COVID-19: EUROPEAN COMMISSION DETAILS PLANS TO POSTPONE EU MEDICAL DEVICE REGULATION AND EUROPEAN DEROGATION PROCEDURE TO GET MEDICAL DEVICES TO MARKET FASTER

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The European Commission (EC) has published details of its proposal to postpone the application date of the Medical Devices Regulation (MDR) for one year. In addition, the EC proposes introducing a new procedure to address potential EU-wide shortages of vitally important medical devices, e.g. shortage of medical facial masks and other equipment required in the COVID-19 epidemic, in an effective manner by allowing medical devices to be placed on the market of the entire Union without a conformity assessment procedure having been completed.

Medical device manufacturers and notified bodies as well as national authorities can use the additional year to focus on the challenges in combating COVID-19 rather than implementing the numerous changes imposed by the MDR. This period also gives economic operators, notified bodies, national authorities, and the EC more time to implement the various requirements of the MDR.

BACKGROUND

On 25 March 2020, the European Commission (*European Commission* or *EC*) announced that it is working on a proposal to postpone the date of application of regulation (EU) 2017/745 on medical devices (*Medical Device Regulation* or *MDR*) and extend the applicability of directives 90/385/EEC on active implantable medical devices and 93/42/EEC on medical devices (together *Medical Device Directives* or *MDDs*) for one year respectively. This extraordinary measure is made as EU Member States, notified bodies, economic operators (manufacturers, importers, and distributors), and national health institutions will not be able to devote the necessary attention to the introduction of the MDR due to the COVID-19 outbreak.

Also, the EC perceived it as imperative given the COVID-19 pandemic and the resulting public health crisis to secure supplies of safe medical devices for the treatment of European patients. To this aim, it desires to prevent shortages caused by regulatory hurdles for any already approved medical devices and to make vitally important new medical devices available as quickly as possible.

NEW DEVELOPMENTS

On 3 April 2020, the EC published its proposal for a regulation to amend the MDR (i) postponing the application of the MDR and extend the applicability of the MDDs for one year and (ii) introducing a new EU-wide derogation

from conformity assessment procedures to put products quickly on the market amidst the COVID-19 pandemic. On 6 and 8 April 2020, the presidency of the Council of the European Union (the *Council*) has invited with few additional comments the Permanent Representatives Committee to agree to a mandate for the text amended by the presidency of the Council (the *Proposal*) to be submitted to the EU Parliament and to be agreed by the Council.

Selected Details of Postponement of MDR

- *General postponement.* According to the Proposal, the MDR shall generally apply, subject to certain exceptions, as from 26 May 2021, i.e., one year after its originally intended date of application (Art. 123 para. (2) of the new MDR). Consequently, the Proposal also postpones the implementation date in several further provisions, for example:
  - the date (26 May 2021) on which the EC shall have adopted common specifications for (i) those groups of products without an intended medical purpose listed in Annex XVI to which the MDR shall apply following the adoption of such common specifications (Art. 1 para. (2) of the new MDR) and (ii) the reprocessing of single-use devices (Art. 1 para (3) and (5) of the new MDR).
  - the date (26 May 2021) until which the EC shall be obliged to publish the notice that the European database on medical devices (Eudamed) is fully functional (Art. 34 of the MDR) and that all other relevant deadlines laid down in Art. 123 and in Art. 113 of the MDR are met. Notwithstanding this obligation of the EC, in case such notification is not made by the EC until 26 May 2021, the obligations and requirements set forth in the MDR in connection therewith shall apply six months after the EC has published its notice.
  - the date (25 May 2021) until which each EU Member State shall notify to the European Commission the rules on penalties applicable for infringement of the MDR and the measures taken to ensure that these are implemented (Art. 113 of the new MDR). This gives the Member States additional time to implement such rules and measures. According to the Council, so far only two or three Member States have sent notifications to the EC.
- *Notified bodies.* The MDR still provides that the accreditation of any notified bodies notified under the MDD shall end as of the date of application of the MDR. Given that the date of application of the MDR shall be postponed by one year, the accreditation of notified bodies would continue to be in force and effect for one additional year and, hence, such notified bodies could continue their work until 26 May 2021 (Art. 123 para. 3 lit. (a) of the MDR).
- *Clinical investigations.* Clinical investigations that have started in accordance with the MDDs prior to 26 May 2021, may continue to be conducted. As of 26 May 2021, however, the reporting of serious adverse events and device deficiencies needs to be carried out in accordance with the MDR (Art. 120 para. (11) of the MDR).
- *UDI carriers.* The presidency of the Council has deleted the proposal of the EC to change the date of application of the obligation to place UDI (*unique device identification*) carriers on the label of a device and on all higher levels of packaging. The MDR currently provides that this obligation (Art. 27 para. (4)) should apply to class I devices as from 26 May 2025, to class IIa and IIb devices as from 26 May 2023, and to class III devices as from 26 May 2021.

