ESC
European Society of Cardiology

Revising the EU Medical Device Regulation: Recommendations by the European Society of Cardiology

The **Medical Device Regulation** (EU 745/2017, MDR) was adopted in 2017, following extensive debate, with the aim of enhancing the quality and safety of medical devices within the European Union while simultaneously supporting innovation in the sector. In spite of its intended goals, the implementation of the new regulatory framework has brought to light several **criticalities**.

In particular, increased regulatory complexity, and high costs of certification have led to a **reduction in the availability of medical devices in the EU**. This issue is especially pronounced in care sectors serving smaller patient populations, such as orphan and paediatric devices, where the impact has been particularly severe.

Despite the adoption of various guidance documents and emergency measures to extend the transition periods in March 2023, a more structural revision of the MDR has been called for by various stakeholders, as well as by the European Parliament (Resolution 2024/2489) and a number of Member States.

In order to identify the appropriate legislative tools for a revision of the framework, the European Commission has launched a **Targeted Evaluation of the framework**, with the goal of assessing if the rules are 'effective, efficient and proportionate', 'meet current and emerging needs', 'align with other actions' and 'have added EU value'.

The European Society of Cardiology (ESC) strongly **supports a revision of the framework** and stresses that extensive dialogue with stakeholders, particularly with Healthcare Professionals Organisations (HCPs), will be essential at all stages of the process. Consequently, we wish to highlight some of the most relevant outstanding issues posed by the current framework, particularly regarding its negative impact on patients and practitioners, and to propose recommendations for its improvement.

1. Protecting access to "disappearing devices" that impact practice

Representatives of the ESC were the first to notify European regulators in October 2021 about product withdrawals which challenged clinical practice. In a survey conducted with the Biomedical Alliance in Europe targeted to European clinicians, asking them if devices they use were no longer on the market, 49% of the respondents confirmed issues with availability. Subspecialities such as paediatric cardiology have been particularly impacted.

Regulators have put in place several actions to address these issues, such as the application of the Art. 59 of MDR, according to which National Competent Authorities are allowed to exceptionally grant market approval for a device on the grounds of public health protection. Even though this derogation can be referred to the European Commission to allow an EU-wide extension, the procedure would be more responsive and effective if coordinated at the EU level.

Another action was the introduction, by the European Commission, of Article 10a to the MDR, to require medical device manufacturers to notify regulators 6 months in advance of a device withdrawal from the market. Nevertheless, it is unclear as to what regulators will do if notified of an essential device being withdrawn.

Recommendations:
The ESC recommends the implementation of a clear, responsive and streamlined policy for the issuance of EU-wide derogations, inclusive of an assessment of the consequences of the withdrawal of a medical device on clinical practice to be conducted in close cooperation with Patients' and HCP Organisations, once the withdrawal is notified as per Art.10a of the MDR.

2. Expanding the use of clinical expertise

A highly valued feature of the MDR was the introduction of **expert panels**, responsible for providing input on the clinical and performance assessment of certain high-risk medical devices their conformity assessments and for advising manufacturers on their clinical development strategy or proposals for clinical investigations. Even though the initiative has helped to bring independent expert clinical perspectives into the regulatory system, their work is currently limited in scope.

In January 2023 the EMA, who took over the expert panels initiative in 2022, launched a pilot scientific advice programme, prioritising medical devices that: (1) benefit a small number of patients (orphan/paediatric devices); (2) address an unmet medical need; and (3) have the potential to provide a major clinical impact. The EMA has communicated in February 2025 that, following the success of the pilot, it has standardised the procedure for the request of scientific advice.

The MDR has also led to the structural inclusion of stakeholders as observers in the MDCG and its subgroups, which has facilitated communication, collaboration, and the timely reporting of urgent issues in the medical device field. In particular, it allowed clinicians, as the individuals who interact with patients and medical devices daily, to provide their insights into real-world challenges and their recommendations on key guidance documents.

Recommendations:

- The ESC welcomes the **implementation** of the expert panels procedure by the EMA and calls for their role to be extended earlier in the regulatory process, where they could expand advice structures and support notified bodies and competent authorities with regulatory assessments. Furthermore, the ESC believes that expert panels could play a crucial role in the defining criteria for identifying breakthrough and/or orphan devices.
- In addition to expert panels, HCP organisations should also be consulted as, thanks to their expertise and collective views, they could provide helpful advice at various levels, including for the development of guidance and common specifications.
- The ESC recommends that the revised framework incorporates greater support and involvement of Healthcare Professional Organisations in the revised framework, including in the MDCG, acknowledging their key role in fostering innovation and shaping clinical practice across Europe.

