2024

COCIR POSITION ON THE FUTURE GOVERNANCE FRAMEWORK FOR THE MEDICAL TECHNOLOGIES SECTOR

COCIR
Advancing Healthcare

Contents

Executive Summary

COCIR and its Members fully support the objectives of the Medical Device Regulation (MDR), which aims 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". The MDR is a welcome update to patient safety, transparency and access to medical devices for patients and citizens in the European Union. COCIR Members are well advanced in the MDR transition. However, despite the significant efforts made by the European Commission, the national Competent Authorities, the Notified Bodies and manufacturers to implement its requirements, the objectives of the Regulation have not been fully met.

The governance structure currently in place does not offer the necessary efficiency and flexibility to implement the MDR objectives due to its complex and non-predictable decision-making process. Moreover, lengthy conformity assessment procedures and multiple regulations applying to the sector represent a major barrier to a streamlined and efficient regulatory system, significantly increasing the administrative burden for manufacturers. Horizontal legislation is frequently developed without considering sectoral requirements and often implemented without sufficient transition periods allowing manufacturers a workable adaptation plan. In parallel, the lack of regulatory convergence at international level and discrepancies among Member States in MDR implementation pose an additional administrative burden to manufacturers, especially SMEs. In that context, the delays in functioning of the European database for medical devices (EUDAMED) further undermine the pledge of a more efficient and transparent system under the MDR.

Those challenges are already impacting the availability of medical devices for European patients, potentially leading to shortages. Furthermore, the significant administrative burden and the unpredictability of certification processes under the MDR pose a serious risk to the timely delivery of innovative medical technologies for patients and citizens in the European Union. That risk encompasses the potential inability to introduce or maintain such technologies on the market. Consequently, many companies are re-evaluating the European Union as their primary choice for releasing their products and are opting to prioritise other markets instead. Therefore, COCIR advocates structural reform of the regulatory and policy framework governing the medical devices sector in Europe to address the root causes of the current challenges. COCIR's vision for the future governance framework for the medical technology sector is based on three main priorities:

A. **Ensuring availability of medical technologies** for patients, health professionals and healthcare systems.

B. **Supporting efficiency and predictability** of the medical device regulatory system.

C. **Promoting innovation ecosystems** for developers of innovative medical solutions in Europe.

To achieve those objectives, COCIR and its Members recommend the development of a single governance structure with specific competences for medical devices. It should address the current fragmentation of the governance system for medical devices and reduce the complexity and inefficiencies of certification processes. The proposed structure would ensure alignment, transparency, harmonised implementation and interpretation of requirements, fostering a predictable and trusted environment for all actors in the medical device sector.

Please note that for the purpose of this position paper COCIR surveyed COCIR Members. However, the term 'COCIR Members' does not include all COCIR Members but only the responding ones. The number in responses varied per question. In addition, it is important to note that the results should not be seen as definitive or exhaustive representation of industry trends or practices but a collection of examples. COCIR does not assume responsibility for the accuracy, completeness, or reliability of the information provided by Members.

COCIR advocates structural reform of the regulatory and policy framework governing the medical devices sector in Europe to address the root causes of the current challenges.

Situation Analysis

COCIR envisions personalised and sustainable care that benefits patients, health professionals and healthcare systems. COCIR and its Members support[1] the objectives of a strong European Health Union, namely common preparedness and response to health crises, availability of innovative medical supplies and improvement of prevention, treatment and aftercare.[2]

With the adoption of Regulation (EU) 2017/745, the regulatory framework for medical devices has changed significantly. Like all other stakeholders, medical device manufacturers have invested considerable resources in compliance with the new requirements to adapt their conformity assessment processes. However, despite the significant efforts made by all actors concerned, the MDR has not fully achieved its purpose of ensuring enhanced safety and innovation in Europe.

