Implications of the one-year postponement of the application of the Medical Devices Regulation (MDR)

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Life Sciences analysis: Regulation (EU) 2020/561 amends Regulation (EU) 2017/745, the Medical Devices Regulation (MDR) by postponing its application to 26 May 2021. Elisabethann Wright and Fabien Roy, partners at Hogan Lovells International LLP, undertake an analysis of the broad implications of this postponement.

Since the MDR came into force in May 2017, many manufacturers and others have been preparing to achieve compliance. Why has the application of the MDR been postponed and which stakeholders benefit the most from this delay?

The preambles to Regulation (EU) 2020/561 make a number of references to the implications of coronavirus (COVID-19) for the availability and supply of vital medical devices in the EU.

It is unquestionably true, as mentioned in the Third Preamble to Regulation (EU) 2020/561, that medical gloves, surgical masks, equipment for intensive care and other medical equipment, play a crucial role in the context of the coronavirus outbreak. The Fifth Preamble to Regulation (EU) 2020/561 provides that in light of the coronavirus outbreak, the associated public health crisis and the additional resources required by EU Member States, it is appropriate to defer the application of those provisions of the MDR by one year.

There can be no doubt that the coronavirus has placed incredible pressure on health services and that postponement of entry into application was necessary in the circumstances. In light of the struggles that many faced in ensuring compliance with the MDR it could not be excluded, however, that the European Commission would have been obliged to propose suspension of entry into application of the MDR even in the absence of the coronavirus.

It is, however, unclear whether this delay in application of the MDR will enable more manufacturers to begin a new certification process with their Notified Bodies under Directive 90/385/EEC, the Medical Devices Directive rather than the MDR.

A number of Notified Bodies have already made clear to their customers that they will not take new applications under the Medical Devices Directive despite the postponement of the MDR. The benefit of postponement of entry into application of the MDR may in practice, therefore, be limited to those manufacturers in the final stages of their conformity assessment procedures with their Notified Bodies and who benefit from additional time to address their Notified Bodies' questions.

Which provisions of the MDR have been amended?

The provisions of the MDR that have been amended by are largely those governing the dates of entry into application of the MDR, with the date 26 May 2020 being replaced by the date 26 May 2021 in a number of provisions of the MDR.

In the interest of public health or patient safety or health, the provisions of the MDR permitting the competent authorities of the EU Member States to rely on the existing provisions of the Medical Device Directive and Directive 90/385/EEC, the Active Implantable Medical Devices Directive, to permit the placing on the market or putting into service within their territory of specific medical devices that are not

fully compliant with the applicable provisions of the Directive have also been modified to extend this power by just over one year.

Of interest, however, is the fact that the provisions of the MDR permitting CE certificates of conformity issued on the basis of the Medical Devices Directive and the Active Implantable Medical Devices Directive to remain valid until the end of the period indicated on the certificate and, at latest, until 27 May 2024 have not been revised.

What is the practical impact of these amendments to the transitional regime?

Postponement of entry into application of the MDR should provide competent authorities, Notified Bodies and manufacturers with an additional 12 months within which to establish processes and procedures to ensure the application of the MDR.

In theory at least, postponement could also permit manufacturers seeking either CE certificates of conformity or renewal of existing certificates with an additional 12 months during which to complete the related conformity assessment process to the Medical Devices Directive or the Active Implantable Medical Devices Directive. Some Notified Bodies are, however, demonstrating reluctance to agree with this approach seeking to retain 25 May 2020 as the final data on which CE certificates of conformity to the Directives will be issued.

What are the wider implications of these amendments to the medical devices regime as set out in the MDR?

Postponement of entry into application of the MDR will give the Commission a welcome additional year during which to prepare much needed related guidance documents.

As the Commission has already announced a delay the launch of Eudamed until May 2022 it would appear unlikely that postponement will have an impact in that respect.

What should be done by the Commission, the MDCG and stakeholders before 26 May 2021 for the MDR regime to be properly implemented?

Adoption of as many of the guidance documents as possible and fulfilment of as many of the requirements for which the MDR provides during this period would be much appreciated.

Of major benefit would be the designation of more Notified Bodies to the MDR. This could assist both the notified bodies and medical device manufacturers in taking the necessary steps to comply with their obligations under the MDR.

The medical devices industry called for the postponed application of the In Vitro Diagnostic Regulation (IVDR) too. What are the likely consequences for businesses of the IVDR coming into application in May 2022?

The entry into application of the IVDR is likely to result in a major upheaval to the current process of classification and assessment of in vitro diagnostic medical devices (IVDs) in the EU and, potentially, impact the availability of some types of IVD in the EU. This may have particular impact on IVDs that are currently CE marked on the basis of self-assessment by their manufacturers.

On entry into application of the IVDR, conformity assessment of most IVDs placed on the market in the EU will require the intervention of a Notified Body. The procedure for determining the appropriate new classification of these IVDs, preparing the related technical documentation and having a Notified Body involved in the CE marking process may be challenging for some manufacturers. This will particularly be the case if further Notified Bodies are not designated to the IVDR in the near future.

Considering the current Brexit transition period and the ongoing UK-EU negotiations on the future relationship, what are the possible implications of the MDR's postponed application for the UK medical devices regime?

It is difficult to anticipate the impact of postponement of entry into application of the MDR within the context of Brexit. The outcome of the current negotiations between the EU and the UK may have a greater impact than the postponement of the MDR.

Interviewed by Elodie Fortin