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SPECIAL ARTICLE
Digital health and innovation

Priorities for medical device regulatory approval: a report from the European Society of Cardiology Cardiovascular Round Table

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Abstract

The European Union (EU) Medical Device Regulation increased regulatory scrutiny to improve the safety and performance of new medical devices. An equally important goal is providing timely access to innovative devices to benefit patient care. The European Society of Cardiology strongly advocates for the evolution of the Medical Device Regulation system to facilitate priority access for innovative devices for unmet needs and orphan cardiovascular (CV) medical devices in EU countries. Although device approval is currently executed by Notified Bodies in the EU, it will be advantageous in the mid-term to consider a single EU regulatory agency for devices. In the short term, steps can be taken to transform the current system into a more efficient, predictable, cost-effective, and user-friendly service. Key strategies include the following: enhancing predictability of the approval process through use of early scientific advice from regulators; establishing unique regulatory pathways for CV orphan, paediatric, and innovative devices; promoting more efficient (re)certification of essential legacy CV devices; improving transparency of sponsor interactions with Notified Bodies; expanding the roles of the Expert Panels to assist in the approval of CV devices; promoting global regulatory harmonization, considering streamlined authorization of CV medical technologies across selected jurisdictions; developing an efficient system to monitor device safety; and ensuring funding for data collection platforms. Some strategies that could help include considering a pilot programme for joint approval processes of selected devices in partnership with other regions (i.e. US Food and Drug Administration); developing priority pathways for accelerated access to innovative or orphan devices; and increasing recognition of the importance of early feasibility studies in the EU.

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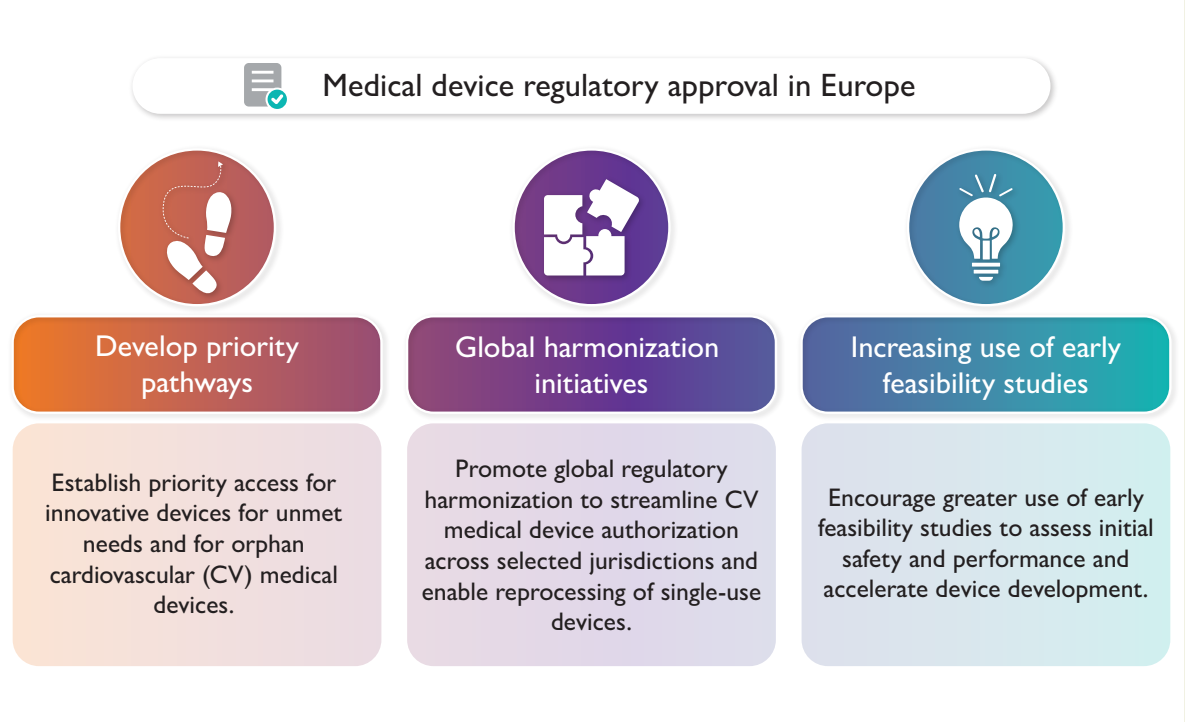
Graphical Abstract



