Patient Perspectives on Implementation Challenges of the EU Medical Devices Regulations:

EPF Survey Findings

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Introduction

Medical devices are vital for patients, significantly improving life expectancy and quality of life. With current technological advancements, devices will play an even larger role in healthcare in the future. Patients are becoming increasingly well informed and taking active control of their own devices, such as wearable devices, monitors, and injection systems, while in the past healthcare professionals were often considered as the primary users. In this context, a fit-for-purpose regulatory framework is crucial to ensure patient safety and timely patients' access to the devices they need. This requires a strong patient voice in ongoing debates.

The Medical Devices Regulation (MDR) and In-Vitro Diagnostic Medical Devices Regulation (IVDR) were adopted in 2017 to address serious shortcomings in the existing regulatory framework, including insufficient oversight leading to major safety issues, and inconsistent interpretations. MDR and IVDR introduced stricter quality standards, performance evaluations, and oversight across the device lifecycle, enhancing patient safety, transparency, and information. Although the MDR and IVDR promised significant improvements, full implementation is still pending[1] and benefits to patients are yet to be fully fulfilled.

To understand the situation for patients since the adoption of the new framework, the European Patients' Forum (EPF) conducted an **online survey on the MDR/IVDR implementation** for its member organisations and their networks between 25 July and 30 September 2024. The survey centred around three key aspects from a patient perspective: **patient safety, availability/shortages and accessibility of medical devices, and information to patients.** Key findings are presented in this paper, focusing mainly on the timeframe 2017-2024. A few cases shared proactively by patient representatives in the past year were also added in the relevant sections to provide additional concrete examples of the issues raised.

Almost 100 respondents participated in the survey, including 45% individuals (patients and informal carers) and 55% (umbrella) patient organisations, either disease-specific or national coalitions, from 24 European countries[2], 21 of which are EU member states. For this report, input related to non-EU/EEA countries was not considered. Neurological and cardiovascular conditions, diabetes, rare diseases, and cancer were the most represented. The age range of individual respondents was relatively well distributed, ranging from 21 to 90+.

Key limitations of the survey are that it was only available in English, it was disseminated only among EPF's direct and extended network, and not all respondents completed the full survey. This survey aimed to provide an initial overview of patients' experience with medical devices and the regulatory framework. EPF will consider opportunities to re-launch the survey in the coming years to analyse developments and obtain additional information.

Findings and recommendations based on this input aim to inform the review of the legislation by the European Commission in 2025. While increased coordination, guidance and targeted support measures can help smoothen the MDR/IVDR implementation process, any potential legislative adjustments identified at the end of the review should be based on public health needs, thorough impact assessments, and close consultation with those the system is supposed to benefit the most, namely the patients.

[1] See EPF statements from Jan 2023, Mar 2023, Feb 2024

[2] Austria, Belgium, Croatia, Cyprus, Czech Republic, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Netherlands, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom.

Key Points and Recommendations

1. **Strengthen oversight and responsiveness to patient safety issues**. This includes a rapid, risk-based response mechanism with adequate and properly enforced timelines for investigation of incidents and corrective action, especially for high-risk devices. Our survey indicates that concerns about the system's ability to effectively respond to incidents and adequately inform patients remain.

2. **Establish clear safety incident reporting pathways for patients** at national level and widely communicate them to ensure patients are aware. Patient organisations play a key role in raising awareness and informing patients and need to be involved in this process.

3. **Systematically investigate the root causes of shortages of existing devices.** Our survey highlights the multiple causes of device shortages, from supply chain and production disruptions to provider decisions and compliance with new requirements. It is crucial to assess what shortages stem from MDR/IVDR challenges versus other root causes, focusing on impacts on patient care.

4. **Identify effective support measures to address shortages of devices that patients need, with a specific focus on orphan devices, prioritising patient safety and transparency.** Medical device shortages, withdrawals, and supply disruptions should be monitored, anticipated, and addressed through coordinated action among key stakeholders. The reporting of supply interruptions or discontinuations under Regulation (EU) 2024/1860 should support such efforts.

5. **Enhance communication with patients in case of device shortages and recalls** ensuring that replacements and alternative options can be discussed with patients and quickly provided.

6. **Improve equitable access to innovative devices that provide a real added value to patients**, to minimise patients' reliance on older, less effective device options. Beyond a sole focus on regulatory barriers, affordability, financing, as well as healthcare systems' ability to absorb innovation should be investigated and addressed to improve health equity across the EU.

7. **Fully operationalise and promote EUDAMED as soon as possible** to close information gaps. The Commission must partner with patient representatives to raise awareness of EUDAMED, ensure it is user-friendly and includes the information patients need. Transparency in clinical evaluation, conformity assessment, and post-market vigilance is paramount to improve patients' trust.

