MPP Association Welcomes European Commission's Proposal to Amend MDR and IVDR To Foster Innovation

17 December 2025

The Medtech & Pharma Platform Association (MPP) welcomes the European Commission's publication of the long-awaited proposal to amend EU Medical Devices (MDR) and In Vitro Diagnostic (IVDR) Regulations. This initiative represents a meaningful step toward addressing long-standing concerns raised by industry and Member States regarding the complexity, cost, and unpredictability of the current regulatory environment.

Since the MDR and IVDR entered into force, manufacturers have reported a range of practical challenges, such as certification bottlenecks, differing interpretations across EU Member States, and increased compliance efforts. These aspects may influence the availability of devices, particularly for niche and innovative products, as well as competitiveness and the pace of innovation. The new proposal seeks to address these considerations while continuing to uphold Europe's high standards of health and safety. The European Commission's proposal aims to simplify and modernize the regulatory system without compromising safety by reducing administrative burden, expand digitalisation and the use of remote audits, clarify post-certification change processes, and offer priority review pathways for certain devices.

"Europe must remain a center of excellence for innovative combined products. The revision of MDR and IVDR was essential to reduce complexity and accelerate patient access. MPP stands ready to collaborate with regulators and stakeholders to establish a framework that safeguards patient safety while fostering innovation," says Shayesteh Fürst-Ladani, MPP President.

This proposal, together with broader European initiatives such as the Biotech Act and the reform to the pharmaceutical legislation, signals constructive momentum toward a modernised regulatory ecosystem that better supports innovation. *"Innovation occurs at the intersection of regulatory frameworks. For products such as combined products at the interface of multiple regulatory frameworks a harmonised and predictable EU system is essential. A predictable, harmonised system supports developers of combined products,"* says Nathalie Schober, MPP Secretary-General.

The MPP Association highlights the continued need for clearer roles and responsibilities among key stakeholders when it comes to combined products. It also emphasises the

importance of streamlined and harmonised pathways to ensure competitive timelines across the EU.

The MPP Association views these initiatives as a promising foundation for a more enabling environment that strengthens Europe's attractiveness for developing and launching innovative combined products.

Media Contact:

Adrian Sutter
Medtech & Pharma Platform Association
Email: a.sutter@medtech-pharma.com

About Medtech & Pharma Platform Association (MPP):

The MPP Association is a European industry association dedicated to enhancing synergies between the pharma, medtech and tech sectors to develop and improve access to health technologies. Our association provides industry actors with a platform to exchange knowledge and collaborate in technology and regulatory matters, with the shared goal of shaping a future European framework that fosters the development of innovative combined products.

We represent companies combining health technologies such as medicinal product, medical devices or in vitro diagnostics and digital technologies for a medical purpose. The MPP Association is a recognized stakeholder by the European Medicines Agency and engages with regulators, national competent authorities, notified bodies and key stakeholders.