Potential strategies to help transform the current European medical device regulatory system into a more efficient, predictable, cost-effective, and user-friendly service

Keywords Cardiovascular • European Union • Harmonization • Medical device regulation • Notified Bodies • Orphan diseases

Introduction

Regulatory science and scrutiny are essential to advancing public health and in assessing the safety and performance of high-risk cardiovascular (CV) devices. Regulatory procedures must also facilitate timely access to innovative devices for the benefit of patient care. A central objective of the Medical Device Regulation (MDR) enacted in the European Union in 2017 [(EU) 2017/745] was to increase the quantity and improve the quality of clinical evidence to support the use of new high-risk medical devices. Following its introduction, concerns have arisen that research and clinical care in Europe, traditionally a global leader in CV medical device innovation, may be unintentionally altered.[1–3] The lack of a central regulatory agency for medical devices, which has resulted in a decentralized approval system, may be one important problem. Creation of a single entity in analogy to drug approval in Europe has been suggested.[4]

The European Society of Cardiology (ESC) Cardiovascular Round Table (CRT) meetings provide a forum for regulators, industry sponsors (pharmaceutical, device, and diagnostic companies), clinicians, patients, and ESC Board Members to identify and discuss issues related to improving health in Europe. This paper summarises some key topics discussed at the second ESC CRT meeting on CV device innovation. A summary of the topics discussed at the first meeting in November 2022 has been published.[1] Of note, these meetings do not develop official ESC policy. However, the Coordinating Research and Evidence for Medical Devices Consortium has been established to review and develop methods for the clinical evaluation of high-risk medical devices in Europe.[5] The consortium, under ESC leadership, evaluated the evidence that was available before CV medical device market approval under the previous EU Medical Device Directive 93/42/EEC, and has made efforts to provide expert knowledge to the European Union (EU) regulators.[6]

This paper focuses on strategies to facilitate priority access into the European market for innovative CV devices that address unmet medical needs; promote progress in the global harmonization of regulatory systems; and support expedited access to orphan medical devices targeting rare diseases.

Innovative devices

Although the dictionary defines 'innovation' as 'a new idea, method, or device', true CV device innovation goes beyond mere newness. Definitions of innovative devices that may warrant priority regulatory review processes vary but generally include the criteria shown in *Table 1*.[7–11]

European investigators have played an essential role in developing innovative CV devices, performing numerous first-in-man interventions, and refining devices and their implantation techniques.[1] These efforts promoted global communication of early experiences, and interaction with non-European regulatory agencies, and nurtured networks crucial for developing scientific standards for new device evaluation.[12–14] The introduction of the MDR resulted in critical procedural uncertainties. The absence of dedicated, predictable pathways for regulating novel

Table 1 Summary of main criteria for priority regulatory review processes for devices in use in some countries

- Priority review is limited to specific innovations addressing unmet medical needs:
  - They treat a life-threatening or severely debilitating disease for which there is no authorized treatment, or which causes high morbidity or mortality, despite existing treatments
  - They are first-in-class technologies, or they represent a breakthrough, or they offer a significant improvement compared to approved alternatives
  - The benefit of the innovation's immediate availability to patients is considered greater than the risk inherent in requiring additional data

Based on references.[7–11]

and orphan devices impacts the leadership role of Europe in device innovation and the quality of clinical care despite the availability of already approved lifesaving CV devices.

Need for evolution and legislative update of European regulatory device approval

The EU MDR was introduced in 2017 to establish '…a robust, transparent, predictable, and sustainable regulatory framework for medical devices which ensures a high level of safety and health whilst supporting innovation.'[15] The necessity for improved evaluation of the safety and performance of CV devices was highlighted in a 2024 systematic review that demonstrated insufficient quantity and quality of published clinical evidence before regulatory approval (CE-marking) of many devices.[6]

Device approval is currently executed by Notified Bodies in the EU. The European Commission defines Notified Bodies as '…an organization designated by an EU country to assess the conformity of certain products before being placed on the market. These bodies carry out tasks related to conformity assessment procedures set out in the applicable legislation, when a third party is required.'[16] Numerous concerns have been voiced about the certification of new products since the introduction of the MDR. They include a lack of transparency of the process and clinical evidence;[17] insufficient interaction between Notified Bodies and developers; uncertainty around Notified Body scientific expertise; no clear dedicated pathway(s) for approval of paediatric, orphan or innovative products; and a lack of EU common specifications for specific device types. Of note, Notified Bodies that assess medical devices have societal responsibilities for assessing the safety and performance of devices, but not of the medical procedures and patient pathways in which these devices are used.

