

Ms. Ursula von der Leyen, President of the European Commission
Mr. Olivér Várhelyi, Commissioner for Health and Food Safety
European Commission
B-1049, Brussels

Brussels, 11 September 2025

Open letter:

Meeting the needs of patients, healthcare practitioners and hospitals in the targeted revision of the Medical Devices Regulation

Dear President Von der Leyen, dear Commissioner Várhelyi,

The EU Medical Device Regulation (MDR) was introduced to protect patients and support innovation. These are laudable objectives. However, several years after the adoption, the regulation is not yet fully implemented and there are both, remaining and new challenges – for example, device shortages, unmet needs, and insufficient transparency and information for patients and healthcare professionals. The system is not delivering as expected for the healthcare practitioners, patients, and hospitals whom we represent, who rely on these technologies and depend on their safety and availability.

We believe that the objectives of the Regulations remain valid and that any new measures must be guided by the interests of patients and the public health. In this context, we have identified three urgent priorities:

1. Clarify Clinical Evidence Requirements and make Clinical Evidence Public

One half of the high-risk devices that have been reviewed by EMA Expert Panels were judged to have insufficient clinical evidence—yet every one of them still gained a CE mark. This is unacceptable. Without transparency, and consistent, practical application of strengthened evidence requirements, unsafe or unproven devices may enter our hospitals. Publishing all Clinical Evaluation Reports in an enhanced publicly accessible EUDAMED would:

- Improve clinical decision-making and patient safety
- Give innovators clarity on clinical evidence requirements
- Strengthen public trust in the regulatory system

2. Improve consistency and create a Central Body for Scientific Co-ordination

The MDR currently suffers from fragmented oversight: notified bodies, competent authorities, and expert panels all operate in silos. There is insufficient coordination and no central entity that coordinates clinical and scientific requirements, prepares common specifications, or provides regulatory support to micro-, small- and medium-sized enterprises. We need a significantly expanded EU body with medical, scientific, and regulatory experts who can:

- Provide binding clinical and scientific advice
- Standardise evidence requirements
- Ensure consistent application of clinical and scientific evidence requirements across all notified bodies

3. Improve coordination to address safety issues

While the MDR strengthens post-market requirements, more efforts are needed to ensure timely and consistent responses to safety issues across all member states. Improved collaboration between healthcare professionals, regulators, manufacturers, and notified bodies are essential to protecting patients' health. A strengthened post market surveillance system should include:

- Clear communication and timelines for competent authorities to investigate, respond to, and communicate about safety signals
- Mechanisms to empower healthcare professionals and patients to report safety issues
- Improved information sharing and coordination among EU member states

Without these reforms, this system risks remaining bureaucratic rather than scientific, patients will continue to lose access to essential devices, and Europe will fall behind global competitors.

We call on the European Commission to incorporate these proposals in the targeted revision of the MDR, to make the system more transparent, science-driven, and fit for purpose. These measures should also be accompanied by provisions to improve patient and healthcare professionals' involvement in the governance of the system to rebuild trust.

These recommendations should be seen in conjunction with earlier recommendations provided by our respective organisations, including in the context of the targeted evaluation. We will continue to support a comprehensive review of the regulations to identify all existing gaps and adopt the most effective solutions to protect patients and the public health.

Yours sincerely,

The Biomedical Alliance in Europe ([BioMed Alliance](#))

European Patients Forum ([EPF](#))

European Association of Hospital Pharmacists ([EAHP](#))

European Hospital and Healthcare Federation ([HOPE](#))