

Transformation of European Medical Device Regulation: The role of expert panels

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Abstract

The European Medical Device Regulation (MDR) (EU 2017a) and In Vitro Diagnostic Regulation (IVDR) (EU 2017b) represent a transformative shift in medical device oversight, replacing outdated directives with comprehensive safety and transparency requirements. This review analyzes the historical context driving regulatory reform, including critical incidents involving medical devices that exposed weaknesses in previous regulatory frameworks, and examines the structure and function of expert panels established by the European Commission and European Medicines Agency. These panels provide independent scientific consultations through Clinical Evaluation Consultation Procedure and Performance Evaluation Consultation Procedure, supporting notified bodies in assessing high-risk devices while offering voluntary advice to manufacturers. The article evaluates the MDR's impact on manufacturers, notified bodies, patients, healthcare professionals, and market competitiveness, highlighting both enhanced patient protection and implementation challenges. Despite increased costs and extended certification timelines, the MDR positions the EU as a global leader in medical device regulation, balancing innovation with rigorous safety standards.

Keywords

medical devices, regulations, expert panels

Introduction

Regulation (EU) 2017/745 on medical devices – MDR (EU 2017a) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices – IVDR (EU 2017b), adopted on April 5, 2017, mark a pivotal moment in the evolution of European medical device legislation, replacing the outdated Directive 93/42/EEC (MDD), Directive 90/385/EEC (AIMDD), Directive 98/79/EC (IVDD) and Commission Decision 2010/227/EU. These regulations were introduced to address the growing de-

mands for safety, efficacy, and transparency in a rapidly evolving sector where technological innovations and globalization have completely transformed the medical device landscape.

Central to their implementation are the expert panels of the European Commission (EC) and the European Medicines Agency (EMA), which provide scientific consultations to notified bodies for certain high-risk medical devices, assist manufacturers in developing innovative solutions, and contribute to ensuring a high level of patient protection in the EU.

This review article aims to analyze the historical reasons behind the adoption of the MDR and IVDR, examine the structure and requirements of the new regulations, the role of the Medical Device Coordination Group – MDCG, detail the activities of the expert panels (including the Clinical Evaluation Consultation Procedure – CECF, the Performance Evaluation Consultation Procedure – PECF, advice to manufacturers, support for orphan devices), and provide an analysis of its influence on the international competitiveness of the European market.

Historical context of the regulation change

Shortcomings of the previous directives

The medical device legislation in past decades was built upon EU directives – AIMDD, MDD, Directive 98/79/EC and Decision 2010/227/EU. These documents played an important role in this period for harmonization of medical device regulations within the union. The regulatory system relied mostly on manufacturer self-declaration and oversight by notified bodies.

Over time, however, it became clear that this approach was insufficient to address the complexity of modern devices, such as implants, software applications, and high-tech diagnostic systems. New regulations for medical devices and in vitro diagnostics were drafted and proposed in 2012 (EC 2012) but public discussions and working group efforts on creating a new regulatory framework started in 2008–2009.

In 2010, the Poly Implant Prothèse (PIP) breast implant scandal was uncovered when it was revealed that the French manufacturer PIP had used industrial-grade silicone instead of medical-grade material. This case affected over 300,000 women in Europe and led to numerous health complications, including inflammation and implant ruptures (Lampert et al. 2012).

While some authors attribute the greater exposure of European patients to health risks to limitations of MDD (Martindale and Menache 2013), it's important to recognize that the PIP scandal was fundamentally a case of criminal fraud that even the most robust regulatory framework could not have prevented (EC SCENIHR 2013, 2014). The founder of the PIP, Jean-Claude Mas, was sentenced to four years in prison in December 2013 for using cheap industrial grade silicone (The Guardian 2013) and TÜV Rheinland was found liable and paid over 60 millions euros to affected women (BBC News 2017).

However, a valid criticism can be made regarding risk assessment: European authorities failed to adequately appreciate the significance of this producer's regulatory history and its exclusion from the US market several years earlier. The contrasting processes and outcomes in these two markets cannot be attributed simply to regulatory frameworks, but rather stems primarily from how production control measures were technically implemented,

with the FDA's centralized approach performing more effectively than the EU's decentralized model (Martindale and Menache 2013).

A particularly illustrative example is the recall of the DePuy ASR hip prostheses in 2010, following the discovery that their metal components generated cytotoxic metallic debris within the body, with adverse outcomes documented in approximately 93,000 patients and requiring revision surgery for tens of thousands of cases (Cohen 2012).