There continue to be issues with the timely implementation of the legislation. The initial transition period has been extended to December 2027 for high-risk devices and to December 2028 for medium- and lower-risk devices.[18] Initial challenges included the limited capacity of Notified Bodies to handle applications quickly, but substantial progress has been made. As of May 2024, there were 61 Notified Bodies; 49 designated under the MDR and 12 under the *In Vitro* Diagnostic Medical Devices Regulation (IVDR)[19]—up from 39 designated as of June 2023.[20] The ongoing European Commission survey of Notified Bodies reported that 20 424 MDR applications had been filed for recertification, and 6978 certificates had been issued, as of the end of February 2024 (*Figure 1*).[20] The number of certificates that have been filed doubled in one year, but the backlog remains substantial. In addition to the limited Notified Body capacity, the backlog may be related to the lack of special provisions for well-established, previously approved legacy devices, particularly those that raise no significant safety concerns. This raises a more general question about the need for, and usefulness of, recertification for all devices.

High recertification costs have been highlighted by medical technology companies, especially for older or low-profit devices.[3] This has led to the unavailability of some previously approved devices and shortages of well-established devices, which are particularly concerning for treating orphan diseases. Surveys report that about 17% of *in vitro* diagnostic devices (IVDs) and 20% of medical devices will be discontinued in Europe because the costs of transitioning to the new regulations outweigh revenue expectations, particularly among small and medium-sized enterprises (SMEs).[3] Furthermore, almost half of medical device manufacturers report that they are deprioritizing the EU market for first regulatory clearance of new devices, due to unpredictability, cost, and inefficiency, in favour of the well-structured FDA regulatory processes that facilitate access to the large US market.[3]

These issues related to the MDR suggest a need for evaluation and revision of the EU regulatory approval system. The MDR mandates that by May 2027, the European Commission must assess and report on the implementation of the Regulation and the progress towards achieving its objectives.[15] The Medical Devices Unit of the Commission has recognized that there are problems, and the review is underway.

Priority access for innovative devices in the EU

Priority review pathways are needed to facilitate patient access to innovative devices in the EU. The goal of expedited pathways is to shorten the time from development to availability of treatments, primarily for life-threatening diseases and in areas of unmet medical needs. Promotion of greater use of certificates with conditions may be a facility to improve the efficiency of certification in such scenarios where appropriate.[21]

Substantial unmet needs can be identified by the Expert Panels or professional societies. Accelerated pathways typically include a predictable, defined process with strict eligibility criteria and ideally include early interactions between developers and regulators. Guidance on study methodology, expected outcomes, structured and transparent review, and recommendations for subsequent follow-up studies to gain market approval are particularly useful.[6–10]

Relevant precedents for these approaches to priority review pathways used around the world are shown in *Table 2*.[22] In the United Kingdom, the Innovative Devices Access Pathway (IDAP), launched in September 2023, involves a team of experts to help device manufacturers develop a product-specific Target Development Profile roadmap. The roadmap includes a fast-tracked clinical review; scientific advice; discussions around commercial challenges and reimbursement options; and potentially exceptional use authorization (if safety standards are met).[10]

In the United States, the FDA offers programmes to facilitate access to innovative medical devices. The FDA's Breakthrough Device Program launched in 2016, expedites the development, assessment,