3. Further governance of the regulatory framework for medical devices

Medical devices are regulated in a **decentralised system** in the European Union, which includes National Competent Authorities responsible for the assessment of pre-market clinical investigations and notified bodies responsible for assessing medical devices for marketing. In 2011, the ESC recommended the incorporation of a single unified European regulatory agency to work with a co-

ordinated structure of notified bodies. This recommendation was only partly followed with the incorporation in the EMA of Expert Panels.

Recommendations:

The ESC reaffirms the recommendations made in 2011 to entrust a **single agency** with the task to coordinate guidance for clinical evidence generation, from the early stages of product development, including the development of common specifications. This transition would require coordination with National Competent Authorities for pre-market development and coordination with notified bodies for market approval.

The coordinating Agency should be the pinpoint of the EU regulatory system. Such a system, developed in consultation with Patients' and HCP organisations, must adopt a methodological framework for clinical evidence generation that guarantees high-quality clinical investigations for high-risk medical devices, while ensuring that lower-risk medical devices are subject to proportionate and streamlined clinical evidence requirements.

4. Tackling the technology gap

As a result of the time, cost and complexity associated with compliance with the MDR, there has been a significant, and very unfortunate shift in the number of manufacturers seeking to introduce new medical devices in the EU versus other regulatory jurisdictions. MedTech Europe have noted a decrease of 33% of large manufacturers and a decrease of 19% of small and medium sized enterprises seeking to introduce their devices to the EU first. This may result in fewer breakthrough technologies reaching European patients in a timely manner.

For medical devices that were approved under the previous Medical Device Directive 93/42/EC framework (referred to as '**legacy'** devices), the introduction of significant iterative changes has been disincentivised as any 'significant change' requires full compliance to the MDR. This means that new versions of medical devices may take more time to be introduced in the EU. This is important as the lifecycle of medical devices used in cardiology can be rapid and new versions of devices will be prepared prior to the end of the transition timelines of 2027 or 2028.

Recommendations:

The ESC stresses the need for a regulatory system that facilitates patient access to safe and innovative medical devices. **Priority pathways** have the potential to help achieving this goal, based on the experience in other jurisdictions (e.g., Innovative Devices Access Pathway in the UK, Breakthrough Devices Program and Total Product Lifecycle Advisory Program (TAP) in the US) and, in the EU, of the PRIME scheme for medicines addressing Unmet Medical Needs.

The potential for increased market entry should not compromise regulatory rigor, necessitating a careful evaluation of the proposed measures. For this reason, the introduction of priority pathways for medical devices should include clear eligibility criteria and early dialogue between developers, regulators, patients and healthcare professionals' representatives, and should address specific categories of devices, such as Orphan and Paediatric devices, and breakthrough devices addressing an Unmet Medical Need. Expert Panels should play an instrumental role in priority pathways by supporting eligibility assessments and by providing early advice.

Certificates with conditions should be considered for certain medical devices requiring longer-term clinical datasets that cannot be efficiently generated in the pre-market phase, provided that the

immediate availability to patients offers a greater benefit than the potential risks associated with the incomplete data at the time of approval.

The adoption of additional measures outlined in this statement, including enhanced harmonisation and centralisation, would also indirectly contribute to enhancing predictability for manufacturers and researchers alike and, thereby, fostering innovation.

5. Improving transparency and data availability

One key aspect of the reform introduced by the MDR framework is the enhanced **transparency** allowed by the European Database on Medical Devices (EUDAMED, Art. 33 MDR) aimed at enabling public access to information on all medical devices placed on the EU market and devices that have undergone clinical investigations. Unfortunately, the clinical module of EUDAMED is still not operational, and not expected to roll out before January 2026. This engendered a chronic lack of information that does not allow healthcare professionals to assess the evidence for marketed devices.

Recommendations:

Enhanced clinical and safety data collection and a strong collaboration between all stakeholders - regulators, clinicians, patients, and the industry – are key ingredients to get innovative, safe, and effective medical technologies for our patients. To achieve this, the following are necessary:

- Strengthening **data collection** is essential to ensuring that innovative, safe, and effective medical technologies reach patients. Achieving this goal requires robust support for data collection and analysis, enabling the generation of high-quality evidence to guide decision-making and enhance post-market surveillance of medical devices.
- Ensuring a functional **data infrastructure** at the EU level is crucial for monitoring device safety and performance. This infrastructure would facilitate the implementation of priority pathways and conditional certificates. A centralised database for obligatory reporting of the results, experience and outcomes of devices is particularly needed for novel devices and off-label use. This approach would, enhance innovation, and increase the availability of Orphan and off-label devices while still maintaining their proper use. Additionally, it enables close monitoring of the safety and outcomes for the selected patients.
- Securing **public funding** and institutional support for initiatives such as **European registries** is vital. Public funding should also be ensured for **clinical trials** addressing specific public health needs or regulatory purposes, for instance with respect to the safety profile of certain medical devices;
- Advancing **data harmonisation** should be a key priority, leveraging the full potential of Real World Data for care and research, in line with the implementation of the European Health Data Space framework. Beyond the EU, we stress the importance of funding and supporting global research initiatives, fostering international collaboration in the field of medical device innovation.