Some researchers attribute this failure to regulatory mechanisms under the MDD as European regulators failed to recognize that the ASR hip resurfacing system differed fundamentally from conventional hip replacement devices. This oversight led to market approval based solely on limited simulator-generated data rather than extensive preclinical trials. Differences in design of the ASR from traditional hip replacements resulted in adverse device-body interactions and delayed complications in patients (Cohen 2011).

The question remains whether a small-scale premarket study could have identified these problems, given that the primary issues involved delayed biocompatibility complications arising from long-term implant-tissue interactions. For market approval the FDA request premarket study data, but the application was withdrawn by the company later as more cases of systemic toxicity were reported (Cohen 2011).

The need for reform

These two major medical device scandals could not be simply characterized as the main catalysts for new regulations as the MDR draft was already in preparation, but they demonstrated at precisely the right moment the need for reform in market approval process, post-market manufacturer control and regulatory frame in general (Eikermann et al. 2013). Furthermore, they functioned as a stress test of the reforming regulatory infrastructure of the EU.

With technological advancements and the globalization of the medical device market, it became evident that the old system could not meet new challenges. The emergence of software as a medical device (e.g., diagnostic and monitoring applications) and the increase in high-risk implantable devices demanded stricter safety and efficacy standards. Meanwhile, global competition led some manufacturers to use the European market as a "testing ground" for devices with insufficient clinical data before certifying them in stricter markets like the U.S.

In response to this historical context, the European Commission initiated a comprehensive legislative reform process (EC 2012) with two primary objectives: first, to achieve the highest level of regulatory harmonization across member states, and second, to address the challenges posed by rapid scientific and technological advancement. The revision process commenced with stakeholder consultations as early as 2008, culminating in the 2012 regulatory proposal following a systematic analysis of more than 300 documented medical device incidents occurring between 2005 and 2010.

The main goals of the reform were to prevent the market entry of devices without sufficient evidence of safety

and performance, improve post-market traceability, and strengthen coordination among Member States through a unified and transparent system. These efforts culminated in the adoption of the MDR and IVDR, which introduced stricter requirements and created mechanisms such as expert panels providing independent opinions and advice.

The New Medical Device Regulations (MDR and IVDR)

Legal basis and timeline

The MDR entered into force on May 25, 2017, with full implementation initially scheduled for May 26, 2020. However, the COVID-19 pandemic necessitated a one-year delay via (EU 2020), moving the new deadline to May 26, 2021. Due to significant challenges faced by manufacturers and notified bodies, as well as the risk of medical device shortages extension was adopted in March 2023 (EU 2023). This regulation extended the transitional periods until December 31, 2027, for high-risk devices (Class III and some Class IIb) and until December 31, 2028, for lower-risk devices, provided they have valid MDD or AIMDD certificates and manufacturers have taken steps to transition to the MDR (Table 1).

Table 1. MDR Transition Periods.

Device class	Deadline	Conditions
High-risk (Class III)	Dec 31, 2027	Valid MDD certificate, steps toward MDR
Low-risk	Dec 31, 2028	Valid MDD certificate, steps toward MDR

Key changes

Expanded scope of regulation

The MDR significantly broadens the scope of regulated products, including categories previously under less stringent oversight (Table 2):

Table 2. Comparison Between MDD and MDR.

Aspect	MDD (93/42/EEC) & AIMDD (90/385/EE)	MDR (2017/745)
Clinical Evaluation	Limited data	In-depth, continuous
Scope	Medical devices, limited scope on medical software	Includes aesthetic devices, software encompassed completely
Transparency	No UDI	Mandatory UDI and EUDAMED
Conformity Assessment	Lighter process	Stricter checks, expert panel consultations

MDD had limited provisions on software but with MDR Software as a Medical Device (SaMD) was included - applications and programs used for diagnosis, monitoring, or treatment are qualified as medical devices. Complex systems of sensors for measuring blood sugar plus user interface on

mobile app or wearable software analyzing heart rhythm fall under the MDR. This reflects rapid advancements in digital healthcare, with the SaMD market projected to reach €86 billion by 2027. An example is the FreeStyle Libre app, which allows diabetics to monitor glucose levels via a sensor and smartphone – now requiring full MDR certification.

Aesthetic Devices without Medical Function: Products like dermal fillers, skin laser devices, and decorative contact lenses are regulated due to potential health risks. For instance, improper use of tattoo removal lasers can cause burns or infections, and dermal fillers have been linked to complications like necrosis when improperly administered.