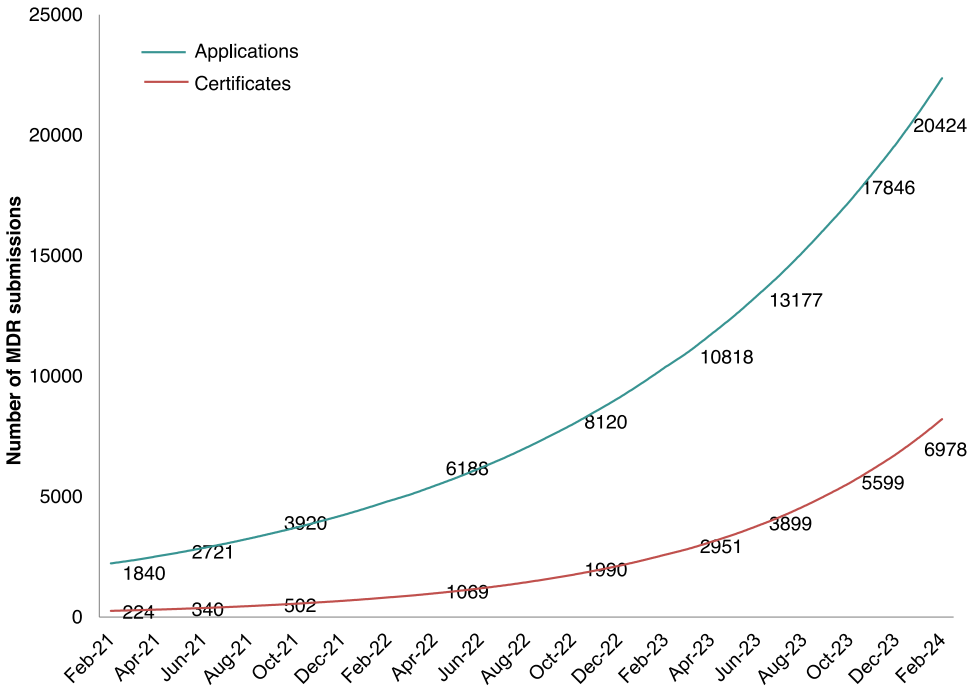


Figure 1 Numbers of applications received and certificates issued in Europe under the MDR, according to a survey of Notified Bodies (June 2023). From reference.[20] ©European Union; MDR, Medical Device Regulation

and review of devices that provide for a more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions, especially those intended to address unmet clinical needs.[9] In addition, in January 2023, the FDA launched the Total Product Life Cycle Advisory Program (TAP) Pilot to help spur more rapid development of innovative medical devices that are critical to public health.[23] The TAP Pilot's primary goal is to expedite patient access to devices by providing early, frequent, and strategic communications with the FDA and by facilitating engagement between developers and key non-FDA parties.

Currently, the European Medicines Agency (EMA) provides accelerated pathways for approval of medicinal products, such as the Priority Medicines (PRIME) programme introduced in 2016.[7,8] During the first 5 years of the programme, the EMA received 384 PRIME requests, of which 95 were granted.[8] Unfortunately, a similar pathway for devices is not yet available in the EU.

In March 2022, the EMA took over coordination of the medical device Expert Panels, and in January 2023 they launched a pilot scientific advice programme. The pilot prioritises 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.[24] Programme updates in 2024 concluded that early advice was helpful to guide a clinical development plan, complemented by later advice to guide the post-market clinical follow-up (PMCF) plan. Effective communication between Expert Panels and the manufacturers was considered vital to meet short timelines.[25]

The lack of a central regulatory agency for medical devices (similar to the EMA for drug approvals) results in a decentralized approval system that lacks adequate coordination. There are gaps in determining who would decide that devices meet the criteria for being 'innovative' and how they should be evaluated consistently. Manufacturers report concerns about an unpredictable roadmap, including a lack of early scientific advice, transparency regarding the information required for device certification, and approval timelines.[3] Given a much shorter product lifecycle of many devices (compared with drugs) and the greater number of individual products and manufacturers in the device sector, compared to the drug sector, this can present a substantial burden. Although the Medical Device Coordination Group (MDCG) encourages Notified Bodies and manufacturers to have 'structured dialogues' before and throughout the review process, it is unclear to the manufacturers what can be discussed during these meetings, and they report a lack of responsiveness from Notified Bodies.[3] Evaluation of the MDR, begun by the Commission in 2024, has highlighted the area of innovative or breakthrough devices, including the need to assess whether it is fit for purpose for fostering the availability of such devices in the EU.[26]

One suggested approach is the greater use of early feasibility studies (EFS) to speed the development of innovative devices and investigate initial safety and performance. In 2013, the FDA introduced an EFS programme in the United States. The programme has been well perceived by industry, contract research organizations, and clinical scientists, due to the responsiveness of FDA staff in direct interactions, which have enabled rapid protocol adaptations and resulted in a measurable shift to start clinical investigations earlier. In contrast, standards for EFS in the EU are not yet available.[27]

The HEU-EFS Project (Harmonized Approach to Early Feasibility Studies for Medical Devices in the EU) is a public–private partnership that aims to develop an EU harmonized framework to improve the uptake of EFS (www.heuefs.eu). Launched in January 2024, the project includes 22 consortium partners who will work over the next 4 years to assess the current status of pre-market evidence generation and develop and validate robust methodology for EFS in the EU.