The existing EU multi-stakeholder governance framework for medical devices is marred by complexity, bureaucratic procedures and unpredictability. Lengthy certification processes have led to bottlenecks in the certification of medical devices and to an increased administrative burden for companies in Europe. Additionally, manufacturers must navigate a complex landscape of multiple and different requirements at the national and international levels, horizontal legislation applicable to the sector and swiftly evolving implementation measures. Insufficient alignment within the governance framework for medical devices, coupled with the lack of an overarching structure tasked with designing, tracking and overseeing the connection between the MDR and other pertinent regulations, exacerbates those challenges and fosters an environment of volatility, uncertainty, complexity and ambiguity. Overall, the current EU governance framework does not offer the necessary predictability for developers of innovative medical technologies to plan their investments. That situation is compounded by recurring delays to the full establishment of EUDAMED, the European database on medical devices, which was designed to provide more transparency and predictability. Those dynamics contribute to administrative inefficiencies and escalate costs for economic operators and enforcement bodies, including Notified Bodies and competent authorities. Consequently, manufacturers are discouraged from investing in innovation within the European market, prompting them to seek certification and launch new medical technologies in other jurisdictions first. That challenges the established tendency for manufacturers to choose the EU as their first market for innovative products. That in turn may lead to availability issues for clinicians in Europe due to

[1] Please find the COCIR Priority Actions in Healthcare 2024-2029 here: https://www.cocir.org/latest-news/position-papers/article/cocir-priority-actions-in-healthcare-2024-2029

[2] Source: European Commission https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/promoting-our-european-way-life/european-health-union_en

limited access to diagnostic and treatment options and delayed access to innovative medical devices. The impact is particularly pronounced for innovative or specialised devices. Conscious of the MDR implementation challenges, EU Member States[3] and the European Parliament[4] have urged the European Commission to investigate and address the root causes. National health authorities and MEPs have emphasised the importance of reducing the administrative burden on companies producing medical devices, especially SMEs, and ensuring compliance with current rules more effectively. Within that context, the European Commission has undertaken a targeted evaluation of the Medical Device Regulation[5], with the aim of assessing whether the rules meet current and emerging needs.

This paper aims to contribute to the ongoing evaluation of the Medical Device Regulation by presenting the main challenges identified by COCIR Members within the current legal framework for the medical technology sector in Europe. Drawing upon the experiences and data collected, this paper further proposes a set of recommendations for the future governance system regulating medical devices in the EU.

[3] EU Health Ministers meeting, 30 November 2023. Source: Council of the EU: https://data.consilium.europa.eu/doc/document/ST-15385-2023-REV-2/x/pdf

[4] European Parliament plenary debate, 29 February 2024. Source: European Parliament: https://multimedia.europarl.europa.eu/nl/photoset/ep-plenary-session-commission-statement-next-steps-towards-greater-patient-safety-by-swiftly-ensuring-the-availability-of-medical-devices-through-a-targeted-transitional-period_EP-164968B

[5] Source: European Commission: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14155-EU-rules-on-medical-devices-and-in-vitro-diagnostics-targeted-evaluation_en

A Ensuring availability of medical technologies for patients, health professionals and healthcare systems

MAIN CHALLENGES

The main aspects that significantly impact the development, approval and launch onto the EU market of medical devices include:

01 LONGER CERTIFICATION PROCEDURES COMPARED TO PROCEDURES UNDER THE MEDICAL DEVICE DIRECTIVE

The MDR does not provide for clear deadlines for conformity assessment procedures and quality system review. Lengthy and complex conformity assessment processes, including clinical and performance evaluations, prolong the time-to-market for medical devices, leading to delays in availability for patients. Compared to certification procedures under Council Directive 93/42/EEC (Medical Device Directive/MDD), manufacturers report a longer certification timeframe **(FIGURE 1)** from initial innovation to the launch of new innovative products. COCIR Members identified several reasons for the delays in certification under the MDR. Those mainly relate to:

a. **Increased technical file requirements:** The additional technical file requirements under the MDR extend the time needed to compile and review documentation. For instance, COCIR Members report spending an average of five months longer on preparing documentation.

b. **Lengthier process and complex technical file review:** Notified Bodies require more time to conduct thorough and comprehensive reviews of technical files under the MDR due to the increased complexity and stricter requirements. On average, COCIR Members report that it takes Notified Bodies nine months longer to review applications for new products (from initial submission of Technical Documents through to final approval).

c. **Complex clinical validation requirements:** The more stringent requirements for clinical validation under the MDR add complexity and time to the certification process, contributing to delays in market entry.

d. **Insufficient capacity among Notified Bodies:** There is a shortage of Notified Bodies and insufficient availability of expertise and resources to handle the increased workload and complexity imposed by the MDR.