Nanomaterials: Devices containing nanoparticles, such as orthopedic implants or catheter coatings, are classified into higher-risk categories due to their potential effects on the body. Nanoparticles can penetrate cells, requiring thorough biocompatibility testing. An example is titanium implants with nanocoatings that enhance osseointegration but require additional long-term effect studies.

This expanded scope affects over 8,000 products, enhancing consumer protection but also imposing additional requirements on manufacturers, particularly in digital technology and aesthetic medicine.

Stricter clinical evaluation requirements

The MDR emphasizes clinical evidence to ensure device safety and efficacy:

Long-Term Clinical Studies: High-risk Class III devices (e.g., heart valves, orthopedic implants) require continuous post-market clinical follow-up. This is a significant improvement over the MDD, where long-term studies were rarely mandated. For example, cardiac stents must now demonstrate not only short-term safety and performance but also an acceptable rate of late complications like restenosis over years.

Post-Market Clinical Follow-Up (PMCF)

The MDR Article 86 (EU 2017a) mandates continuous post-market monitoring, including annual reports (class III and class IIb implantable devices). These reports must be submitted to the competent authorities and include:

- Safety data analysis
- Risk-benefit evaluation
- Information on any corrective actions taken
- Updates on clinical evidence

Unique Device Identification (UDI) system

The UDI system is a key innovation improving medical device traceability:

- **UDI-DI (Device Identifier):** A unique code for each device model, linked to the manufacturer. For example, each insulin pump model has its own UDI-DI.
- **UDI-PI (Production Identifier):** A code for specific batches or serial numbers, enabling individual unit identification. This facilitates recalls of defective batches without affecting the entire product line.

- UDI not only significantly improves incident management but combats counterfeit devices, costing billions annually. In the EU, the system has helped identify and remove counterfeit surgical instruments imported from third countries.

EUDAMED database

EUDAMED (EC 2025a) is a centralized database aimed at increasing transparency and information access. It includes modules for:

- Registering manufacturers, authorized representatives, and devices.
- Managing clinical investigations and approvals.
- Reporting serious incidents and corrective actions.

Although full EUDAMED implementation is delayed until Q1 of 2027, partial functionality already allows healthcare professionals and patients to check device statuses. For example, a patient with an implanted pacemaker can verify its registration and certification, enhancing trust. However, the delay creates temporary challenges as much data remains managed at the national level.

Impact of the MDR on stakeholders

Manufacturers

The new regulation has extended time-to-market and increased financial and administrative burdens. These additional costs and delays pose significant challenges for manufacturers. According to a Medtech survey in 2024, manufacturers faced significantly increased clinical trial costs after the MDR's introduction, reflecting both financial burdens and heightened quality focus (MT EU 2024).

However, the MDR also offers long-term benefits for manufacturers that successfully adapt. For example, stricter safety and efficacy standards can enhance company reputations, which is crucial in the competitive international market where consumer and healthcare system trust is key.

One illustrative case involves a manufacturer of an implantable cardioverter-defibrillator (ICD) that received recommendations from an expert panel during the in July 2022. The panel advised additional long-term reliability data for the battery and electrodes, leading to design modifications before market entry. This intervention not only prevented potential future incidents but also allowed the manufacturer to launch an improved product, strengthening its market position (EC 2022a).

Notified bodies

Notified bodies (NB), responsible for medical device certification, are also significantly impacted by the MDR, with new requirements leading to changes in their structure, workload, and operational processes (EC 2025b).

MDR requires notified bodies to demonstrate greater technical competence, employ qualified personnel, and conduct more detailed manufacturer inspections, including site audits. The number of NB in the EU dropped sharply from 56 in 2017 to 42 by the end of 2023 due to stricter accreditation standards under the MDR, but to date the number of active NB under MDR is 50.

This designation process is highly complex and time-consuming, and leading some smaller or less-prepared organizations to exit the market. The remaining notified bodies faced a sharp increase in workload, as they had to process a large number of certification applications under the new rules with limited capacity.

Patients

Patients are among the primary beneficiaries of the MDR, as the regulation significantly raises safety and transparency standards, directly impacting the quality of medical devices reaching them. Strict clinical evaluation and post-market surveillance requirements mean that marketed devices have undergone rigorous safety and efficacy testing, reducing risks like those seen in the past.

For example, mandatory UDI use enables rapid identification and recall of problematic devices if adverse effects arise, significantly improving patient protection compared to the previous system, which lacked such traceability mechanisms. Additionally, public access to the EUDAMED database allows patients and their families to obtain information about devices used in their treatment – from intended use and manufacturer to reported incidents. This increases awareness and trust in the healthcare system, giving patients greater confidence that their devices have passed stringent checks.