Table 2 Examples of priority review pathways around the world

Jurisdiction (Responsible body)	Program/pathway name	Details
Australia (TGA)	Priority Review designation	Priority application guidelines and application forms are available
Canada (Health Canada)	Pathway for Advanced Therapeutic Products	Consultation period closed on March 2023. Innovation information meetings take place
China (NMPA)	Innovation Green Pathway	Applicant's ownership of legal patent rights of the product's core technology in China
European Union (EU)	No priority programme for innovative devices	European Commission pilot of Expert Panels to support conformity assessment
Japan (PMDA)	Fast Track Review Process (Sakigake)	Fast-track review and conditional fast-track review pathways
United Kingdom (UK) (MHRA, NICE and other partners)	Innovative Devices Access Pathway (IDAP)	The pilot launched September 2023
United States (US FDA)	Breakthrough Devices Program	Expedite pathways to speed development, assessment, and review of devices for life-threatening or irreversibly debilitating diseases or conditions

Adapted from reference.[22]
FDA, Food and Drug Administration; IDAP, Innovative Devices Access Pathway; MHRA, Medicines & Healthcare products Regulatory Agency; NICE, National Institute for Health and Care Excellence; NMPA, National Medical Device Authority of PR China; TGA, Therapeutic Goods Administration.

In 2022, the IDEAL framework for device innovation was expanded to include preclinical development.[28] The proposed recommendations suggest a pragmatic approach that minimizes the risk of first-in-human studies against the benefits of rapid access to new devices in clinical practice. They suggest that the need for evidence of safety and performance before progression to larger clinical studies increases with increasing invasiveness and risk of a device.

A representative from the ESC Patient Forum provided insights from patients who live with CV conditions. Patients feel there are pros and cons associated with accelerated pathways. They appreciate that they have the potential for faster access to devices that address unmet medical needs, for possible improvements in quality of life, and may encourage innovation. However, they recognise that there may be limited clinical evidence and experience with rapidly approved devices, and thus, a potential for harm and false hope if the device is unsuccessful.

Single governing body for medical devices in Europe

A key goal of the evolution of the EU regulatory system is to improve its efficiency, ensure the predictability of reviews, provide reliable guidance to manufacturers, and provide timely product access for patients. Efficient timelines are particularly important for devices. MedTech Europe, a European trade association representing 140 multinational corporations and 45 medical technology associations, supports the objectives of the MDR and the IVDR but has made suggestions to address some of the challenges that have arisen during their implementation.[3] They propose a more efficient system that prioritises innovation and is managed under a single, dedicated governance structure (*Table 3*).[3]

There has long been a call for a single governing body for medical devices in the EU. As early as in 2011, an ESC policy conference called for '…a single, coordinated European system to oversee the evaluation and approval of medical devices.'[4] Notably, this has been achieved in other countries; for example, the FDA in the United States and the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan oversee both drugs and devices. Even within the current system of Notified Body approvals, substantial centralization could be considered. For example, greater use of National Agencies and the Expert Panels in the designation, assessment and certification (conformity assessment) of innovative, orphan or other high-risk CV devices could accelerate processes and improve predictability while maintaining high standards. Recently one of the political groups in the European Parliament proposed that revision of the MDR could achieve a degree of centralization of responsibilities and powers by establishing a 'European Medical Devices Office'.[29]

Harmonizing global regulatory systems

International standards are a key step towards the harmonization of regulatory approval processes across countries and continents and potentially can lead to a system for mutual recognition across different jurisdictions.[30] A shared focus on getting better, safer devices to patients faster will foster collaborative approaches to interpreting existing statutes and may promote joint approvals without necessitating new legislation or cumbersome political processes. Standardixed consensus definitions help to ensure data interpretability across jurisdictions and may allow for international generalizability of research data, as well as improved global surveillance of devices pre- and post-approval, particularly supporting early detection of safety signals.

