EPF's position on the European Commission's proposal for regulations to simplify rules on medical and in vitro diagnostic devices

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The European Patients Forum (EPF) welcomes the European Commission's **proposal for amendments of the Medical Devices Regulation (MDR) and In-Vitro Diagnostic Medical Devices Regulation (IVDR)** as a means to address ongoing challenges in implementation and prevent disruptions in the availability of medical devices and diagnostics for patients. **EPF acknowledges both strengths and areas for improvement in the proposal.** We welcome more centralised governance and coordination and the introduction of **specific frameworks for orphan and breakthrough devices** to support patient access to critical or highly innovative devices that address patients' needs.

We also strongly support the Commission's efforts to keep patient safety at the core of the regulations, **although some changes require close monitoring to avoid any unintended consequences.** In this regard, while we recognise the Commission's rationale for introducing less prescriptive and more risk-based requirements, the system's track record of protracted timelines, insufficient transparency and pragmatism raises concerns about the effective functioning of this approach.

In addition, we are concerned that the proposal weakens patient information and transparency and continues to lack meaningful patient involvement in governance and regulatory processes. Some existing shortcomings in the system have also not or insufficiently been addressed, especially regarding clear timelines and coordination for investigation and response to safety events. In addition, we remain concerned about the current trend to publish **wide-ranging legislative proposals without an impact assessment**, which undermines stakeholders' and policy-makers' ability to assess the overall and cumulative impacts of all proposed measures.

While we recognise the need to reduce regulatory burdens that don't add value to improve the functioning of the current system and availability of much needed devices, further action is needed to ensure appropriate safeguards, improve transparency and trust. We also would like to note that the review of the regulatory framework alone will not be sufficient to improve equitable access to innovation across the EU. **EPF stands ready to work with the European Parliament and the Council to design a truly patient-centric regulatory framework for medical devices, which ensures both patient safety and timely access to new and existing devices.**

Key recommendations for improvements:

- **Preserve strong oversight throughout the device lifecycle** – this includes harmonising evidence requirements through e.g. common specifications and removing provisions aimed at simplifying reliance on equivalence, and ensuring that simplification measures do not weaken post-market surveillance and AI oversight.

- **Improve vigilance and response to safety events –** this includes establishing clear timelines for investigation, risk assessment, and response to safety events across the EU, as well as strengthened coordination between national competent authorities and timely communication to patients.

- **Strengthen patient involvement in governance and regulatory decision-making** – this means empowering patients to contribute to decisions that affect them through the creation of a specific platform for dialogue under the MDCG, similar to the EMA Patient and Consumer Working Party (PCWP), with adequate financial support. Other measures include the inclusion of patients in expert panels and the establishment of reporting channels for safety issues.

- **Improve transparency and access to information for patients** – prioritise the roll-out of a clear, searchable, and accessible EUDAMED, including expanding available information to strengthen trust in the clinical evidence base and notified bodies' decisions, and maintain implant cards for all implantable devices, including well-established technologies (WET).

- **Address unmet patients' needs and innovation gaps** – ensure breakthrough and orphan pathways work in practice in a decentralised system and effectively address patients' needs, with a particular focus on adequate oversight and post-market follow-up.

- **Ensure adequate resources, governance structures, support mechanisms for sharing of best practices and commitment across the system to ensure successful implementation. Further, recognise patient organisations as real partners in the system to share data and experiences from their community and amplify public health communications.**

Maintaining high patient safety standards

We note the Commission's commitment to safeguarding the spirit of the framework and the initial objectives of the MDR. The 2017 regulations were adopted to improve patient safety as a result of severe issues related to unsafe devices, and it is important that the review does not undermine this goal.

However, a number of provisions in the proposed text raise questions:

- **Equivalence:** Increased flexibility for manufacturers to **rely on "equivalence" and thereby forego clinical investigations** to prove the safety and performance of a device is highly concerning and could put patients at risk. In particular, the proposal removes the requirement for manufacturers to have a contract ensuring access to the equivalent device's technical documentation (Article 61(5)) and broadens the equivalence criteria in Annex XIV to allow reliance on devices with "similar" rather than identical characteristics. The MDR/IVDR were precisely introduced to improve the evidence base and clinical data available to prove the safety and performance of high-risk devices. The re-introduction of exemptions and the risk of expanded, inappropriate use of equivalence appears like a step backward.
    - In general, we are concerned that 9 years after the adoption of the MDR, **clinical evidence standards** are still insufficient for some devices. In the field of diabetes, significant accuracy and quality issues have been identified with continuous glucose monitors, with significant impacts on patients. Harmonised, fit-for-purpose, and, when needed, device-specific requirements are essential to ensure devices are safe. The regulations already provide for such tools, which should be better utilised, such as common specifications. In addition, recommendations from the EU-

funded CORE-MD project provide high-level guidance on study design and should be complemented by further methodological development.