AVERAGE CERTIFICATION TIME INCREASE FOR MDR COMPARED TO MDD

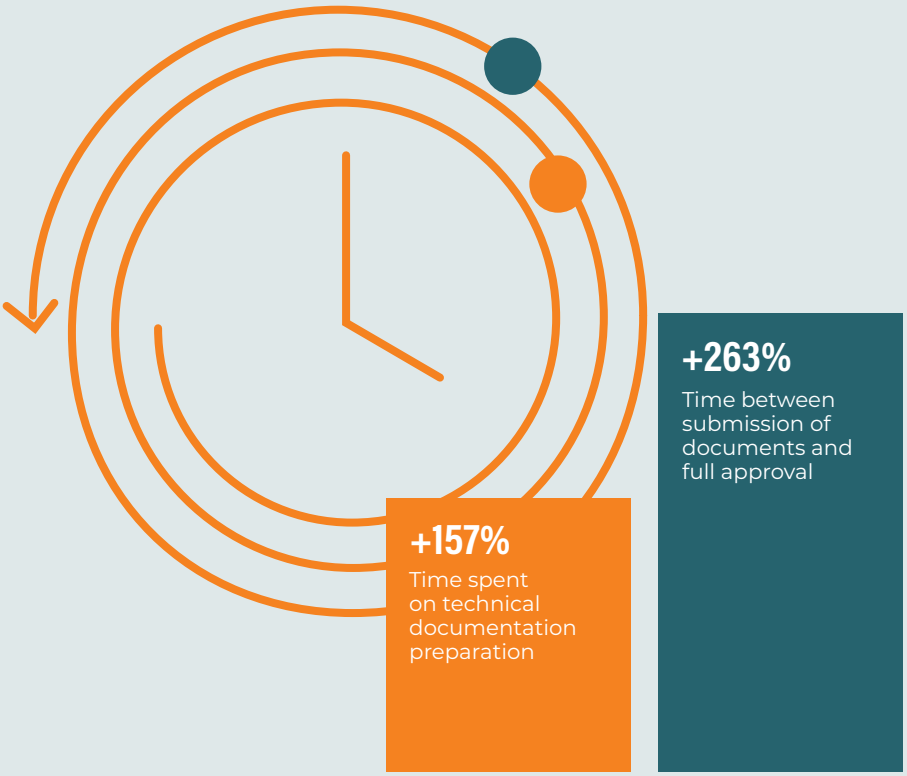


Figure 1.
Time increase experienced by COCIR Members for Conformity Assessment Procedures compared to the average time for MDD

02 INCREASED ADMINISTRATIVE BURDEN AND COST COMPARED TO PROCEDURES UNDER THE MEDICAL DEVICE DIRECTIVE

The increased administrative burden and cost resulting from obligations under the MDR pose significant challenges for companies wishing to recertify medical devices in Europe. In some cases, that may result in the decision to discontinue legacy products in the EU[6]. The challenges reported include:

a. **Increased regulatory/quality assurance staff and compliance costs:** Compliance with the MDR demands additional resources, including hiring more regulatory and quality assurance personnel. That translates to higher operational costs for companies **(FIGURE 2)**. On average, responding COCIR Members now have twice the number of staff dedicated to certification requirements under the MDR compared with under the MDD **(FIGURE 3)**.

[6] In some cases, the legacy devices have been discontinued in Europe (due to the burden of MDR submission) but will continue to be maintained in other jurisdictions. While every effort has been made to present accurate information, it is essential to recognise that the information provided is based on rough estimates rather than precise statistics. These estimates are intended to offer an overview and highlight the main trends of the current situation.

INCREASE OF CONFORMITY ASSESSMENT PROCEDURES COSTS COMPARED TO MDD

Figure 2.
Overall cost increases experienced by COCIR Members in relation to Conformity Assessment procedures

b. **Rising certification costs:** Certification costs under the MDR have surged substantially, compared to under the Medical Device Directive, adding to the financial strain on companies.[7]

c. **Discrepancy between compliance investment and expected revenue:** The investment required to meet administrative requirements and recertification costs may not align with the anticipated revenue from continuing to market products in the EU.

d. **Lack of regulatory convergence:** Multiple – and sometimes diverging – requirements related to medical devices at national and global levels complicate compliance efforts for companies operating in multiple jurisdictions, increasing the administrative burden.

e. **Extended and additional reporting obligations:** The MDR introduces long and additional reporting requirements, such as Periodic Safety Update Reports (PSUR), further increasing the administrative burden. Additionally, the new obligations in case of interruption of supply of certain devices will potentially add to the administrative workload.[8]

[7] Responding COCIR Members, when comparing the relative costs of certification under the US FDA system to MDR, state it is between 1.5-2 times more costly under the MDR.