For global device manufacturers, regulatory harmonization facilitates planning of research and development across international markets. More efficient approval pathways can lead to faster and less expensive access for patients to innovative devices.[31]

There are cross-national dimensions in the initial evaluation and approval of a device when different geographies are considered. There

Table 3 Some of the suggested strategies proposed by the medical technology industry (MedTech Europe) to improve the current EU regulatory system

Areas for improvement	Strategies
Efficiency System that is lean and adaptable	• Reduce unnecessary bureaucracy in conformity assessment • Use an efficient benefit-risk approach • Define total expected cost for all necessary procedures • Fully digitise the EU system for submission to Notified Bodies, ensuring a harmonized process • Permit digital labelling • Increase the differentiation between IVD class B and class C devices, to reduce the submission requirements • Reconsider the limited validity of certificates
Innovation System to rapidly make innovative technologies addressing unmet needs available to patients	• Prioritise innovation principles • Provide a system for early scientific advice/structured dialogues between manufacturers and scientific experts, regulators and Notified Bodies to set the level of evidence expectations • Create accelerated assessment pathways for technologies that address unmet needs • Improve EU emergency pathways • Adopt pre-certification or conditional certification categories • Adapt evidence requirements to include real-world and post-market data, and consider EFSs • Participate with other jurisdictions in developing systems for joint regulatory decisions
Governance A single governance structure to oversee the medical technology system	• Govern the system to ensure predictability, efficiency, transparency, pragmatism, and cost-efficiency • Identify accelerated pathways, emergency use pathways, or decisions from other regulatory bodies to speed availability of needed technology • Manage the decentralized system of Notified Bodies, including designation, efficiency, and harmonization of practices • Author guidance documents, ensure harmonized application of common specifications • Represent the system in the EU and globally • Develop a system for ongoing stakeholder dialogues

Based on reference.[3]

could be concerns if lower levels of evidence for device approvals are required in some regions than others.[30] Differences in approval standards may favour clustering trial sites in countries with accelerated device approval processes, which may lead in other regions to reduced clinician experience with, and hindered access to, new devices. However, early access respecting independent national decisions can be supported if it benefits patient care in that region. In sum, efficient, collaborative approaches to global evidence development will likely mitigate significant variations in evidence requirements for device approval.

Global collaboration is also particularly important for developing devices for paediatric or orphan indications. These indications usually pertain to smaller patient populations, with fewer treatment options, and have minimal clinical trial evidence.

A system for cross-jurisdictional approvals, which has also been called inter-country 'reliance', would be beneficial to all medical device stakeholders. The MDCG recommends adherence to ISO 14155:2020 Clinical Investigation of Medical Devices for Human Subjects, but it is not mandatory according to the MDR. Although these guidelines help to achieve universally recognized standards, specific harmonization initiatives would be helpful across device clinical trials. Fortunately, such initiatives are currently underway and firmly supported by the medical community (*Table 4*).

The CRT workshop participants suggested that EU regulators could collaborate with the FDA and the ESC in a pilot project focused on CV device review policies and practices, as has been developed between the FDA and Japan. The US-Japan joint regulatory convergence programme, called Harmonization By Doing (HBD), is an academic, governmental, and industrial consortium that has been operative since 2003,[32] with 'HBD-for-Children' established in 2016.[33] HBD has seen success in CV device trials and post-market registries, as well as in study infrastructure, methodologies and communications.[32,34,35] The programme has included global CV device clinical trials using a single trial protocol resulting in data accepted by both the US FDA and Japan's PMDA.[32,33] Overall, HBD has demonstrated efficient and viable pathways for bringing CV devices to market through the collection of harmonized clinical data and simultaneous regulatory applications in both countries.[36] Further, data from clinical trials conducted in Japan have been used to support FDA approval of some devices, such as drug-eluting coronary stents, and vice versa.[37,38]

Another area in need of harmonizing efforts is that of global regulatory standards related to the assessment of evidence supporting the adoption of mobile health (mHealth) solutions. The ESC Regulatory Affairs Committee published a clinical consensus statement on this topic in 2024.[39] The consensus proposed criteria that clinicians could use to evaluate mHealth solutions for diagnostic, therapeutic, follow-up, and educational purposes.

