MEDTECH & PHARMA
PLATFORM

MPP Position on improving coherence for single integral drug-device combinations in the evolving EU legal framework

The Medtech & Pharma Platform (MPP), representing stakeholders across the pharmaceutical and medical device sectors, supports a targeted evolution of the regulatory framework in the European Union (EU) for integral drug-device combination products. In light of the ongoing transition towards the revised pharmaceutical legislation[1], this evolution should improve coherence, efficiency and regulatory predictability, while maintaining robust oversight of the device constituent part and a high level of patient protection. This approach should support constructive cooperation between EU institutions, regulators, Notified Bodies and industry stakeholders in an area where legal frameworks and responsibilities intersect.

MPP proposes the following priorities.

1. A more coherent legal interface for integral drug-device combination products

MPP supports a review and rationalization of the legal interface between Article 117 of Regulation (EU) 2017/745 (MDR) and the provisions on integral drug-device combinations in the revised pharmaceutical legislation. As the evolving pharmaceutical framework is expected to provide a more coherent basis for such products, its implementation offers an opportunity to reduce overlap, improve legal clarity and avoid unnecessary duplication across the two frameworks, while preserving an appropriate level of oversight for the device constituent part and continued protection of patients.

2. A coordinated EU pathway for MDR Article (1) 9 products

MPP supports a more coordinated EU pathway for products falling within Article 1(9) MDR, where the medicinal product has the principal mode of action and the device constituent is not CE marked as a separate device. In this context, MPP supports a strengthened role for the European Medicines Agency (EMA) as the primary regulatory interface and coordinator of the assessment process.

MPP also supports an appropriate route for device-manufacturer involvement in matters relevant to the device constituent part, while maintaining the legal responsibility of the medicinal product applicant or marketing authorization holder.

While the detailed governance model should remain high-level at this stage, the framework should enable efficient interaction between EMA, the relevant Notified Body and, where appropriate, competent authorities, in order to improve consistency, reduce

[1] The revised EU pharmaceutical legislation is currently in transition, following political agreement in December 2025 and ongoing implementation work in 2026.

avoidable divergence, and support a more predictable assessment pathway. Any supporting role of other actors should be designed in a manner that preserves clarity of responsibilities, supports efficient coordination and avoids fragmented decision-making.

3. Greater flexibility and predictability in the use of Notified Body opinions

MPP supports a more proportionate and predictable approach to the lifecycle management of Notified Body opinions for integral drug-device combination products. In well-defined cases, particularly where the device constituent is established and remains unchanged, the framework should allow an appropriate degree of reliance on prior assessments, including re-use of previous assessments and reduced-scope reassessments, in order to support consistency, reduce avoidable delays and align with shortened variation timelines in the medicinal product framework. This should remain a core element of the policy discussion.

4. Platform and master file concepts for device constituents

MPP supports the development of platform and master file concepts for suitable device constituents used in integral drug-device combination products, taking into account the opportunities emerging from the revised pharmaceutical legislation and its future implementation. Where the same established device platform is used across multiple medicinal products, the future framework should enable efficient reliance on core platform data and thereby reduce repeated assessment of unchanged foundational evidence.

Such an approach could improve efficiency, consistency, and regulatory predictability for both applicants and device manufacturers, while preserving appropriate oversight of the final integral product.

Closing statement

MPP remains committed to constructive engagement with EU institutions, regulators, Notified Bodies, and industry stakeholders to support the development of a coherent, efficient, and predictable framework for integral drug-device combination products, with the shared objective of safeguarding patient protection while facilitating timely access to innovation in Europe.