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European Commission proposes postponement of the new EU Medical Device Regulation and broadens Emergency Use Authorization Rules

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Food, Drug, and Device Practice Group

On April 3, 2020, the European Commission published its proposal for a new Regulation to amend the application date of the Medical Devices Regulation 2017/745 ("MDR") by one year. The proposed new legislation also amends the MDR rules on exceptional special authorizations of non-CE-marked medical devices with immediate effect.

Postponement of MDR Application

This publication comes about a week after the Commission announced its plans to postpone the MDR (see the Covington *InsideEULifeSciences* blog post here). The European Parliament and the Council will now need to approve the proposal before the MDR's current application date of May 26, 2020. If approved, the date of repeal of Directives 90/385/EEC and 93/42/EEC will also be delayed, meaning they will remain current law until May 2021.

The Commission's legal basis for the postponement are Articles 114 and 168(4)(c) of the Treaty on the Functioning of the European Union ("TFEU"). This gives the European Parliament and Council the authority to adopt measures that ensure the establishment and functioning of the internal market, and, in particular, where necessary for reasons of public health. The Commission also cites the principles of subsidiarity and proportionality, arguing that the measure will ensure a high level of protection of health for patients and users, the smooth functioning of the internal market and avoid potential market disruption. Specifically, it notes:

> "*This Union action is necessary to achieve the objective of the proper implementation and application of [the MDR] by all involved parties, taking into account the magnitude of the current COVID-19 outbreak and the associated public health crisis. The proposed amendment aims to ensure that the intended purpose of [the MDR], that is, to establish a robust, transparent, predictable and sustainable regulatory framework for medical devices, which guarantees a high level of protection of public health and patient safety and the smooth functioning of the internal market for such devices, can be attained*."

The Commission confirmed that its proposal does not alter the MDR substantively nor does it impose any new obligations on manufacturers or other concerned parties.

The delayed implementation of the MDR will be welcome news to all manufacturers of medical devices intended for the EU market, as well as other economic operators in the supply chain.

The postponement of the implementation date will allow companies to deploy resources to address the current pandemic and will give them extra time to become MDR-compliant. The postponement of the MDR will similarly help the Notified Bodies in the EU.

Broadening of Special Authorization Rules for non-CE-marked devices

The Commission's proposal also includes an amendment of Article 59 of the MDR that governs the rules for special authorizations of medical devices that are not yet CE-marked. Article 59 allows the EU Member State authorities to grant special authorizations for the placing on the market or putting into service of specific medical devices that are not yet CE-marked if this is "in the interest of public health or patient safety or health". This special authorization applies only for the territory of the respective Member State. Pursuant to Article 59 (3) MDR, the Commission can extend the validity of such special authorizations to the entire EU.

The current version of Article 59 MDR would only apply after the MDR becomes applicable and would therefore be limited to special authorizations obtained under the MDR. The now proposed amendment to Article 59 MDR will broaden the scope of this competency of the Commission as it would include special authorizations granted under the currently applicable Medical Devices Directives 93/42/EEC and 90/385/EEC. This means that this proposed MDR amendment would practically have an immediate effect.

With the proposed amendment of Article 59 (3) MDR, the Commission can extend for a limited period of time the validity of a special authorisation granted by a Member State to the entire EU territory. This would currently also extend to the UK based on the transitional period after Brexit.

Medical device manufacturers should closely monitor this development and review the options for using this special authorization pathway. Products eligible for this special authorization need to be "in the interest of public health or patient safety or health".

No postponement of the IVD Regulation

The Commission's proposal is limited to the postponement of the application date of the MDR and does not apply to the IVD Regulation (EU) 2017/746 which will apply from 26 May 2022.

Next Steps and Practical Consequences

The European Parliament and the Council will now need to approve the Commission's proposal before the MDR's current application date of May 26, 2020. If approved, the date of repeal of Directives 90/385/EEC and 93/42/EEC will also be delayed, meaning they will remain current law until May 2021. This will also apply to the certificates obtained under the current regulatory regime. Similarly, this will apply to the accreditations of those Notified Bodies that could not yet be designated under the MDR.

The MDR postponement will especially help the European Commission to work on the many other open action items to make MDR workable. Today, 50 days before its application date, the MDR system is far from being operational for reasons that have nothing to do with COVID-19.

Nevertheless, the proposed MDR amendment does not postpone or delay the transition periods under the MDR and also leaves many other questions open that device companies and Notified Bodies are currently facing with respect to the implementation of the new regulatory requirements under the MDR.

The extended rules for special authorizations of medical devices that are not CE-marked can be a powerful tool in the current COVID-19 pandemic but also beyond this time. This may be an interesting regulatory pathway for medical device companies whose products have obtained a special authorization under the current Directives or whose new products may be eligible for this exceptional authorization track. Companies will first need to analyse the requirements in the EU Member State as the application for a special authorization still needs to be obtained from a Member State authority.

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