[8] At the time of writing this paper, the new obligations have not been implemented yet. As such, we cannot provide opinions based on experiences. The new provisions establish that a manufacturer shall inform the competent authority of the Member State where it or its authorised representative is established, as well as the economic operators, health institutions and healthcare professionals to whom it directly supplies the device of the anticipated interruption. That obligation will add to existing reporting requirements.

03 UNPREDICTABLE PROCESSES AND INCONSISTENCIES IN INTERPRETATION AND APPLICATION OF REQUIREMENTS

The lack of uniform interpretation of regulatory requirements generates inconsistencies in implementation, resulting in uncertainty and delays in product approvals. Those may be summarised as follows:

a. **Ambiguity of Medical Device Coordination Group (MDCG) Guidance:** Insufficient clarity of the MDCG guidance, and its voluntary nature, results in different and inconsistent interpretations, creating confusion for all actors.

b. **Fragmented approach to Technical Documentation review:** Manufacturers experience a fragmented approach during the review of Technical Documentation and audits, resulting in inconsistencies in the assessment of conformity and compliance.

c. **Evolution of expectations:** Due to the insufficient clarity in existing guidelines, in some cases implementation requirements during the Technical Documentation review have changed over time, leading to changes in interpretation and application of regulatory standards.

REGULATORY STAFF

Figure 3.
Number of regulatory/ quality assurance staff required as a percentage of the organisation's headcount according to information from COCIR Members

RECOMMENDATIONS

The current regulatory system for medical devices and in vitro diagnostics (IVDs) in Europe fails to ensure the timely availability of essential medical technologies for patients. To mitigate those challenges and maintain the availability of medical devices on the EU market, it is imperative to establish a streamlined and harmonised regulatory environment with predictable and linear processes. COCIR and its Members welcome the established system of certification by Notified Bodies as third-party, independent institutions, which has functioned effectively under previous Directives. However, they face difficulties related to lack of harmonised policy and delayed implementation of the MDR and In Vitro Diagnostic Regulation (IVDR). Therefore, while certification activities should remain under the purview of the Notified Bodies, COCIR recommends establishing a single governance structure to ensure predictability of the certification process. In particular, it should be responsible for the following measures:

- **Designate Notified Bodies:** Establish a single accountable structure to oversee the designation of Notified Bodies in order to enhance predictability and consistency of the certification process.
- **Define clear and predictable timelines:** Establish clear and predictable timelines for conformity assessment procedures and review of Technical Documentation, with a maximum duration of 6 months.
- **Adopt harmonised methodology for Technical Documentation:** Implement harmonised methodology for submitting Technical Documentation to Notified Bodies, possibly by adopting an international standard to develop Technical Documentation according to MDR requirements.
- **Eliminate the requirement for recertification every five years.**
- **Promote stakeholder engagement:** Establish a system for active stakeholder engagement without violating conflict-of-interest rules. This system should allow for early dialogue between economic operators, regulators and Notified Bodies, with regulatory advice provided through a structured dialogue platform.

B Supporting a predictable, streamlined and efficient policy environment for the medical technology sector

MAIN CHALLENGES

The fragmentation of the governance system and the insufficient harmonisation and coherent implementation of requirements in the medical device sector create regulatory uncertainty and hurdles in regulatory compliance for manufacturers in the EU. Parallel legal regimes often result in inconsistencies, duplications and uncertainties, ultimately leading to capacity and availability problems. Specific challenges identified by COCIR Members include:

01 LEGAL UNCERTAINTY

The interplay and divergences between different legal requirements, such as the MDR and other regulations (including national legislation), create uncertainty as to their implementation. Dependencies between horizontal and vertical policies lead to inefficiencies in conformity assessment procedures, with diverging terms, definitions and obligations across legislation. Due to those differences, diverging standards and guidance may be developed for product rules, thereby aggravating incompatibilities with legislation, guidance and harmonised standards in the medical device sector. Specific divergencies have been identified in the interplay of the MDR with digital legislation and with environmental and sustainability requirements.[9]

02 DUPLICATION OF REQUIREMENTS

Manufacturers face duplication of requirements due to multiple applicable legislation and additional national-level obligations (often applied in their local language). That duplication is particularly burdensome for multinational companies navigating global regulatory requirements, leading to inefficiencies in compliance and increased complexity and time for placing devices into the market. Inefficiencies caused by regulatory duplications are particularly prevalent in registration and reporting requirements.[10]

[9] Please see paragraph 5 for more details. Parallel legal regimes and regulatory inconsistencies: the specific cases of environmental and digital policies.

