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NOTE

Origine:	Secrétariat général du Conseil
Destinataire:	Conseil
Objet:	Mise en œuvre des règlements relatifs aux dispositifs médicaux *- Informations communiquées par la Commission sur l'état des travaux*

Les délégations trouveront en annexe une note contenant les informations communiquées par la Commission sur la mise en œuvre des règlements concernant les dispositifs médicaux qui sera traitée sous point « Divers » lors de la session du Conseil EPSCO (santé) du 14 juin 2022.

ANNEXE

State of play on the implementation of the Medical Device Regulations

The **Medical Device Regulation (MDR)** has been applicable since 26 May 2021. Considerable progress has been made over the last year towards its full implementation.

At present, we have 30 notified bodies designated under the MDR, soon there will be 31. This is eleven more than at the end of May last year, which indicates good progress. The applications of more than 20 conformity assessment bodies are currently being processed. The new expert panels, set up to provide scientific advice regarding high risk devices, are fully operational and have issued several opinions. Three sets of harmonised standards have been published to support development and certification of medical devices. Moreover, two implementing acts have been adopted on electronic instructions for use and the European database for medical devices - EUDAMED. The development of EUDAMED has further advanced with three out of six technical modules now available for voluntary use.[1]

Despite these achievements, more needs to be done to make the most effective use possible of the transitional period before May 2024. In the fruitful discussions at the last Medical Device Coordination Group meeting on 19 and 20 May 2022, the Coordination Group endorsed a notice calling on manufacturers to ensure the timely application of MDR requirements. While necessary, it is not sufficient in itself to address the current situation. The Coordination Group therefore agreed to work on a list of possible actions that aim to enhance notified body capacities and preparedness of economic operators in order to ensure the availability of safe medical devices. The Commission is fully committed to supporting and facilitating this process and will continue to work closely with national competent authorities over the next months and years to implement the necessary measures. For this to work in the most optimal way, we call on Member States to commit necessary resources and provide their political support.

Such efforts from all sides are necessary to avoid any risk of shortages of essential medical devices at the end of the transitional period.

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1 Actor module since December 2020; UDI/devices and notified bodies & certificates since October 2021.

The ***In Vitro*** **Diagnostic Medical Device Regulation (IVDR**) has been applicable since 26 May 2022. This new framework introduces significant changes for the sector: while under the previous IVD Directive, only around 10% of devices required notified body involvement, under the IVDR, around 80% of devices will need the involvement of a notified body.

The COVID-19 pandemic has illustrated the need for a more robust regulatory framework for diagnostics in the EU. At the same time, it has brought additional challenges for the implementation of the IVDR for all actors, including the manufacturers, notified bodies, competent authorities, and the Commission. To reflect this reality, in January 2022, the European Parliament and the Council adopted amendments of the IVDR transitional provisions. This allows a gradual roll-out of the new requirements over the coming five years.

Progress is being made towards full implementation of the IVDR. Two soon-to-be-adopted implementing acts provide the basis for the process of designation of EU reference laboratories. A call for interest will be launched within the coming weeks. Laboratories that want to become EU reference laboratories need to submit their application at national level. Member States will then forward the validated applications to the Commission. Together with common specifications for a number of high risk *in vitro* diagnostic devices, those measures will complement the IVDR's regulatory infrastructure.

However, the number of notified bodies designated under the IVDR remains low. At present, only seven bodies are designated, while 11 applications for designation are in progress. The actions to enhance notified body capacities and ensure availability of medical devices mentioned in the context of the MDR are therefore also essential for the implementation of the IVDR.

The Commission is committed to smooth implementation of the two Regulations on medical devices, which were adopted in 2017. They are an important step forward for the EU regulatory system, improving patient safety, and device performance for the benefit of patients and public health.