8. **Foster equity and inclusion of patients in decision-making processes** to help shape healthcare systems that truly serve patients. For this purpose, exchanges between patients/patient representatives and regulators in a structured forum are essential, e.g. via a permanent patient advisory board. Patient participation ensures patients' perspectives and concerns are heard.

9. **Provide comprehensive, easy-to-understand information to patients** about the devices they use. As digital information becomes increasingly prevalent, increased availability of electronic instructions for use for patients is helpful, but paper-based instructions must remain accessible to avoid inequalities in information access.

Patient Safety

A central objective of introducing the Medical Devices Regulatory Framework in 2017 was to improve patients' safety through several measures such as stricter pre-market control and post-market surveillance, better traceability of devices, and enhanced oversight of high-risk devices. The MDR also further strengthened obligations for the reporting of serious incidents impacting patients' health and safety.

Device safety issues

Despite these improvements in the legislation, the EPF survey shows that safety issues and concerns with medical devices persist within the patient community. 28% of survey respondents reported that they had experienced safety issues since 2017. Specific examples listed included:

- Low quality prosthetics resulting in revision surgery after hip or knee implants and significant impacts on patients' quality of life
- Several cases of recalls of insulin pumps due to identified risks and mechanical issues
- Issues with software updates and connection affecting the functioning of various devices
- Recalls of deep brain stimulation implants
- Lack of patient information about known adverse effects of transcranial magnetic stimulation

Safety complaints further refer to pain, skin irritation, allergies, reduced quality of life, as well as concerns about data protection and cybersecurity. Such safety issues are not only problematic for their direct impact on patients, but also when replacement options are of lower quality, unsuitable, or simply not available. For example, feedback received referred to how dangerous device malfunctioning can be for patients with pulmonary hypertension. *"If a patient goes without the medication administered via this device [infusion pump for pulmonary hypertension] for just 15 minutes, the consequences can be severe — even fatal."*

Patient satisfaction with the way safety complaints were handled was mixed. While some survey participants described a quick reporting process and adequate solutions, others stated that there was either no response to their complaint or corrective action took too long. In some cases, the issue is still not resolved. For further insights into the issue, see Box 1 below. Some patient representatives also mentioned to need to effectively empower NCAs to conduct independent testing to investigate safety issues.

Where corrective action was taken and fully implemented, it was mostly found effective and included device recalls, replacements, resets, and updates. In the case of less serious incident reports, some patients were concerned that they might disappear into a "black box" without any information on potential follow-up by the manufacturer.

Reporting and timely communication to patients about safety incidents

What distinctly emerged from the survey results is that incident reporting pathways for patients are not always clear, and many do not know where to turn. A significant 20% of survey participants wanted to report a safety issue but did not know whom to contact. Some patients regretted that there appears to be no official channel for patients to report issues in their country, as national competent authorities (NCAs) are not formally required to establish reporting systems for patients.

Patients who did report an issue typically turned to health care providers (HCP) (64% of respondents), followed by the manufacturer (45% of respondents) and the NCA (36% of respondents). Further, preferences for whom patients would like to contact in case of safety complaints indicate that trust in, and perceived independence of, the contact point plays an important role. Survey participants showed a preference for sharing their safety issue or concern with an HCP (48%) or NCA (31%) rather than a manufacturer (only 12%). Some respondents pointed out the need for increased coordination at EU level and the importance of an independent body/authority which can address patient safety complaints without the influence of commercial interests. Similar results on patient trust have emerged in previous surveys conducted by our members.[3] Examples of a lack of responsiveness of NCAs were also provided, with one particular case of an NCA referring the patient to EPF for information about an adverse event in 2022/2023.

Overall, the findings highlight a lack of clear and reliable pathways for patients in Europe to share safety issues and receive timely solutions. Better communication about main points of contact for incident reporting and timely reaction and follow-up from manufacturers and NCAs is essential to ensure that patients use safe and suitable devices.