Expediting access for orphan medical devices and devices for use in rare diseases

Developing priority pathways in the EU for innovative devices would expedite patients' access to devices for rare diseases. The prevalence

Table 4 Examples of global harmonization initiatives for medical device regulatory approval

Group	Details of membership and history
International Medical Device Regulators Forum (IMDRF)	• Medical device regulators • Aim to accelerate international medical device regulatory harmonization and convergence • Established in October 2011 (As a successor to the Global Harmonization Task Force) with representatives from regulatory bodies around the world, with the WHO as an observer • www.imdrf.org
Global Harmonization Working Party (GHWP)	• Experts from the medical device regulatory authorities and the medical device industry • Designated as the GHWP in 2021 • Aim to develop recommendations on ways to harmonise medical device regulations and to work with other related international organizations • www.ahwp.info
Harmonization By Doing (HBD)	• Stakeholders of academia, industry and regulatory agencies in Japan and the US • Established in 2003 • Aim to streamline processes of medical device development for CV medical devices • In 2016, HBD established the 'HBD-for-Children' programme • www.fda.gov/medical-devices/cdrh-international-affairs/us-japan-regulatory-collaboration • www.pmda.go.jp/english/index.html

or incidence used to define rare diseases varies across jurisdictions. In June 2024, the MDCG published guidance for the clinical evaluation of orphan medical devices (MDCG 2024-10).[40] 'Orphan devices' were defined as those for treating, diagnosing, or preventing a disease or condition that presents in ≤12 000 Europeans/year and lacks alternative treatment options, and those that have an expected clinical benefit compared to available options.[40] The guidance recognises the limitations of pre-market clinical data and provides guidance for legacy orphan devices, including the potential for generating new clinical data in the post-market phase following CE-marking. In parallel to the publication of the guidance, the EMA Expert Panels have now extended their activities to offer specific advice to manufacturers on orphan device status regarding the new definition, the intended clinical development strategies, proposed clinical investigations, or data required for clinical evaluation during conformity assessment.[41]

Devices for orphan indications have unique market dynamics. The costs of development, production, clinical evaluation, and regulatory assessment often lead to a limited return on investment for manufacturers.[42] Therefore, innovation of paediatric and orphan devices lags behind provision for adults with common conditions. Furthermore, previously approved orphan devices are in danger of being withdrawn from the EU market, due in part to the MDR recertification policies and the associated requirements for increased clinical data, as well as to costs and long approval times.

There are specific challenges associated with generating clinical evidence for orphan devices. Only small populations of patients are available to enrol in clinical trials, and long approval processes may have major negative impacts on these vulnerable patients due to the lack of therapeutic alternatives. A global approach may help facilitate access while maintaining high safety standards.

Clinical evidence for orphan devices can be generated both pre- and post-market. Clinical development phases are very product-dependent, and devices, particularly permanent implants, can have irreversible effects on patients. The MDR requirement for increased PMCF is a substantial challenge, especially for SMEs, because it entails ongoing maintenance and resources from manufacturers throughout the device's market lifetime. The creation of a central body to coordinate long-term monitoring of medical devices could help address these issues. One option is public and industry-funded global registries and trials for devices intended for orphan diseases/conditions. This will help overcome the issue of small numbers of patients, which impede the collection of adequate data. As many manufacturers market their devices globally, all patients could be enrolled in international registries.

Among the programmes funded by the European Commission to support the implementation of the MDR and IDVR are specific initiatives targeting innovative and orphan devices (*Table 5*). These initiatives are primarily part of the EU4Health programme and include the orphan device support programme (especially for paediatrics), and horizon scanning for medical devices. In terms of the legislative framework and future potential adapted pathways, orphan devices have been highlighted for attention as part of the targeted evaluation of the MDR by the European Commission.

Summary

The ESC is deeply involved in advocacy to refine device regulatory systems and facilitate patient access to safe and effective innovative CV medical technology. An important goal is to support the development of a single EU regulatory mechanism or agency for devices to harmonise requirements throughout the European market and facilitate access to innovative products for patients in need. Another dimension for such a centralized agency could be to engage in dialogue with other jurisdictions, to leverage global research efforts in support of more efficient approvals of innovative devices, to the benefit of clinical care in the EU. Short- and mid-term steps include evolving the current system into a more efficient, predictable, cost-effective, and user-friendly service.

