COVID-19: APPLICATION OF EU MEDICAL DEVICE REGULATION TO BE POSTPONED AMIDST COVID-19 OUTBREAK

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German Corporate/M&A Alert

In April 2017, the EU has revised the regulatory framework for medical devices and in vitro medical devices in the EU. The package, which includes regulation (EU) 2017/745 on medical devices (Medical Device Regulation or MDR) and regulation (EU) 2017/746 on in vitro diagnostic medical devices (IV MDR), became effective in May 2017. Additional implementation acts have been and are still being adopted in order to specify the requirements of the MDR and IV MDR. While part of the provisions (in particular, regarding notified bodies) have already been applicable since November 2017, the majority of provisions of the MDR under the current regime shall apply as from 26 May 2020 (Date of Application or DoA). Pursuant to the IV MDR, most provisions of the IV MDR shall apply as from 26 May 2022.

MDR and IV MDR have updated the regulatory framework in the EU. Among others, the MDR:

- Refines the responsibilities of economic operators (including manufacturers, distributors, and importers),
- Modifies the classification system for medical devices;
- Reinforces the requirements of clinical evaluations and clinical trials;
- Provides increased requirements for post-marketing surveillance (including the preparation of periodic safety update reports);
- Adds new traceability and transparency requirements and procedures.

The implementation timeline for the requirements of the MDR has been a challenge for national authorities, notified bodies, and companies active in the industry alike.

NEW DEVELOPMENTS

On 25 March 2020, the European Commission (EC) issued a very brief statement that the EC would be working on a proposal to postpone the application date of the MDR for one year. The details and scope of the amendments have not yet been published. The decision to postpone the MDR Date of Application is published at a time when the EC has adopted further acts in relation to medical devices aimed at addressing the outbreak of the coronavirus and COVID-19, such as the adoption of new harmonized standards to manufacture and put onto the market high-performing devices to protect patients, health care professionals, and citizens in general.

At this stage, the statement only mentions a proposal to postpone the Date of Application of the MDR and does not mention any changes to the application of the IV MDR.

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The details of the proposal will need to be reviewed carefully to assess how the delay in the application will impact other timing questions under the MDR, e.g., the temporary validity of certifications made prior to the DoA under the old regulatory regime and the impact on currently ongoing certification procedures.

TIMING

According to the statement, the European Commission plans to submit the proposal to the EU Parliament and Council in early April with a view of having it adopted by both the Parliament and Council by the end of May.

Given the current Date of Application (26 May 2020), the amendment to the MDR needs to be adopted as soon as possible in order to avoid conflicting regulations for companies, notified bodies, and/or authorities.

We will provide additional updates once the details of the EC plan materialize.

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