the Act on Medicinal Products[2] became effective to reflect adoption of a new EU Regulation on Medical Devices[3]. Amendment to the Act on Medicinal Products was scheduled to become effective on the same day as the Regulation, which was due to introduce stricter standards for medical devices. However, numerous medical device manufacturers reported that they would be unable to implement changes meeting the new requirements by 26 May 2020. The Regulation was supposed to lay down new obligations to medical device manufacturers, as well as to other stakeholders such as medical devices importers, authorised representatives of manufacturers outside of the EU, and distributors.

Considering the difficulties associated with the Covid-19 pandemic, EU authorities accepted the manufacturers' requests and postponed the effective date of the Regulation until 26 May 2021. However, Slovak legislators were slow to react and did not reflect this change in the legislation. Therefore, something of a "legal vacuum" arose, because not only did the Slovak law fail to deal comprehensively with medical devices and relied on the Regulation to cover these deficiencies, it also continued to refer to the Regulation as if it had already come into effect, when in fact this would not be the case until May next year.

In order to remedy this unhelpful situation, the Slovak Parliament adopted a new amendment to the Act on Medicinal Products, which reintroduces the legal regulation of medical devices, valid prior to 26 May 2020, with minor differences. This new amendment should become effective within days, after being published in the Collection of Laws. However, it should only remain in force until 26 May 2021. From this date, unless a further postponement is applied, those involved in the production of medical devices will have to begin applying the requirements as set out in the Regulation.

We understand that continuous changes in legal requirements may cause time consuming uncertainty in navigating obligations associated with the manufacture and sale of medical devices. Consequently, EY professionals specializing in the field of pharmaceutical law are ready to offer comprehensive legal advice relevant to this field, including assistance in implementing new requirements.

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[1] Act No. 383/2019 Coll. On amendment and supplementation of Act No. 362/2011 Coll. On Medicinal Products and Medical Devices

[2] Act No. 362/2011 Coll. On Medicinal Products and Medical Devices, as amended

[3] 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