Despite these benefits, extended certification timelines may temporarily limit access to some innovative devices, which could be problematic for patients needing urgent or specialized treatments.

Healthcare professionals

Healthcare professionals are also affected by the MDR, with the regulation presenting both advantages and challenges. A key advantage is improved access to information via EUDAMED, enabling them to check device specifications, clinical data, and device-related adverse effects.

This facilitates informed decision-making when selecting appropriate devices for patients, especially for high-risk implants or diagnostic systems. For example, positive expert panel opinion on high-risk implantable devices augments the confidence among clinicians using such devices in their procedures on patients.

At the same time, the MDR's new requirements necessitate familiarity with more complex tracking and reporting systems like UDI and EUDAMED, requiring time for training and adaptation. This process may be particularly challenging for smaller hospitals or regions with limited resources, where staff are already burdened with clini-

cal duties. Additionally, temporary delays in new device approvals may limit professionals' access to cutting-edge technologies, potentially affecting care quality, especially in rapidly evolving fields like minimally invasive surgery or personalized medicine.

European Administration (EC and EMA)

The European administration, including the European Commission and the European Medicines Agency, plays a key role in implementing the MDR and is also impacted by its consequences. The MDR harmonizes regulations across the EU, replacing previous national variations with a unified framework, simplifying oversight and coordination among member states.

The EUDAMED database, managed by the EC, provides a centralized tool for monitoring medical devices on the market, enabling the administration to quickly identify problematic devices and take action, such as recalls or imposing additional requirements. This significantly enhances the EC's ability to protect public health compared to the previous fragmented system, where each member state had its own incident reporting and response procedures.

The EMA, meanwhile, supports the process by organizing and managing expert panels that provide scientific opinions on high-risk devices. This new approach, however, requires significant administrative resources, staff training, and panel coordination. Despite these costs, the benefits of enhanced market safety and transparency are substantial, with the MDR positioning the EU as a leader in global medical device regulation standards.

The European market

The European medical device market, one of the world's largest, faces mixed consequences from the MDR, with the balance between enhanced safety and temporary innovation challenges at the forefront. On one hand, stricter clinical evaluation and certification requirements ensure that only devices with proven safety and efficacy reach the market, boosting consumer and healthcare system confidence in European products. This may strengthen the EU's position as a supplier of high-quality medical devices globally.

On the other hand, extended certification timelines (18–24 months compared to the previous 12) delay new device launches, which is particularly problematic in fast-evolving fields like cardiology, oncology and neurology. For example, innovative devices like radiotherapy machines or neurostimulators, which could improve cancer or neurodegenerative disease treatment, often remain in certification limbo longer than patients need.

This delay may lead to a temporary decline in new technology availability, putting the EU at a disadvantage compared to markets like the U.S., where approval processes are faster. In the long term, however, higher standards may attract more investment to the European sector, as

manufacturers focus on developing high-quality devices meeting MDR requirements.

As this phenomenon was partially related to the reduced number of notified bodies, now as they have returned to pre-MDR levels and most of the transition processes are completed we could expect the timelines to be shortened and this to have a positive impact on the EU market.

Focus on the work of expert panels

The expert panels established under MDR and IVDR are a key component of the new regulatory framework, with their primary goal being to provide independent, high-quality scientific opinions on notified bodies' assessments of high-risk medical devices and in vitro diagnostic devices.

They operate under the coordination of the European Commission (EC) and the European Medicines Agency (EMA), providing consultations to notified bodies during conformity assessments and advising manufacturers on developing innovative solutions.

Structure and role

The expert panels are organized into a complex yet well-coordinated structure ensuring device assessments are conducted by specialists with deep expertise in relevant fields. They consist of three main components: a screening panel, thematic panels, and a coordination committee.

Screening Panel: Acts as an initial filter, reviewing all applications from notified bodies and determining whether a device requires further evaluation by a specialized thematic panel. This process is critical to avoid unnecessary system overload and focus resources on the highest-risk devices.

Thematic Panels: The core of the structure, covering all major medical disciplines and comprising eleven specialized groups (Fig. 1):

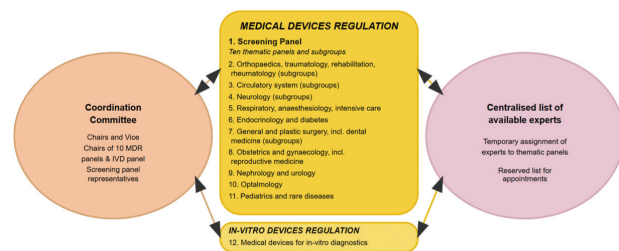


Figure 1. The core of the structure, covering all major medical disciplines and comprising eleven specialized groups.

