

Legislation of medical devices and Covid-19

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Introduction

After 20 years, two Regulations on medical devices have been published, replacing the Directives on medical devices. Covid-19 virus pandemic occurs in a very sensitive period of transition from the Directives to the new Regulations of the European Union.

Legislation of medical devices during the Covid-19 virus pandemic is strongly influenced by the need for timely placement of medical devices on the market in the European Union, especially medical devices associated with Covid-19. Hence, the need for regulatory flexibility and finding alternative pathway in placing a medical device on the market in the European Union has arisen, given the fact that the medical device industry is at the forefront in the fight against Covid-19.

The implications of the pandemic on the legislation of medical devices were seen in the postponement of the new Regulation on Medical Devices for one year, numerous laws, regulations, guidelines, recommendations, surveys, covering all stakeholders in medical legislation, a list of medical device essential for Covid-19 epidemic and the way they are marketed in the event of a pandemic, as well as information that provides tools to expedite conformity assessment procedures.

Implications of Covid 19 on the Regulations

The transition period referring to the Regulation on Medical Devices (2017/745 /EC) was extended by one year

from the originally determined date of implementation of the Regulation (26.05.2020) and the final date of implementation was 26.05.2021. That left an opportunity

for an additional year in a pandemic to be placed on the market under the existing Directives, so that the EU was timely supplied with the necessary medical devices (MD).

The transition period of the new Regulation on In Vitro Diagnostic Medical Devices (2017/746/EC) remained unchanged (date of implementation-22 May 2022) (Binmöller, 2020)

Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on Medical Devices, as regards the dates of application of certain of its provisions, postponed the date of application of most medical device regulation provisions by one year- until 26 May 2021 (Trevino, 2020).

It also amended Article 59 of the Regulation: Until Medical Device Regulation (MDR) is applied, the current Medical Devices Directives are also included in Article 59. While the MDR was valid from 26 May 2021, Article 59 was applied from 24 April 2020. Article 59 lays down how the authorization to deviate from the requirements for CE marking of medical devices may be exercised. (Boumans, 2020; Regulation (EU)2020/561).

The extraordinary circumstances created by the Covid-19 pandemic have had a significant impact on the work of notified bodies, the Member States and the Commission, in connection with the renewal of the appointment process, as well as the oversight and monitoring activities related to the notified bodies.

As a result, the European Commission adopted the new one Implementing Regulation (EU) 2020/666 amending Implementing Regulation (EU) No 920/2013 as regards the renewal of designations and the surveillance and monitoring of notified bodies. The most important provisions of the regulation are the following:

Notified bodies retained their ability to issue certificates for obtaining the CE mark of the manufacturers

of medical devices under Medical Device Directive (MDD) and Active Implantable Medical Devices Directive (AIMDD) for an additional year;

The condition for appointment of the notified body is removed by including on-site visits when processing the requests for appointment of a notified body with immediate effect. However, the Implementing Regulation makes it clear that designating authorities must still assess an adequate number of reviews by the notified body for the manufacturer's clinical assessments and on-site inspections and audits (Regulation (EU) 2020/666).

In the interest of public health MDCG (Medical Device Coordination Group) published a guide (Guidance on temporary extraordinary measures related to medical device Notified Body audits during Covid-19 quarantine orders and travel restrictions (04.2020)-MDCG) and MDCG 2020-17: Questions and Answers related to MDCG 2020-4, in order to determine the emergency measures that should temporarily follow the notified bodies in this period, in order to enable continuous availability of safe medical devices on the market and to minimize the risk of lack of medical supplies. The Guide provides that notified bodies may introduce temporary alternative emergency measures in place of on-site conformity assessment audits as a result of limitations of Covid-19 (Trevino, 2020).

On January 11, 2021, the European Commission issued a notification which sets out the conditions under which remote audits may be performed under Regulation 2017/745/EC of 5 April 2017 on Medical Devices (MDR) and Regulation 2017/746 of 5 April 2017 on In Vitro Diagnostic Medical Devices (IVDR): Commission Notice on the application of Sections 2.3 and 3.3 of Annex IX to Regulation (EU) 2017/745 and Regulation (EU) 2017/746 with regard to notified bodies audits performed in the context of quality management system assessment 2021/C 8/01. This notification was a long-awaited decision that has direct implications for manufacturers who are willing to switch to Medical device Regulation or In vitro medical device Regulation, but have not been able to pass a conformity assessment due to the inability of their notified bodies to audit the quality management system. However, the decision to conduct remote audits will be made on a case-by-case basis and it will be important for manufacturers to duly justify their request to the notified body. In order to more easily deal with the pandemic, the European Commission has published a "List of essential medicines for Covid-19 (MS and IVD medicines)", which serve as a guide for notified bodies when considering which products should be given priority in conformity assessments.

Also available is the Covid-19 In Vitro Database for Diagnostic MD and Testing Methods: Covid-19 In Vitro Diagnostic Devices and Test Methods Database, which is

described as a repository for browsing all publicly available information for CE-marked IVD performance.

The European Commission published a guide to medical devices in the context of the Covid-19 pandemic: Guidance on medical devices, active implantable medical devices and in vitro diagnostic medical devices in the Covid-19 context, which explains the legal requirements for placing medical devices on the EU market, how standards can be used under current legislation and whether it is possible to deviate from the usual conformity assessment procedures in light of the urgency caused by the Covid-19 epidemic.

Conclusion

In order to successfully deal with the biggest health crisis in recent history, all stakeholders in medical legislation have a proactive role and have adapted to the mentioned changes in the legislation.

All measures that have been taken, are being taken and will be taken in the future must be aimed at increasing the availability of medical device, but at the same time all medical devices on the market should be safe, properly used, while taking care of the public health and safety of the EU population.

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