6. Improving the clinical trial eco-system for cardiovascular devices

New cardiovascular devices are typically subject to pre-market clinical investigations which often include multiple sites across multiple countries. In each EU country, clinical investigations are subject to independent assessments by both National Competent Authorities and research ethics committees.

A pilot has begun for **coordinated clinical investigation assessments**, by which a single application could be made covering all EU sites. This is an important activity that requires greater support to be implemented on a wider basis and incorporate EU level advice and would benefit from the inclusion of learned societies as observers.

Recommendations:

- From a translational research perspective, the EU clinical trial landscape can present as complex and challenging, and different authorities and ethics committees may have different requirements and expectations. Therefore, the ESC recommends much greater coordination of multi-state clinical investigations, and the establishment of clear early advisory mechanisms including HCP organisations. These should involve experts with both clinical and regulatory expertise, in a similar fashion to the 'pre-submission' process offered by the US FDA. This could be supported by specialist communities of assessors in National Competent Authorities supported by members of the EMA Expert Panels and healthcare professional organisations. The implementation of such a system will require robust frameworks to ensure consistent standards across Member States, as well as adequate resources to support the increased workload on regulatory bodies.

- In order to strengthen trust and coordination within the MDR Framework, experience sharing amongst National Competent Authorities and ethics committees will be vital. The **harmonisation by doing** approach first developed between the US FDA and PMDA in Japan, with support from academic and clinical communities, represents a valuable initiative to develop trust and coordination. This initiative enables regulatory assessors to share experience and to align assessment methodologies for clinical investigation applications. Additionally, it allows developers to better understand the regulatory processes in different jurisdictions to support them in translational development.

7. Impact on AI and Digital Health innovations

The MDR has increased the regulatory oversight for the innovations in digital health that qualify as medical devices. However, the lack of standardized criteria leads to variability in how AI tools are evaluated and implemented, creating barriers to translational development and widespread adoption.

Recommendations:

- **Clarify requirements for AI enabled medical devices** within the MDR and explicitly define the interplay and alignment with the AI Act to ensure consistent, coherent, and effective regulation across legislative frameworks.
- **Establish a unified European framework for evidence grading dedicated specifically to AI-based medical software.** A harmonised framework for evaluating clinical evidence, by setting standardised criteria to assess AI algorithms, developed in consultation with Patients and HCP organisations, is needed. Development of harmonised validation formats and pan-European gold-standard datasets for testing data models is needed. Introducing such clarity would streamline approval processes and encourage development and commercialization of innovative digital health solutions within the EU. International regulatory guidance from the

the IMDRF and US FDA should be utilised (e.g., Characterization Considerations for Medical Device Software and Software-Specific Risk; Good machine learning practice for medical device development: Guiding principles; Good Machine Learning Practice for Medical Device Development: Guiding Principles; Draft guidance on Artificial Intelligence-Enabled Device Software Functions).

- **Establish EU-wide programs** similar to the FDA's Medical Device Development Tools (MDDT) **to qualify tools capable of reliably assessing the safety**, effectiveness, or performance of digital and AI-based medical devices, facilitating the regulatory evaluation and certification processes.
- **Create a proportionate regulatory framework for lower-risk digital tools** (such as clinical calculators) to reduce unnecessary regulatory complexity while ensuring appropriate safety and performance standards.

8. Reprocessing of medical devices

Device reprocessing can reduce costs and environmental impact, while impacting positively on supply chain security, and it has been proven as an effective strategy to reduce the carbon footprint of healthcare.

According to Article 17 of MDR, reprocessing of single-use devices is possible only if permitted by national law. At the moment, only 10 countries permit reprocessing of medical devices, applying different options, restrictions and prohibitions. Reprocessing in practice is extremely challenging for hospitals, due to (amongst other things) difficulty in finding a notified body that can certify reprocessed devices.

Recommendation

The European Commission should explore actions to promote a harmonized approach to the safe reprocessing of medical devices across EU member states considering its potential in the reduction of their environmental impact while maintaining patient safety and regulatory compliance. In addition, the Commission or coordinating Agency should provide notified bodies with further guidance and advice and support from HCP organisations and expert panels, as needed.