- Cardiovascular Devices (e.g., stents, pacemakers, heart valves).
- Orthopedics, Traumatology, Rehabilitation, Rheumatology (e.g., prostheses, joint implants).
- Neurology (e.g., neurostimulators, brain implants).
- Respiratory System, Anesthesiology, Intensive Care (e.g., ventilators, oxygen systems).
- Endocrinology and Diabetes (e.g., insulin pumps, glucose monitors).

- General and Plastic Surgery, Dental Medicine (e.g., surgical instruments, aesthetic devices).
- Obstetrics and Gynecology (e.g., intrauterine devices, fetal monitors).
- Gastroenterology and Hepatology (e.g., endoscopes, gastric balloons).
- Nephrology and Urology (e.g., dialysis machines, renal implants).
- Ophthalmology (e.g., intraocular lenses, laser systems).
- Pediatrics and rare diseases.

A twelfth panel is dedicated to in vitro diagnostic devices, focusing on high-risk tests like those for infectious diseases or genetic markers. Coordination Committee: Ensures methodological consistency and standards across panels, facilitating information exchange and maintaining overall harmony in their work.

Panel experts are selected through a rigorous public process organized by the EMA, requiring high scientific qualifications and clinical experience to ensure opinion quality. Their main role is to enable consultation procedures for notified bodies on the safety and efficacy of high-risk devices, thereby raising standards across the EU.

Clinical Evaluation Consultation Procedure (CECP)

The CECP represents a critical regulatory mechanism designed to ensure that the highest-risk medical devices undergo independent scientific scrutiny before reaching patients MDR Article 54 (EU 2017). This procedure operates as a mandatory safeguard for specific device categories where the potential consequences of inadequate clinical evidence could have severe implications for patient safety and public health.

Mandatory Application Scope: The CECP applies with absolute requirement to all Class III implantable devices, recognizing that these devices present the highest level of risk due to their permanent or long-term placement within the human body and their critical therapeutic functions. Additionally, certain Class IIb devices fall under this requirement, specifically active therapeutic devices that administer or remove medicinal products.

This expansion to include active removal and administration devices reflects the regulatory system's recognition that devices which actively manipulate drug delivery or removal carry inherent risks that warrant enhanced scrutiny regardless of their traditional classification boundaries. The workflow of CECP is outlined in Fig. 2.

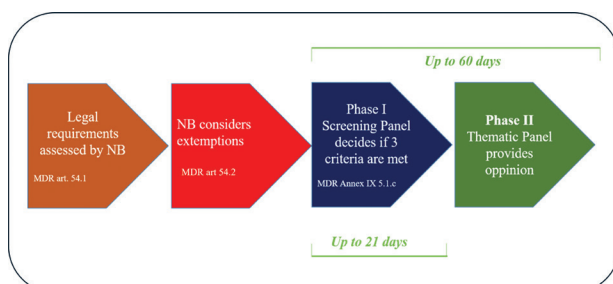


Figure 2. The workflow of CECP.

The procedure ensures that notified bodies cannot proceed with certification decisions in isolation but must incorporate independent scientific evaluation from expert panels into their assessment process. This creates a dual-layer review system where both technical regulatory compliance and independent scientific validation must align before market authorization.

Statistical performance analysis and regulatory trends

Implementation results for the period 2021–2022 were published in late 2022 (EC 2022a). During this initial implementation period, notified bodies submitted 215 notifications under Article 54(3), representing all potentially applicable devices. Of these submissions, only 24 devices (11.2%) actually required CECP application, with the vast majority (191 devices, 88.9%) qualifying for exemption under Article 54(2)(b). This pattern suggests that most high-risk devices either had sufficient equivalence evidence or did not present novel technology concerns requiring expert consultation.

Among the 24 devices that underwent CECP screening, expert panels decided to provide full opinions for only 6 applications (25.0%). This relatively low rate of full expert consultation indicates that the screening process effectively identifies cases where independent scientific input provides the greatest regulatory value (EC 2022b).

Second report encompasses the period 2022–2023 this second implementation period showed increased notification volume with 353 submissions under Article 54(3), reflecting growing familiarity with the process and potentially increased device submissions. The proportion requiring CECP application remained consistent at 36 devices (10.2%), suggesting stable regulatory patterns as the system matured (EC 2023).