Introduction of a New EU-wide Derogation from Conformity Assessment Procedures

In addition to the postponement of most of the provisions of the MDR as described above, the EC also proposes to introduce a new EU-wide derogation procedure in addition to the national derogation procedure under the currently applicable Art. 59 of the MDR and the MDDs.

The MDD as well as Art. 59 of the MDR empower national competent authorities, on a duly justified request, to authorize companies to place on the market in the territory of a Member State medical devices for which the relevant conformity assessment procedures have not been carried out but the use of which is in the interest of protection of health or in the interest of public health or patient safety or health respectively (*National Derogation*.) The Member State may inform the Commission and the other Member States about a National Derogation granted under the MDDs. In exceptional cases relating to public health or patient safety and health, and following notification by a Member State, the EC may extend a National Derogation to the entire territory of the EU for a limited period by way of implementation acts and set conditions under which the device may be placed on the market or put into service (*EU Derogation).*

Taking into account the COVID-19 outbreak and the associated public health crisis, the EC wants to be able to adopt an EU Derogation in response to National Derogations in order to address potential shortages Union wide of vitally important medical devices in an effective manner.

For this purpose, the new EU Derogation procedure in Art. 59 of the amended MDR shall apply already as from the date on which the regulation to amend the MDR comes into force and effect (Art. 123 para. (3) lit. (j) of the new MDR).

Transposition in National Laws

The MDR is a regulation and, therefore, applies generally, is binding in its entirety and directly applicable in all Member States (Art. 288 para. (2) of the Treaty on the Functioning of the European Union). The MDDs on the other hand are directives which are binding only as to the result to be achieved and need to be implemented into national laws of the Member States by way of transposition acts.

Due to the initially anticipated date of applicability of the MDR most Member States have already enacted laws pursuant to which those national laws, which originally implemented the MDD, shall cease to apply as of 26 May 2020. In Germany, for example, the German Parliament (*Bundestag*) on 5 March 2020, adopted the German Medical Device EU Amendment Act (*MPAnpG-EU*) pursuant to which, amongst others, the German Medical Device Act (*Medizinproduktgesetz; MPG*) is repealed with effect as of 26 May 2020 (Art. 16 para. (1) of the German Medical Device EU Amendment Act).

Hence, in addition to the Proposal being adopted by the Council and the EU Parliament, it is necessary that each Member State ensures that its national laws continue to implement the MDD also after 26 May 2020.

TIMING

Prior to coming into effect, the Proposal needs to be agreed with, and voted upon by, the EU Parliament and the Council. The EU Parliament is expected to vote its position at first reading at its plenary on 16 April 2020. In addition, a consultation of the European Economic and Social Committee and the Committee of the Regions is compulsory, as this proposal concerns public health. Both consultations must be finished before the Proposal can be adopted. Following adoption of the Proposal, it will still need to be implemented into national laws to ensure

that the transposition acts for the MDDs continue to apply. We will continue to monitor the Proposal and its adoption in the EU and its transposition in the Member States.

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