[10] Due to current delays in the full implementation of EUDAMED, companies' administrative resources are being stretched to comply with multiple national database requirements to register economic operators and device data. Moreover, divergent regulatory requirements across different regions and countries necessitate adaptation to multiple regulatory frameworks, increasing the complexity and time for placing devices into the market.

03 INSUFFICIENT TRANSITION PERIOD

Horizontal and vertical legislation often does not offer sufficient transitional periods for manufacturers to adapt to new requirements, resulting in excessive costs for compliance, as well as hindering availability of legacy devices and – ultimately – obstructing a streamlined and efficient regulatory system.

04 INTERPRETATION AND IMPLEMENTATION INCONSISTENCIES

Differences of interpretation in relation to the interaction of the MDR with other EU policies result in inconsistencies in implementation. The absence of an overarching authority to clarify inconsistencies related to interpretation and implementation leads to additional conformity assessment procedures for companies, even in cases where the MDR covers such obligations.

05 PARALLEL LEGAL REGIMES AND REGULATORY INCONSISTENCIES: ENVIRONMENTAL AND DIGITAL POLICIES

a. **Impact of digital legislation on medical devices**: In the context of the EU Digital Strategy, several legislative initiatives have been adopted in recent years, some of which apply to all sectors (e.g. Data Act, Artificial Intelligence Act (AIA), while others are sector-specific (e.g. European Health Data Space). All those initiatives will have a considerable impact on medical device manufacturers potentially resulting in legal uncertainty and incoherence, delay in the delivery of products to patients and significant barriers to innovation in the EU.

- **Legal uncertainty and incoherence.** Several legislative digital policies will potentially create significant challenges in compliance. There is ambiguity about the application of certain concepts and definitions to the medical device industry; the data access and sharing obligations have far-reaching consequences for the sector and may complicate or even hinder compliance with the existing frameworks such as MDR and GDPR. Moreover, the **Data Act** requires manufacturers to design and develop their medical devices to allow users direct access to use-generated data. That requirement may pose cybersecurity and safety risks and thus undermine manufacturer's obligations under the MDR.
- **Delay in delivery of products.** The **Artificial Intelligence Act** will potentially impact the availability of AI-based medical devices on the EU market due to overlaps with existing legislation regulating the medical device sector **(FIGURE 4)**. High-risk AI system requirements in the AI Act will apply to specific AI-enabled medical devices, imposing additional requirements and a whole ecosystem of guidance, standards and common specifications, which will overlap and potentially conflict with those under the MDR.[11]

[11] Key challenges and recommendations may be found in the COCIR recommendations on alignment of the Artificial Intelligence Act (AIA) with the Medical Device Regulation (MDR) https://www.cocir.org/latest-news/position-papers/article/cocir-recommendations-on-the-artificial-intelligence-act-aia-s-alignment-with-the-medical-devices-regulation-mdr

- **Barriers to innovation.** New legislation regarding data sharing and AI (Data Act, European Health Data Space, AI Act, NIS2 Directive) will increase the burden on companies and add to the already complex regulatory framework. The **European Health Data Space** results in further complexity and requirements in relation to the availability of health data, especially through the requirements for secondary use data. Additional requirements for Electronic Health Records and national obligations in the local language add to the complexity.

b. Impact of environmental legislation on medical devices: Environmental legislation has significant implications[12] for medical device manufacturers, leading to barriers, legal incompatibilities and legal uncertainties.

- **Barriers:** Compliance with environmental and sustainability provisions requires design adaptation to ensure compliance of new models and often the redesign of existing medical device models (the majority of companies' portfolios). Business strategies or the technical impossibility of redesign may lead to the discontinuation of such legacy models.
- **Legal incompatibilities:** Fragmented legal approaches in relation to derogations create challenges. For instance, when derogations are granted by one legislation, another addressing the same substance may reach different conclusions regarding validity periods or threshold values.
- **Insufficient coherence between different legal instruments:** While certain regulations recognise the specific characteristics of the medical device sector, others impose more detailed sustainability reporting requirements. Those obligations often place a significant burden on companies, diverting resources away from research and development, and may also create challenges in compliance.