The exemption patterns in the second period showed even stronger concentration under Article 54(2)(b), with 314 of 317 exempted devices (99.1%) qualifying under this provision. This concentration indicates that equivalence-based exemptions remain the primary pathway for avoiding CECP consultation.

Among devices undergoing CECP screening in the second period, expert panels provided opinions for only 4 of 35 applications (12.0%), showing a decreased rate compared to the first period. This reduction might reflect improved screening efficiency or more appropriate application of exemption criteria by notified bodies.

Performance Evaluation Consultation Procedure (PECP)

The PECP mirrors the CECP but is specific to high-risk in vitro diagnostic devices (Class D), such as tests for infectious diseases (e.g., HIV, hepatitis) or genetic markers for serious conditions. Introduced under the IVDR, this procedure ensures that critical diagnostic devices are accurate and reliable.

Gateway Criteria: The device must first qualify as a Class D (EU 2022) in vitro diagnostic device according

to the classification rules outlined in Annex VIII of the IVDR (EU 2017b). Class D represents the highest risk category for IVDs, encompassing devices that detect life-threatening conditions, blood screening applications, or companion diagnostics that directly influence critical treatment decisions.

The PECP requires that manufacturers and notified bodies satisfy both trigger conditions simultaneously. The first condition requires the absence of Common Specifications for the specific class D device under review. The second condition focuses on the concept of “first certification for that type of device”.

Required Documentation includes the Complete Performance Evaluation Report addressing scientific validity, analytical performance, and clinical performance. IVDR-Enhanced Risk Management Documentation represents a significant departure from traditional ISO 14971 approaches, requiring comprehensive benefit-risk analysis for all identified risks.

By the end of 2024, according to EMA annual report, total of 21 PECP were performed by in vitro diagnostics expert panel. (EMA 2024a)

Advice to manufacturers

In addition to mandatory consultations, expert panels provide voluntary advice to high-risk device manufacturers, particularly useful for companies developing innovative technologies or addressing unmet medical needs (EMA 2024b).

This procedure was introduced in 2023 as a pilot completed in December 2024. Based on the successful outcome, the advice to manufacturers was fully implemented as of February 2025. Improvements to the procedure were made considering the feedback received from both experts and manufacturers during the pilot.

The advice aims to assist manufacturers early in development, before formal conformity assessment, offering guidance on clinical study design, endpoint selection, and preparation to meet MDR requirements.

The pilot phase prioritized certain types of medical devices:

- Devices that benefit a small group of patients in the treatment or diagnosis of a disease or condition, such as devices intended for the treatment of a rare condition, known as ‘orphan devices’, and devices for paediatric use;
- Devices addressing medical conditions that are life threatening or cause permanent impairment of a body function and for which current medical alternatives are insufficient or carry significant risks;
- Novel devices with a possible major clinical or health impact.

In total, 51 letters of interest were received: 26 for the first phase, 16 for the second phase, and 9 for the third phase.

75% of applicants declared meeting the SME definition. The majority of the applications received were for

devices that were considered novel with a possible major clinical or health impact (criterion declared by 86% of applicants) followed by devices addressing an unmet medical need (criterion declared by 55% of applicants).

The Circulatory system thematic panel received the highest number of applications with 31% of applications, followed by the Orthopaedics, traumatology, rehabilitation, rheumatology thematic panel (27%) then Neurology (14%).

Role of the Medical Device Coordination Group (MDCG)

The MDCG, established under the MDR (EU 2017a), plays a vital role in maintaining harmonization and consistency in the regulation’s implementation, including expert panel activities.

Comprising Member State representatives and chaired by the EC, the MDCG develops guidelines and recommendations aiding notified bodies, manufacturers, and expert panels in interpreting and applying MDR requirements – providing guidance on clinical evaluation of high-risk devices, clarifies software classification criteria and etc. These guidelines are crucial for expert panels, ensuring standardized, comparable evaluations across thematic areas.

Orphan device status

Expert panels also support medical devices for rare diseases, affecting fewer than 12,000 annual cases in the EU (~5 per 10,000 people).

These “orphan devices” are critical for patients with unmet medical needs, but their development faces high costs and challenges due to small potential user bases. The MDR offers incentives like reduced consultation fees and accelerated evaluations, with expert panels providing specialized support through advice and clinical data assessment.

