

Call for Evidence for European Commission's Public Consultation on EU rules on medical devices and in vitro diagnostics – targeted revision

MedTech Europe input

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The European Commission has launched a [Call for Evidence](#) to support a **targeted reform** of EU rules on medical devices and *in vitro* diagnostic medical devices (IVD). The aim of the consultation is to *“simplify and streamline the regulatory framework, and make it more cost-efficient and proportionate, while preserving a high level of public health and patient safety and maintaining the overall structure of the current regulatory framework.”*

Please read MedTech Europe submission below – or access it here on the consultation website: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14808-Medical-devices-and-in-vitro-diagnostics-targeted-revision-of-EU-rules/F33079144_en

MedTech Europe welcomes legislative reform, provided it delivers a regulatory system which enhances competitiveness, is efficient, lean and fit for purpose, supports innovation, is well-governed and ensures patients' access to devices.

Short-term relief measures are needed in parallel to the reform (e.g. limit certification and change-approval timelines, reduce re-certification burden and set up fast pathways for breakthrough innovation and other special device types).

In line with the above, the targeted proposal should aim at simplifying and futureproofing the regulatory framework:

Governance

Europe needs a single, accountable governance structure to oversee the regulatory system including Notified Bodies. The primary goal should be to make a broad range of safe and performing existing and future devices promptly available to patients and health systems. Governance should make the system lean, predictable, risk-based and accessible for manufacturers of all sizes.

Predictability

By applying a risk-based approach in conformity assessment, industry gains more planning certainty, reduced lifecycle costs, and a stronger basis for investment. Predictability can be enhanced through early dialogue with Notified Bodies on clinical evidence requirements, greater transparency on their costs and service scopes, and clear, timely processes for certification and change approval.

Administrative burden

The revision proposal should remove duplicative requirements by clarifying economic operators' roles and streamlining rules for clinical investigations/performance studies, and vigilance, clinical and post-market reporting. Certification should follow a lifecycle approach with unlimited validity unless unacceptable risk is demonstrated post-market.

Innovation

Simplified regulatory pathways for low- and medium-risk devices, and accelerated end-to-end pathways for breakthrough, orphan, niche, and paediatric devices should be provided in the legal text. Clinical evidence requirements should better reflect risk class and device history, with broader use of literature and real-world data alongside other post-market activities.

International reliance and competitiveness

Europe should strengthen global recognition of CE-marking and allow for mechanisms to develop reliance pathways e.g., membership of the MDSAP RAC, would reduce duplication, enhance compliance assurance and support competitiveness. Data-sharing enablement via EUDAMED would enhance reliance on CE Marking (e.g. with Switzerland and UK) and a uniform Certificate of Free Sale, preferably in digital format, would further enhance trust in CE-marking globally. Strategic cooperation and convergence with regulators worldwide will attract innovations, ensure faster access for patients and keep the CE-marking system globally competitive.

Digital tools

Digitalisation of technical documentation and enabling wider use of electronic instructions for use (e.g. for lay user devices and IVD near-patient tests), digital certificates, digital implant cards and digital labels would improve usability and support sustainability.

EUDAMED must be completed with proper functionalities, consistent with the regulations - to reduce repeated data entry and provide interoperability, playground environments and user access to enable smooth transition.

Alignment with other legislation

IVDR/MDR must be designed with sufficient flexibility to be future-proof and to remain coherent with current and future horizontal EU laws. Our sector needs one conformity assessment under the Artificial Intelligence Act and the IVDR/MDR which can be completed in a timely way. Coherence with horizontal EU laws is needed with digital and data legislation, pharmaceutical legislation and CTR, GDPR (clarifying lawful bases for clinical investigations, performance studies and PMS), HTA Regulation, green and sustainability rules, the liability/consumer protection framework and other emerging regulatory frameworks.

Please find below the link to MedTech Europe's dedicated webpage, which brings together key position papers, evidence (including the administrative burden document and survey results), and other materials relevant to the ongoing legislative reforms:

<https://www.medtecheurope.org/new-medical-technology-regulations/the-future-of-eu-medical-technology-regulatory-system/>

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 that research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

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