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COVID-19: application of EU Medical Devices Regulation postponed by one year, until 26 May 2021

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The application date of Regulation (EU) 2017/745 on medical devices (MDR), which was originally anticipated on 26 May 2020, has been postponed by one year due to the COVID-19 pandemic. On 24 April 2020, the EU legislator adopted an amendment to the MDR postponing the application of most of its provisions by one year, until 26 May 2021 (Amending Regulation).

As a result, the repeal date of the existing Directive 93/42/EEC on medical devices (MDD) and the Directive 90/385/EEC on active implantable medical devices (AIMDD) has also been postponed by one year and will remain applicable in the meantime.

However, the date of application of the *In Vitro* Diagnostics Medical Devices Regulation (IVDR) will still become applicable on 26 May 2022, as expected.

Background of the MDR's postponement

On 5 April 2017, the EU legislator revised the regulatory framework for medical devices and in vitro medical devices by adopting the MDR and the IVDR, the aim of which is to harmonise medical devices legislation at the EU level.

As such, the MDR expands the scope of the existing medical devices regulatory framework to include previously unregulated products and introduces a list of obligations for the medical devices industry, which intends to improve patient safety with refined rules for the assessment of medical devices based on a risk classification system. A key element of this updated regulatory approach is the reinforcement of the role of notified bodies, with stricter rules applicable to these bodies as regards their control, supervision and evaluation missions. The strict requirements for medical devices set forth in the MDR will affect, notably, clinical investigations and clinical evaluation, conformity assessment procedures, vigilance and market surveillance. These elements will be complemented with the introduction of provisions ensuring the transparency and traceability of medical devices.

As a result of the COVID-19 pandemic, Member States, notified bodies, economic operators, national health institutions and other relevant actors have alerted that they would not be in a position to ensure the proper implementation and application of the MDR due to the COVID-19 outbreak.

In order to prioritise the fight against COVID-19, the European Commission announced on 25 March 2020 that it was working on a proposal to postpone the application date of the MDR, which was adopted on 3 April 2020. This proposal was followed by a vote of the European Parliament on 17 April 2020 which, by urgent procedure, adopted the European Commission's proposal to defer the application of most of its provisions until 26 May 2021.

The Commission considered such a delay necessary given that the public health crisis has created a demand for substantial additional resources and medical devices of vital importance, such as medical gloves, surgical masks, equipment for intensive care and other medical equipment, which could not have been reasonably anticipated at the time of adoption of the MDR. In light of this situation, Stella Kyriakides, EC Commissioner for Health and Food Safety, stressed: "Our priority is to support Member States to address the COVID-19 crisis and protect public health as powerfully as possible—by all means necessary. Any potential market disruptions regarding the availability of safe and essential medical devices must and will be avoided". To achieve this goal, the prolonged transitional period aims to ensure the smooth functioning of the internal market by preventing disruptions for the already approved medical devices and ensuring continuous availability of medical devices on the EU market.

New developments amid the MDR's postponement

As most of the MDR's provisions will apply, subject to certain exceptions, on 26 May 2021, i.e., one year after the initial timeline on the application of the MDR, the Amending Regulation further postpones the application date of several specific provisions.

The Amending Regulation affects the date on which the European Commission will adopt common specifications for: (i) those groups of products without an intended medical purpose listed in Annex XVI, to which the MDR will apply following the adoption of such common specifications; and (ii) the reprocessing and further use of single-use devices.

The Amending Regulation also modifies the date up to which the European Commission is obliged to publish notice that the European database on medical devices (Eudamed) is fully functional. Notwithstanding this obligation, in the event that such a notification is not made by 26 May 2021, the obligations and requirements provided for by the MDR relating to Eudamed will apply from the date corresponding to six months after the European Commission has published its notice.

The MDR still provides that the accreditation of any notified bodies designated under the previous framework will end as of the date of application of the MDR. Taking into account the postponement of the MDR's date of application, the accreditation of notified bodies is still in force and effect until 26 May 2021. The Amending Regulation also gives additional time to notified bodies to conduct conformity assessments under the MDR, issue MDR certificates and renew MDD and AIMDD certificates that can benefit from the MDR's transitional provisions.

Member States will also have, in light of the Amending Regulation, additional time to lay down the rules on penalties applicable for infringement of the provisions of the MDR and take all measures necessary to ensure that they are implemented. The date up to which Member States undertake to notify the Commission of those rules and measures has now been deferred to 25 February 2021.

Regarding clinical investigations, those that have started under the previous framework may continue to be conducted. As of 26 May 2021, however, reporting serious adverse events and device deficiencies will be carried out in accordance with the MDR.

Concerning the Unique Device Identification (UDI) carriers, the Amending Regulation has changed the date of application of the obligation to place UDI carriers on the label of a device and on all higher levels of packaging. This obligation will apply to class III devices from 26 May 2023, to class IIa and IIb devices from 26 May 2025, and to class I devices from 26 May 2027.

EU-wide derogation from conformity assessment procedures newly introduced

Further to the postponement of the majority of the MDR's provisions, the Amending Regulation also modifies Article 59 of the MDR by introducing an EU-wide derogation procedure, in addition to the national derogation procedure.

Article 59 of the MDR empowers national competent authorities, on a duly justified request, to authorise companies to place on the market or put into service in the territory of the Member State concerned medical devices, for which the relevant conformity assessment procedures have not been carried out but the use of which is in the interest of public health or patient safety or health.

Taking into account the COVID-19 outbreak and the associated public health crisis, the European Commission adopted an EU-wide derogation to address potential shortages of vitally important medical devices in an effective manner. To that end, the Amending Regulation provides that, in exceptional cases relating to public health or patient safety and health and for a limited period of time, the European Commission may extend the validity of such national authorisations to the entire EU market through an EU-wide emergency procedure.

The Amending Regulation also allows this EU-wide emergency procedure to apply to national authorisations granted under Article 11(13) of the MDD and adopted prior to the adoption of the Amending Regulation. This new EU Derogation procedure will apply already as from the date on which the Amending Regulation

comes into force and effect, i.e. on 24 April 2020.

What does this postponement mean for the relevant actors in the medical devices sector?

In view of the originally intended date of implementation of the MDR, Member States have already proceeded with the enactment of laws to supplement the EU Regulations at the national level and provide that national laws implementing the Medical Devices Directives would cease to apply as of 26 May 2020. Hence, it is necessary that each Member State considers the changes brought by this Amending Regulation to ensure that the current medical devices framework will continue to apply after 26 May 2020.

From a regulatory perspective, it is to be noted that transition and sell-off periods have not been postponed. The end date of any transitional period remains 26 May 2024, whereas the final date of the sell-off period is still set at 26 May 2025. This means that the medical devices industry will have one less year to sell off the medical devices that were made available on the EU market prior to the MDR's application date.

However, this additional period gives time to all actors concerned to focus on the challenges in combating COVID-19, but also to prepare to implement and ensure compliance with the various requirements of the MDR. Prior to the postponement of the MDR's implementation, companies active in the medical devices industry already set in motion procedures to undertake an assessment of their medical devices' classification, update their technical documentation and review their product surveillance in light of the new framework. This prolonged transition period is expected to facilitate the implementation of rules in accordance with general safety and performance requirements, technical documentation, classification rules, conformity assessment procedures and clinical investigations in order to respond to the obligations set forth in the MDR. ■