For example, the endocrinology panel might provide an opinion regarding the orphan status and provide scientific advice on clinical development on a new rare metabolic disorder monitoring device, suggesting appropriate data collection methods for limited patient populations.

International competitiveness

The introduction of MDR significantly impacted the international competitiveness of the European medical device market, presenting both challenges and opportunities for European manufacturers compared to leading markets like the U.S. and Asia.

As the MDR imposes significantly stricter clinical evaluation, traceability, and post-market surveillance requirements this almost doubles the time needed historically under directives, according to Medtech report 2024 (MT 2024). On the other hand, FDA’s approval process allows manufacturers to market devices much faster if they demonstrate substantial equivalence to an already approved device.

This delay leads to a temporary decline in the speed of new device launches in the EU, putting European manufacturers at a disadvantage against U.S. competitors who can deliver innovations to market faster. This gap is particularly sensitive in fast-evolving sectors like oncology and personalized medicine, where timely access to new technologies can be critical for both patients and market success.

Despite these challenges, the MDR also offers significant advantages that may strengthen European manufacturers' international competitiveness long-term. First, uniform safety and performance requirements level the playing field for all companies entering the EU market, whether European or international. The MDR's high standards may give European companies a competitive edge in markets valuing quality over speed.

According to MedTech Europe report 2023 (MT 2023), about 15% of these companies risk bankruptcy or market exit due to inability to meet new requirements. On the other hand, long-term benefits from enhanced trust and quality may increase European device market share in premium segments, like high-tech implants and diagnostic systems.

Conclusion

MDR and its associated expert panels represent a transformative moment in European medical device regulation, addressing long-standing gaps in previous directives through stricter safety, efficacy, and transparency requirements. Historical incidents like the PIP implant and DePuy prosthesis scandals served as a stress test of the existing legal proposals, and ultimately evinced the need for reform, which the MDR successfully delivers via enhanced clinical evaluation, improved traceability through UDI and EUDAMED, and the independent role of expert panels. These panels, with their complex structure and specialized thematic groups, provide scientific support to notified bodies and manufacturers, ensuring high-risk devices meet the highest standards pre- and post-market. Procedures like the CECP and PECP, combined with voluntary manufacturer advice and rare disease device support, demonstrate the EU's commitment to patient protection while fostering sector innovation.

However, the MDR also brings challenges that cannot be overlooked. For manufacturers, higher costs and extended certification timelines create financial and logistical difficulties, especially for SMEs, the backbone of the European industry. Notified bodies, reduced in number and facing increasing workloads, struggle to process growing application volumes, delaying new device launches. Patients and healthcare professionals benefit from enhanced safety and information access, but temporary limitations on innovative technologies may impact care quality in some areas. The European market gains

trust and quality advantages but risks lagging in innovation speed against markets like the U.S. and Asia.

Long-term MDR success will depend on several factors. First, optimizing certification processes, including expanding notified body and expert panel capacity, will be critical to reducing delays. Second, supporting SMEs through financial incentives or streamlined procedures may prevent losing innovative potential. Third, international recognition of MDR standards could strengthen the EU's global leadership position, attracting investments and easing European device entry into other markets. Future evaluations, like the EC's planned 2026 targeted study on MDR effects, will provide clearer long-term impact insights and help fine-tune the system. In conclusion, the MDR and expert panels represent an ambitious, necessary leap forward in public health protection while laying the foundation for sustainable European medical device industry growth on a global scale.

Additional information

Conflict of interest

The authors have declared that no competing interests exist.

Ethical statements

The authors declared that no clinical trials were used in the present study.

The authors declared that no experiments on humans or human tissues were performed for the present study.

The authors declared that no informed consent was obtained from the humans, donors or donors' representatives participating in the study.

The authors declared that no experiments on animals were performed for the present study.

The authors declared that no commercially available immortalised human and animal cell lines were used in the present study.

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Data availability

All of the data that support the findings of this study are available in the main text.

