MedTech Europe post-EPSCO statement on the necessary reforms of MDR/IVDR

4 December 2024

During yesterday's Employment, Social Policy, Health, and Consumer Affairs Council (EPSCO) debate on the Medical Devices Regulation (MDR) and *In Vitro* Diagnostics Regulation (IVDR), many Member States acknowledged that reforms of MDR and IVDR are critical for ensuring that Europe's regulatory framework supports public health, patient safety, and the sustainability of healthcare systems.

The European medical technology industry fully supports this call for reform, advocating for measures that reduce bureaucracy, increase efficiency, support innovation, and ensure effective governance. A thorough review of the IVDR and MDR is needed, and the European Commission should present reform proposals immediately following their targeted evaluation. MedTech Europe supports the need for a single accountable governance of the IVDR and MDR which is specific to the medical technology sector and has sufficient powers to ensure an effective, sustainable and innovation-friendly regulatory system with a high level of device safety and performance. Should this role be given to the European Medicines Agency (EMA), it would be important to maintain the specificity of the medical technology sector alongside keeping the Notified Body-based system.

At the same time, we call for the swift adoption of immediate measures, and before the targeted evaluation's conclusions. Europe's healthcare systems cannot wait years for reform packages to be debated and enacted. Urgent measures are needed now to address devices availability, the delays in certification, regulatory bottlenecks, and disproportionate burdens on small- and medium-sized enterprises (SMEs), which threaten innovation and access to medical technologies in Europe.

We urge the European Commission and Member States to act swiftly, and implement solutions with sufficient legal weight to:

- Significantly reduce certification time and costs.
- Streamline assessment processes for device updates and innovations.
- Create an accelerated pathway for breakthrough technologies.
- Remove the limited validity of certificates and adopt a lifecycle approach.
- Deliver on the goals of MDCG 2022-14 (structured dialogue, leveraging evidence, reduce technical documentation sampling burden…)
- Promote digital solutions like electronic Instructions for Use (eIFU).
- Support global regulatory convergence, such as through the Medical Device Single Audit Program (MDSAP)

The medical technology sector stands ready to collaborate with policymakers, regulators, and other stakeholders to achieve the objectives initially set out by the IVDR and MDR. We call on the European Commission to prioritise both immediate measures and mid-term reform packages, ensuring Europe remains a global leader in medical innovation while safeguarding patient safety and public health.

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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