



Commission postpones application of the Medical Devices Regulation to prioritise the fight against coronavirus

Brussels, 3 April 2020

Today, the European Commission has adopted a [proposal](#) to postpone by one year the date of application of the [Medical Devices Regulation](#) to allow Member States, health institutions and economic operators to prioritise the fight against the coronavirus pandemic. This decision takes into account the unprecedented challenges of the coronavirus pandemic and the need for an increased availability of vitally important medical devices across the EU whilst continuing to ensure patient health and safety until the new legislation becomes applicable.

Vice-President for Promoting our European Way of Life, Margaritis **Schinus**, said: *"Shortages or delays in getting key medical devices certified and on the market are not an option right now. The Commission is therefore taking a pragmatic approach and delaying the entry into application of new EU rules on medical devices, so we can have our medical industries pouring all their energy into what we need them to be doing: helping fight the pandemic. This shows once again that the European Union is leaving no stone unturned in our support to national public health systems in their hour of need."*

Stella **Kyriakides**, Commissioner for Health and Food Safety, said: "Our priority is to support Member States to address the coronavirus 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. Today's decision is a necessary measure in these very exceptional times."

As the coronavirus crisis increases demands for certain vital medical devices, it is crucial to avoid any further difficulties or risks of potential shortages or delays in the availability of such devices caused by capacity limitations of authorities or conformity assessment bodies related to the implementation of the Medical Devices Regulation.

Today's proposal therefore postpones, for exceptional reasons in the current context, the application of the Regulation by one year - until 26 May 2021.

Whilst the new Medical Devices Regulation is key to ensure patient safety and increase transparency on medical devices across the EU, the currently applicable rules will continue to guarantee the protection of public health.

In addition, the proposal also ensures that Member States and the Commission can address potential shortages of vitally important medical devices in the EU in a more effective manner through EU wide derogations.

The proposal would need the full support of the European Parliament and the Council through an accelerated co-decision procedure.

Background

The coronavirus pandemic and the associated public health crisis presents an unprecedented challenge to Member States and is a high burden for national authorities, health institutions and economic operators. The coronavirus crisis has created extraordinary circumstances that require substantial additional resources and an increased availability of vitally important medical devices. None of this could reasonably have been anticipated at the time of adoption of the Medical Devices Regulation.

Those extraordinary circumstances have a significant impact on various areas covered by the Medical Devices Regulation. It is therefore very likely that Member States, health institutions, economic operators and other relevant parties would not have been in a position to ensure its proper implementation and application from the stipulated date of application on 26 May 2020.

To safeguard an effective regulatory framework for medical devices, it is also necessary to postpone the date of repeal of the [Directive](#) on active implantable medical devices and the [Directive](#) on medical devices by one year.

This proposal will not affect the date of application of the In Vitro Diagnostics Medical Devices Regulation, which becomes applicable from 26 May 2022.

Useful links

[Medical devices](#)

[Dedicated Commission webpage on the EU's response to the coronavirus outbreak](#)

IP/20/589

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