Box 1

Case Study: Remaining Shortcomings in Addressing Safety Events

Recent highly publicised device recalls affecting certain patient communities have raised concerns about the ability of the system to react to large-scale safety events and provide adequate support to patients:

- **Lack of information** about how many and where devices are in the healthcare system/who uses them, and whether all affected patients have been informed and have received a replacement device
- The **extremely long timeline** for implementation of the Field Safety Corrective Actions (FSCA)
- Concerns about the **adequacy of replacement devices**, also subject to follow-up recalls in some cases
- The **lack of transparency and access to documents** for patients including confidentiality of the notified body assessment reports, lack of access to clinical and other data, and lack of information from competent authorities about ongoing investigations and regulatory actions

Availability and Accessibility of Medical Devices

Devices shortages and availability issues

Survey results demonstrate that device shortages are a considerable problem. Almost half of respondents in this section (44%) reported having experienced device supply disruptions, shortages, or withdrawals. According to survey results, a wide range of medical devices was affected, including pacemakers and other cardiovascular devices, cochlear implants, respiratory equipment, infusion pumps, glucose monitors, insulin pumps, mobility aids, functional electrical stimulation devices, catheters, incontinence materials, wound care equipment, etc.

Specific reasons for device shortages that respondents were aware of include transport and delivery problems (in some cases due to the Covid-19 pandemic given the period covered in the survey), safety-related product recalls, manufacturing disruptions, contract discontinuation (e.g. change of supplier who did not produce the same device), issues with re-certification of devices under the current framework, difficulties for SMEs such as

[3] https://ojrd.biomedcentral.com/articles/10.1186/s13023-019-1123-4

regulatory compliance and certification costs, and high demand for specific products. A specific case of lack of availability of an in-house, customised device is outlined in Box 2 below.

In addition, respondents also mentioned burdens related to clinical evidence requirements and device certification, with specific cases of **orphan devices** mentioned. In one instance, the device in question could not be recertified as the evidence was not deemed robust enough due to the very small patient population – an issue that cannot be bridged in the context of rare diseases. In these specific cases, the level of evidence required must be balanced with the unmet need to ensure continued access. The very limited number of dedicated registries gathering real-world data for some orphan devices also hinders post-market data collection to support the safe use of these devices. The European Reference Networks could be leveraged in this regard.[4]

Shortages can last very long, and often no adequate alternatives are available. Shortages were reported to have lasted from a few months to years, and in some cases withdrawals from the market were permanent. In addition to negative physical consequences, the lack of access to necessary devices can also have a profound toll on the emotional and mental health of patients, as they may feel helpless, frustrated, anxious, or isolated while coping with unmanaged symptoms or deteriorating health. This unmet need can also significantly reduce patients' quality of life and independence.

When device shortages or withdrawals occur, quick communication with patients and HCPs is critical to identify alternatives, adapt treatments, and maintain a good quality of patient care. This remains a challenge; survey feedback shows that patients generally did not feel well informed about shortages. Either they reported receiving no information at all or only with a delay. In other cases, some affected patients received notifications while others did not, demonstrating inconsistent communication. Information sources also differed vastly, ranging from family doctors and industry associations to the responsible national agency, showing that systematic communication with patients remains a barrier to their effective care and treatment.

Box 2

Example: Access to Customised In-House Devices

Unfitted cannulas can hurt and cause serious damage, including respiratory distress in some patients. One survey response highlighted the case of lack of patient access to individually designed and shaped trachea cannulas. These devices were manufactured by hospitals in Sweden and previously made available to patients in neighbouring countries. However, new MDR requirements applying to in-house devices and interpreted strictly became a barrier to patient access to these highly specialised products outside the manufacturing hospital. While a framework to ensure the safety of in-house devices is necessary, this case shows the need to clarify and adapt the system to particular cases of small patient populations with very specific needs who cannot rely on alternatives.

Access to innovation

Further, patients' reliance on suboptimal device options and limited access to innovative devices was a common complaint. 45% of survey participants are aware of new and innovative devices elsewhere within or outside Europe but cannot access them. Reasons mentioned include:

- **Slow or no uptake of the new devices** in the country due to high prices, budget constraints, and reimbursement decisions made by public healthcare systems and insurers to cover only cheaper, oftentimes

[4] The EU4Health-funded project DeCODe will further investigate this; for further information see https://www.utwente.nl/en/news/2024/9/1752720/decode-to-support-the-development-of-paediatric-and-orphan-devices and https://eithealth.eu/news-article/decode-project/

older or less effective models, even when better options exist. As reimbursement and pricing are outside the scope of the MDR/IVDR, this highlights the need for a comprehensive review of barriers to access and how to improve health equity across the EU, including healthcare systems' ability to adapt to and absorb innovation.

- **Costly regulatory approval, lack of notified body availability,** and what appears as **non-risk-based requirements** that do not improve patient safety, which can be a problem especially for SMEs and academic researchers (for a practical example mentioned in our survey, see Box 3 below).

