

MedTech Europe's reaction to the European Commission proposal to amend the *In Vitro* Diagnostics Medical Device and Medical Device Regulations

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MedTech Europe acknowledges the European Commission proposal for extending the *In Vitro* Diagnostic Medical Devices Regulation (IVDR) transitional periods, and – for both the IVD Regulation and Medical Devices Regulation – allowing for early mandatory use of European medical devices database (EUDAMED) modules and requiring notification of device discontinuations.

MedTech Europe supports any measures that keep devices available to the patients who need them. The additional time given under the IVDR must be used by the European Commission, Medical Devices Coordination Group (MDCG), Notified Bodies, and other actors to [identify blockages and rectify existing issues](#), to enable all manufacturers to transition on time and meet post-market requirements. In that regard, MedTech Europe welcomes the [European Commission's announcement](#) to start preparatory work for a targeted evaluation of the legislation in 2024, in addition to taking more immediate actions.

The integrity of the EUDAMED database and its practical implementation are essential for ensuring the success of a mandatory EUDAMED. We believe that [four important conditions](#) need to be met before any modules of EUDAMED are made mandatory.

Any future requirement on manufacturers to notify critical device discontinuations must be as administratively simple as possible. The European Commission and MDCG should use the notifications to manage device discontinuations at the EU level, through derogations and other measures. The proposed amendments should avoid creating additional financial implications for device manufacturers and should be accompanied by guidance to support the smooth implementation of the proposed amendments as soon as possible.

Discussions between all stakeholders must continue in 2024 to implement lasting solutions to improve efficiency, foster innovation and improve governance, in order to make the Regulations truly work for patients and European health systems.

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

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