Revision proposal is first step towards fixing Europe's complex Medical Devices & Diagnostics rules

Brussels, 16 December 2025 – MedTech Europe sees the European Commission's targeted revision proposal of the EU Medical Devices Regulation (MDR) and *In Vitro* Diagnostic Regulation (IVDR) as a key milestone in bringing urgently needed reforms to Europe's medical technology sector and most importantly for patients across the region.

The MDR and IVDR have each strengthened the EU regulatory system for medical technologies. At the same time, their structural deficiencies have led to serious unintended consequences, including certification bottlenecks, reduced availability of products for patients, and unsustainable pressure on small and medium-sized enterprises (SMEs). Revising what is not working well, while preserving what already functions effectively, is therefore both necessary and timely.

Supporting innovation through dedicated device pathways

The proposed introduction of pathways for breakthrough innovation and orphan devices is critical for more rapid access to needed, safe and effective technologies. Together with sandboxes, these pathways – if correctly designed and deployed – represent a concrete opportunity to strengthen Europe's innovation ecosystem.

Single governance structure: A missed opportunity for long-term system stability

While the European Commission proposes solid improvements in governance and system resourcing, it misses the opportunity to provide for a single – rather than fragmented – governance structure which is accountable for ensuring that a full range of safe and performing devices are available for patients in a timely way.

Needed simplifications are proposed – but a gap persists for early clinical clarity

Many improvements are proposed to increase system efficiency, including extending the validity of certificates, making reporting more risk-based, simplifying the management of product changes and enabling more digitalization. Yet, lack of early clarity on clinical evidence expectations leads to unpredictability, unnecessary rework and delays in making devices available to patients.

***In vitro* diagnostics cannot be overlooked in the regulatory modernization**

In vitro diagnostics play a crucial role in health systems and in ensuring patients and healthcare providers receive valuable information to determine treatment and management options. Given that the rules for *in vitro* diagnostics are being proposed for revision in the same proposal as for medical devices, it is imperative that the co-legislators do not lose focus on the amendments to the *In Vitro* Diagnostic Regulation which will determine how Europe will ensure access to key diagnostic technologies for decades to come.

Oliver Bisazza, CEO of MedTech Europe, said: *"This revision is a long-awaited and necessary step to fix parts of the EU regulatory system that are clearly not working for patients, innovators and healthcare providers. Significant system improvements are needed to make it more efficient, innovation friendly and well-governed. With the right reforms and investment, Europe can once again lead in inventing, launching and ensuring patient access to medical technology innovation. The task now for the European Parliament and the Council is to fully seize this opportunity in the final legislation."*

-- end --

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.
www.medtecheurope.org.

For more information, please contact:
media@medtecheurope.org