EUROPEAN SOCIAL INSURANCE PLATFORM

ESIP Feedback to the

Call for Evidence
on the upcoming targeted revision
of the Medical Devices Regulation and of the In Vitro Diagnostics Regulation

6-10-2025

The European Social Insurance Platform (ESIP), representing social and health insurers in the EU including those responsible for the assessment and/or reimbursement of medical devices, notes the European Commission's initiative to present a targeted revision of Regulations (EU) 2017/745 (Medical Devices Regulation, MDR) and (EU) 2017/746 (In Vitro Diagnostics Regulation, IVDR). The revision aims to reduce the bureaucratic burden for both manufacturers and notified bodies, accelerate certification processes and alleviate some of the financial pressure on manufacturers.

A balanced revision preserving the MDR and IVDR objectives

ESIP recognises that manufacturers and notified bodies have faced challenges in transitioning from the previous legislative framework, which may justify some adjustments to the current legal framework.

Maintaining and improving patient access to safe and certified medical devices (MDs) and in vitro diagnostics (IVDs) in Europe is one of ESIP's key objectives. Therefore, we would welcome measures that may accelerate the certification process and encourage manufacturers to remain on the European market, only if balanced and justified by reliable evidence.

Any future changes to the legislation must not compromise patient or device user safety. ESIP calls for strict safeguards to ensure that the core objectives of the MDR and IVDR are preserved, particularly with a view to:

- improving the quality of clinical data, which directly impacts patient safety;
- increasing transparency by making certain data publicly accessible via EUDAMED;
- harmonising the quality of notified bodies, and thus the CE certification process, across Europe.

The revision should primarily focus on relieving manufacturers and notified bodies of redundant documentation requirements. Wherever feasible, documentation and notification processes should be digital.

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Facilitating access to orphan and breakthrough devices

Both manufacturers and healthcare providers have stressed the urgent need to facilitate market access for orphan MDs, intended for the treatment of rare diseases or conditions, as well as breakthrough devices. Small and medium-sized enterprises, as drivers of innovation, may otherwise be discouraged from placing their products on the European market due to the MDR and IVDR requirements.

As the Medical Device Coordination Group (MDCG) has already addressed this issue through specific guidance documents, ESIP recommends incorporating their content directly into the MDR and IVDR legal texts.

To reduce the administrative burden on manufacturers and notified bodies, decisions on the designation of devices as “orphan” or “breakthrough” should be made centrally, uniformly, and transparently.

It is essential that patient access to such devices, where clinical data are not yet sufficient to demonstrate safety and effectiveness at the time of CE certification, takes place under clinically controlled conditions. The missing data must be generated during the early Post-Market Clinical Follow-Up (PMCF) period. Evidence requirements for overall clinical performance must remain as rigorous as for other high-risk devices.

ESIP has already issued recommendations for the certification and approval processes of orphan devices (file attached), which can also be applied to breakthrough devices.

In conclusion, ESIP can accept the targeted revision of the MDR and IVDR where it may reduce unnecessary administrative burden and facilitate access to devices, provided that patient safety and the quality of clinical data are not compromised. Any further amendments should only be considered if justified by reliable evidence from the targeted evaluation of the Regulations. Nevertheless, ESIP is critical of the absence of an impact assessment that takes stock of the recent evaluation, examines potential measures to address the identified issues as well as their implications.

Link to the ESIP feedback to the call for evidence on the targeted revision of the MDR/IVDR