References

- BBC News (2017) PIP breast implants: French court tells TUV to pay damages <https://www.bbc.com/news/world-europe-38692678>
- Cohen D (2011) Out of joint: The story of the ASR. *BMJ* 342: d2905. <https://doi.org/10.1136/bmj.d2905>
- Cohen D (2012) How safe are metal-on-metal hip implants? *BMJ* 344: e1410. <https://doi.org/10.1136/bmj.e1410>
- EC (2012) EUR-Lex Proposal for a Regulation Of The European Parliament And Of The Council on the use of railway infrastructure capacity in the single European railway area, amending Directive 2012/34/ EU and repealing Regulation (EU) No 913/2010. <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52012PC0542>
- EC (2022a) Expert decision and opinion in the context of the Clinical Evaluation Consultation Procedure (CECP). https://www.ema.europa.eu/en/documents/other/implantable-cardiac-devices-various-notified-body-0123-11-11-2023-expert-decision-opinion-context-clinical-evaluation-consultation-procedure-cecp_en.pdf
- EC (2022b) Homepage. Annual Overview of Devices Subject to Clinical Evaluation Consultation Procedure. [April 2021-June 2022] https://health.ec.europa.eu/document/download/68774bdc-23d6-432d-871f-7f19cd05abc1_en?filename=md_annual-overview-cecp_en.pdf
- EC (2023) Homepage. Annual Overview of Devices Subject to Clinical Evaluation Consultation Procedure. [July 2022-June 2023] https://health.ec.europa.eu/document/download/4c43abea-b989-434b-9ac1-94134bf1a538_en?filename=md_annual-overview-cecp-2022-2023_en.pdf
- EC (2025a) Homepage. EUDAMED Overview. https://health.ec.europa.eu/medical-devices-eudamed/overview_en
- EC (2025b) Homepage. Notified Bodies for Medical Devices. https://health.ec.europa.eu/medical-devices-topics-interest/notified-bodies-medical-devices_en
- EC SCENIHR (2013) Preliminary Opinion on the safety of Poly Implant Prothèse (PIP). Silicone Breast Implants (2013 update). <https://doi.org/10.2772/66097>
- EC SCENIHR (2014) The safety of poly implant prothèse (PIP) silicone breast implants – update of the opinion of February 2012. <https://doi.org/10.2772/66097>
- Eikermann M, Glud C, Perleht M, Wild C, Sauerland S (2013) Commentary: Europe needs a central, transparent, and evidence based regulation process for devices *BMJ* 346: f2771. <https://doi.org/10.1136/bmj.f2771>
- EU (2017a) Regulation (EU) 2017/745 Of The European Parliament And Of The Council 5 April 2017 Article 54 Clinical evaluation consultation procedure for certain class III and class IIb devices. <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017R0745>
- EU (2017b) Regulation (EU) 2017/746 Of The European Parliament And Of The Council 5 April 2017. <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017R0746>
- EU (2020) Regulation (EU) 2020/561 Of The European Parliament And Of The Council 23 April 2020. <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32020R0561>
- EU (2022) Commission Implementing Regulation (EU) 4 July 2022 – Common Specifications for Class D IVDs. <https://eur-lex.europa.eu/legal-content/BG/TXT/PDF/?uri=CELEX:32022R1107>
- EU (2023) R Regulation (EU) 2023/607 Of The European Parliament And Of The Council 15 March 2023. <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32023R0607>
- EMA (2024a) Homepage. EMA annual report. Figures on opinions by expert panels on high-risk medical devices. <https://www.ema.europa.eu/en/annual-report/2024/medical-devices/index.html>
- EMA (2024b) Homepage. Pilot on the Advice from the Expert Panels to Manufacturers of High-Risk Medical Devices. <https://www.ema.europa.eu/en/news/ema-establishes-regular-procedure-scientific-advice-certain-high-risk-medical-devices>
- EMA (2025) Homepage. EMA Expert Panels. <https://www.ema.europa.eu/en/human-regulatory-overview/medical-devices/medical-device-expert>
- The Guardian (2013) French breast implant firm PIP's founder jailed. <https://www.theguardian.com/world/2013/dec/10/french-breast-implant-pip-jean-claude-mas-jailed>
- Lampert FM, Schwarz M, Grabin S, Stark GB (2012) The “PIP scandal” – complications in breast implants of inferior quality: state of knowledge, official recommendations and case report *Geburtshilfe Frauenheilkd* 72(3): 243–246. <https://doi.org/10.1055/s-0031-1298323>
- Martindale V, Menache A (2013) PIP Scandal Report – The PIP scandal: an analysis of the process of quality control that failed to safeguard women from the health risks. *Journal of the Royal Society of Medicine* 106(5): 173–177. <https://doi.org/10.1177/0141076813480994>
- MT EU (2023) MedTech Europe IVDR Survey 2023. https://www.medtecheurope.org/wp-content/uploads/2023/02/mte_public-report-ivdr-survey_27-feb-2023.pdf
- MT EU (2024) MedTech Europe IVDR & MDR Survey Results 2024. https://www.medtecheurope.org/wp-content/uploads/2025/01/mte_report_ivdr_mdr_2024-v7.pdf