- **Artificial intelligence:** While we support a clear and streamlined regulatory framework that avoids duplication, and in that instance we welcome in principle a single assessment for medical devices, we are concerned that the most critical requirements in the AI Act are no longer reflected in the regulatory framework for medical devices, such as human oversight and data integrity. While the use of AI has extraordinary potential for patient care, it also poses significant risks, such as biased outputs leading to clinical mistakes, and cybersecurity issues. We understand that the Commission may adopt implementing or delegated acts to address missing requirements for high-risk AI systems, but the delay between the main regulation and these measures could have severe negative impacts on patient safety. Reintegrating the requirements set out in Chapter III, Section 2 of the AI Act should be a priority. In this context, we are closely following developments related to the Digital Omnibus on AI.
- **Recertification (art. 56):** While we understand that full recertification of low-risk devices every five years can be burdensome, it is essential to balance simplification with a robust conformity assessment and **vigilance** system. However, the following elements raise questions regarding the system's ability to identify and react to safety issues:
    - Greater flexibility for manufacturers in updating the **Periodic Safety Update Report (PSUR)** (art. 86), in particular for class IIa devices, required only "when necessary";
    - The removal of **unannounced audits** without cause. Unannounced audits are essential for notified bodies to identify issues that may not otherwise be detected in a timely manner;
    - The current absence of a fully operational and robust EUDAMED system, combined with reliance on a future hypothetical signal detection system for notified bodies, which may take several years to become fully effective, and on member states' monitoring and surveillance capacities, which remain uneven across the EU. In view of the reduced sampling requirements and reduced frequency of QMS audits, it is essential to strengthen safeguards.

The cumulative impact of post-market simplifications should be carefully assessed to ensure that some devices do not go unchecked. We note that the lack of reactiveness of the vigilance and post-market surveillance system is already a concern within the current framework. **We regret that the European Commission did not include clear timelines and obligations for investigation and management of safety issues and adequate communication to patients.** In some cases, implementation of Field Safety Corrective Actions takes years, national responses are fragmented – with examples of devices withdrawn in some markets still available in others –, and systematic communication to affected patients about the issue, how it is handled, and how it affects them is often lacking. Significant progress is still needed in this area. We believe that patients have an important role to play in reporting safety events to National Competent Authorities, which should be formalised in the regulation through specific reporting channels.

Patient involvement in governance

We generally welcome increased coordination in the system and the **strengthened role of the European Medicines Agency** provided by the European Commission proposal. We trust that the EMA's experience in evaluation and post-market surveillance in the field of medicines, as well as in engagement with patients and

promoting transparency, will greatly serve the medical devices regulatory system. EPF would like to stress, however, the importance of **sufficient resources** for EMA, the European Commission, and National Competent Authorities to ensure they are able to fulfil their roles. This will be key to address the current fragmentation of the system both at EU and national level. In addition, we support strengthened coordination of notified bodies through NBCG-med and the enhanced role of expert panels in determination of the regulatory status and classification of devices, as well as provision of scientific, technical, clinical, and regulatory advice. We are nonetheless very cautious about the inclusion of regulatory sandboxes at national level, which may rely on uneven levels of pre-market expertise among member states and result in renewed fragmentation. We believe that regulatory sandboxes should be centralised at EMA level and rely on the expertise of expert panels, building on strong cooperation with competent authorities for the evaluation of clinical investigations applications.

We further regret that the Commission did not mandate the inclusion of patient representatives in expert panels and call on the European Parliament and Council to address this gap. **Patients often bring invaluable input to medical product development by highlighting the real-life impacts of diseases and available treatment options on their lives.** Including them across the product life cycle is not just a matter of inclusiveness but ensures that new product address [1] needs[2].

Regarding the governance of the system, there is a strong need to explore the **establishment of a specific forum** to ensure the patient community can meaningfully participate in decisions that affect them and to facilitate dialogue with competent authorities. EMA established the Patient and Consumer Working Party (PCWP) in 2006 as a platform for exchange of information and discussion and to enable patient and consumer representatives to provide recommendations on all matters of interest in relation to medicines. As the only patient organisation with observer status at the Medical Devices Coordination Group (MDCG) currently, **EPF experiences first-hand the significant challenges patient organisations face to follow and meaningfully engage in the governance process.** This is due to the volume of information and type of input required; for example, as MDCG documents are broad and cover a wide range of issues, only limited sections are directly relevant for patient input, with no attempt by the MDCG to highlight relevant sections and consult patient representatives specifically. In addition, the multiplication of taskforces and MDCG subgroups requires significant time commitment. **As the Commission decided to remove operating grants under the EU4Health Programme, patient organisations' input into the MDCG is not supported by any financial resources, and therefore cannot be prioritised, creating a structural imbalance in stakeholder representation.** The creation of a specific forum for information exchange and discussion of the issues of direct relevance to patients would be a first step towards better involvement of patients in the regulatory governance for medical device.