Box 3

Example: Impact of Regulatory Burden on Innovation

One particular case referred to a 2022 Commission decision to reclassify non-invasive brain stimulators without an intended medical purpose from class I to class III following a request by six member states. Research projects are currently exploring the use of this technology to improve wellness and cognitive function in patients with Parkinson's disease, but the reclassification may jeopardise further research. Following an Ombudsman proposal, the Commission requested in 2024 a scientific opinion on health risks associated with these products to the Scientific Committee on health, Environmental and Emerging Risks (SCHEER), due by end 2025. While this reclassification decision may or may not be justified, it is important that regulatory decisions are evidence-based, transparent, informed by an assessment of impacts on patient care, and appropriately communicated. Low awareness of the "Have your say" website and limited stakeholder consultation can hinder acceptance and transparency of regulatory decisions.

Providing adequate guidance and resources to swiftly implement the MDR/IVDR and adapting requirements through evidence-based decisions for specific device types are essential to maintain the availability of devices patients need. In addition, it is important to understand current barriers to access to innovation. Clear pathways for harmonised and efficient assessment of innovative devices that bring a true added value to patients are lacking, but their implementation also requires a broader reflection on healthcare systems' ability to absorb innovation and provide effective, equitable access across the EU. This consideration is closely aligned with the upcoming implementation of the EU Health Technology Assessment (HTA) Regulation. It will support joint assessments at EU level of the clinical aspects of high-risk medical devices and in vitro diagnostics, with mandatory patient involvement in the process. By streamlining assessments and promoting patient involvement, the EU HTA Regulation has the potential to widen access to innovative technologies and minimise inequalities while guiding the development of devices that truly meet patient needs.

Information for Patients

Status quo on information for patients

Information shared with patients is inconsistent across Europe, stressing the need for a quick roll-out of the EU-wide medical devices database EUDAMED to enable patients and the wider public to be adequately informed about medical devices placed on the EU market. EUDAMED has the potential to greatly improve the traceability of devices across their lifecycle, facilitate post-market surveillance by competent authorities, and increase the overall transparency of the system for patients and healthcare professionals. **Survey results confirm this need, as almost half of respondents (43%) do not feel well informed about the devices they are using**.

At present, without a fully functional EUDAMED, considerable differences can be seen in the sources, quality, formats, and speed of information available to patients. Online sources (e.g. manufacturers' websites, social media) and patient organisations are frequently cited as key sources of health information. In addition to these, manufacturers, HCPs, and national authorities are also mentioned as information providers. Although online sources are easily accessible, they vary widely in quality which raises concerns about the potential spread of misinformation, particularly regarding critical health decisions.

Some survey feedback also refers to poor quality information, pointing out that sources can be contradictory, and information is often difficult to understand because of technical language. Some respondents further highlighted the lack of readability of the implant card, which was introduced by the MDR for the very purpose of increasing transparency for patients about their implanted medical devices. Related concerns about patients' lack of awareness and understanding of their implants were also mentioned.

Potential of EUDAMED

At the same time, survey findings suggest that EUDAMED, as a digital source of information, may attract wide patient interest. Through the database, patients had particular interest in accessing safety-related information and documentation in lay language, including data about side effects, safety incidents and corrective actions, recalls, airport safety controls, and longevity as well as summaries of safety and clinical performance and certificates. Improved accessibility of the evidence base and documentation that support a certification decision should be prioritised to improve trust and transparency of the system.

Other requested information related to the unique identification of devices, the number of a device model on the market, instructions for use, troubleshooting, clinical sites trained in a certain device, and responsible national contact points. According to a member's feedback, *"EUDAMED could be transformative for patients if designed with usability in mind."* To ensure its utmost utility, patients' views on EUDAMED's usability (platform design, accessibility, lay language explanations, etc.) should be taken into account in a formal consultation.

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. For the roll out of EUDAMED, it is important that the portal is easily searchable, and information is user-friendly and comprehensive. 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 HCPs, is needed.

Digitalisation of information

While many respondents view increased digitalisation as a positive trend, it is essential that patients with low digital literacy and limited internet access – which is still the case in many rural areas – are not left behind. According to the survey, 58% of respondents are open to receiving device use instructions or other information exclusively in digital form, while 38% prefer a combination of digital and paper format. Electronic instructions for use for patients should be part of an overall strategy to ensure that all patients in the EU have access to comprehensive, high-quality, up-to-date, and understandable information on the devices they are using. **At the moment, many patients still require paper-based information and their right to access it should be guaranteed.**

Meaningful patient engagement

There is a strong need to explore the establishment of **specific forums to ensure the patient community can meaningfully participate in decisions that affect them** and to facilitate dialogue with competent authorities. The European Medicines Agency (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 an observer at the MDCG, EPF is concerned about the difficulty for patient organisations to follow and meaningfully engage with regulators in the decision-making process due to the volume of information and type of input required. 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 devices.