In the short term, prevention of essential device shortages is a top priority, particularly for those for paediatric and orphan patient groups, but increasingly also for devices used during more everyday procedures such as heart catheterization and electrophysiological procedures.[44] Specifically, a system for more efficient and pragmatic regulation for critical

Table 5 Ongoing actions by the European Commission to support the implementation of the MDR and IDVR, including programmes targeting innovative and orphan devices

Targets	Actions
Action to increase NB capacity and help prepare manufacturers	• MDCG position paper (MDCG 2022-14) • Increasing number of NBs • NoBoCap consortium acting to increase capacity of NBs, training of manufacturers, and facilitating access to NBs (matchmaking platform) (EU4Health) • A Technical Secretariat supporting coordination between NBs (funding from EU4Health) • Developing solutions for orphan devices MDCG 2024-10 • Support for SMEs through Enterprise Europe Network • Additional support tools (e.g. translation)
Studies to assess the regulatory framework and transition (EU4HEALTH)	• Governance and innovation • Monitoring device availability • Evaluating MDR/IVDR
Support for infrastructure and processes (EU4HEALTH)	• European database on medical devices • EU reference laboratories (*in vitro* diagnostics) • Joint Action on market surveillance
Support for innovation and to address special needs	• Expert panels for scientific advice including advice on orphan status and clinical development strategy (pilot) • Orphan device support programme (esp. paediatrics) (EU4Health) • Expert Panels to support conformity assessment (pilot) • Horizon scanning for medical devices (EU4Health)

Based on reference.[43]
IVDR, *in vitro* diagnostics regulation; MDCG, Medical Device Coordination Group; MDR, medical device regulation; NB, Notified Bodies; SMEs, small and medium-sized enterprises.

Table 6 Mid- and long-term goals for ESC advocacy to address ongoing issues with the transition to MDR/IVDR and facilitate innovation in Europe

Mid-term goals
- Support the establishment of a single EU regulatory agency for drugs and devices
- Establish rapid, affordable regulatory pathways for orphan devices
- Consider broader application of certificates with conditions for innovative medical devices that require longer-term clinical data that cannot be generated efficiently in the pre-market phase
- Improve oversight, transparency and communication with Notified Bodies
- Develop a proposal to strengthen the role of the umbrella organization for the Notified Bodies (in a transition process to a single agency) with input from all relevant stakeholders
- Expand the Expert Panels' early advice pilot programme
- Enhance the role of professional societies in early dialogues and the approval process
- Develop an efficient mechanism to monitor device safety, including infrastructure and increased research funding for the collection of appropriate data (registries, real-world data)
- Consider mandatory allocation of certification files if needed
- Facilitation of hospital-based reprocessing of single-use devices
- Clarification of regulatory processes related to use of medical device software

Long-term goals
- Promote mutual recognition of medical technologies across selected jurisdictions
- Ensure funding for data collection/registry projects across different jurisdictions
- Retain and increase research and innovation in Europe using strategies such as enhanced legal clarity, research funding, facilitation of clinical trials, and EFSs
- Address inequalities in reimbursement/market access to innovative technologies throughout EU

devices that are about to disappear from the market will help assure continued patient access. The MDR/IVDR processes should continue to be evaluated with input from all relevant stakeholder groups.

Priorities for ESC advocacy to facilitate device access in Europe over the mid- and longer-term are shown in *Table 6* and the Graphical Abstract. Strategies that could be beneficial include consideration of a pilot programme for joint approval processes of selected CV devices in partnership with the FDA (such as a 'HBD–EU'); priority pathways; and possibly advocating with the HEU-EFS to promote EFS in the EU. More frequent use of certificates under conditions for orphan and

innovative devices could be considered. The evolution of the recertification process, with a focus on making requirements proportionate to risks and on reducing the burden for SMEs, seems to be of importance. Finally, future efforts should also include facilitation of hospital-based reprocessing of single-use devices and guidance on the use of medical software.

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Supplementary data

Supplementary data are not available at *European Heart Journal* online.

Declarations

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Data availability

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