[2] Murphy A, Bere N, Vamvakas S and Mavris M (2022) The Added Value of Patient Engagement in Early Dialogue at EMA: Scientific Advice as a Case Study. Front. Med. 8:811855. doi: 10.3389/fmed.2021.811855

Need to improve transparency for patients

Ensuring that patient communities have access to transparent information about medical devices remains a key concern for us. We regret that **the proposal does not promote significant improvements and, in some areas, even reduces information and transparency for patients.**

A key concern is the lack of explicit provisions ensuring that patients are informed about device shortages. This is vital as it allows healthcare professionals and patients to discuss and select alternative treatment options as early as possible. While we welcome recent efforts to improve reporting and better anticipate shortages of medical devices, specific pathways to inform patients of relevant shortages are still missing. Providing information through trusted sources, such as healthcare professionals (HCPs) and public databases (e.g. EUDAMED, national platforms), aids patients in avoiding and acting upon safety risks.

We also question the roll-back of implant cards, which provide patients with essential identification details about their implanted device. Specifically, under the Commission proposal, well-established technologies (WET) would be exempted from implant card requirements. We acknowledge that implant cards for WET such as screws, plates, or wedges are currently not always provided and considered necessary if the devices are not meant to stay. However, as WET may cover a broad range of products now and in the future – which raises the need for a clear and precise definition – and considering patients' fundamental right to access information, we believe that implant cards should remain mandatory for all implantable devices. This would support greater transparency, improve patient awareness of the devices they use, and enable efficient and effective follow-up in the event of safety issues.

While offering both physical and digital formats is welcome, physical cards remain essential for patients with lower digital literacy or limited connectivity (e.g. in remote areas).

Another concern is the proposal's provisions related to Summaries of Safety and Clinical Performance (SSCPs). In particular, the proposal limits publication of SSCPs in EUDAMED to class IIb implantable and class III devices. Further, the explicit reference to making SSCPs clear to "patients" as a target audience where relevant was removed, which threatens patients' ability to receive information about the clinical evidence that underpins a device's benefit-risk assessment. **To strengthen broader transparency in the medical devices system, SSCPs and patient-friendly lay summaries should be accessible to the public on all devices for which a clinical assessment was conducted.** This would support informed patient-doctor decision making about what devices to use. **In addition, patients provide the data and ultimately take the risks associated with participation in a clinical investigation. As a result, the publication of all clinical results is not just an ethical requirement, it is a democratic imperative.**

Finally, EUDAMED is central to transparency and should provide easy access to comprehensive information for patients and the public, including clear and up-to-date post-market surveillance information. **We regret the significant delay in establishing the database and call on the European Commission to prioritise its roll-out as soon as possible. EUDAMED should not only be seen as a tool for competent authorities, but as a unique source of information for patients, clinicians, and hospitals to support not only clinical but also procurement decisions.** In the longer term, digitalisation offers significant potential – while fully respecting data protection

requirements – to enable synergies with the European Health Data Space (EHDS), supporting the use of real-world data on the long-term safety and performance of medical devices in real-life settings.

Of note, article 33 of the Commission's proposal states that one or more electronic systems will no longer be included in EUDAMED but will instead be made interoperable with it. We highlight that it is important to maintain a user-friendly interface and ensure clear, comprehensive information for laypersons. **To avoid fragmentation, EUDAMED should remain a central one-stop shop for reliable, patient-friendly information on all aspects of a device, with possible interoperable systems clearly signposted and easy to access.** We also encourage the Commission to expand the information to be made available in EUDAMED to clearly reflect patients' needs. This includes, for example, a document similar to the EMA's European public assessment reports, in lay-language, which reflects the scientific conclusions of the notified body and provides the ground for the certification decision.

EUDAMED has the potential to significantly enhance transparency in clinical evaluation, conformity assessment, and post-market vigilance, which is paramount to ensure trust and enable patients and clinicians to make informed decisions. At the same time, raising public awareness about EUDAMED, its functions and content is another key step to ensure that patients engage with the platform and understand how to use it. To fully realise the vision of EUDAMED, better collaboration between all stakeholders, including patient organisations and healthcare professionals, is needed.

ABOUT EPF

The European Patients' Forum (EPF) is an independent non-profit, non-governmental umbrella organisation of patient organisations across Europe and across disease areas. Our 80+ members include disease-specific patient groups active at EU level and national coalitions of patients. To read about our vision, mission, and strategy, visit: www.eu-patient.eu

EPF's 2024 report "Patient Perspectives on Implementation Challenges of the EU Medical Devices Regulations: EPF Survey Findings" is available here.