[12] Legislation intended for consumer products often encompasses medical imaging devices although they differ fundamentally from consumer goods.

MAIN CONCERNS OF COCIR MEMBERS REGARDING THE AI ACT

Figure 4.
Main concerns of COCIR Members in relation to the AI Act. This list of concerns is not exhaustive and is based on a preliminary assessment; further points could be added after the AI Act implementation.

RECOMMENDATIONS

Coherent and easy-to-navigate legislation with adequate transition times is imperative for an efficient regulatory system for the medical technology sector. To that end, a fundamental aspect of reform should be the adoption of a structured governance approach for the sector, led by a single accountable architect, supported by specialist layers responsible for specific subject matters. That governance structure would mitigate duplications, errors and inefficiencies by:

- **Integrating product-based horizontal legislation into sectoral legislation**, rather than applying it directly to economic operators. A legislative structure with harmonised terminology should address dependencies between horizontal and vertical legislation and ensure that new product legislation adheres to sectoral regulations while aligning older product rules accordingly.
- **Promoting efficiency through enhanced coordination and synergy among the various stakeholders** thanks to sufficient, dedicated expertise and resources to monitor and identify conflicts between horizontal and vertical legislation with the MDR. Such collaboration is paramount to navigating the complexities arising from the interaction of digital and environmental legislation with regulations governing medical devices.
- **Promoting reliance on regulatory approaches compatible with the European CE-marking system**. Leveraging regulatory decisions from jurisdictions with identical certification procedures would significantly reduce audit procedures for manufacturers operating in different regions. It would also enhance the capacity of Notified Bodies by expediting the certification process for devices already approved elsewhere. Integration of the Medical Device Single Audit Programme (MDSAP) into the EU regulatory framework therefore represents a practical step toward achieving regulatory convergence and ensuring the safety and effectiveness of medical devices on the global market. Such integration would also facilitate greater alignment with international standards, particularly through participation in activities led by the International Medical Device Regulators Forum (IMDRF).

C

Promoting the development of innovative medical solutions in Europe

MAIN CHALLENGES

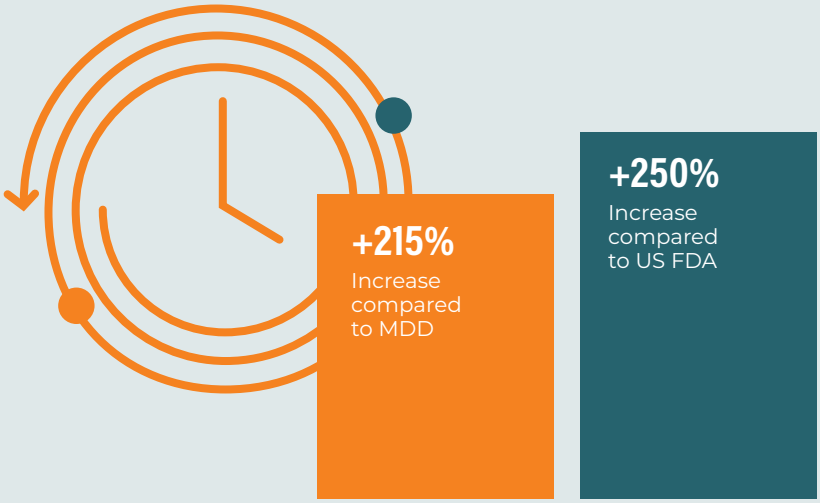
The significant administrative burden placed on medical device manufacturers and the absence of suitable regulatory solutions for innovation pathways cause regulatory and investment uncertainties for companies operating in Europe. Additionally, complex and lengthy regulatory processes often force manufacturers to divert resources from research and development towards regulatory and compliance activities. Ultimately, such hurdles impede innovation, reduce the availability of medical devices and impinge upon timely patient access to groundbreaking digital technologies, resulting in higher costs for society. Specific challenges identified include:

01 EXPONENTIALLY SLOWER APPROVAL PROCESS FOR INNOVATIVE HEALTH TECHNOLOGIES IN EUROPE THAN IN OTHER JURISDICTIONS

Manufacturers note substantial differences in certification timescales under the MDR compared to other jurisdictions, particularly the US FDA[13]. Many companies prioritise certification in other regions since they anticipate that such procedures will be shorter than under the MDR **(FIGURE 6)**. That delay in gaining EU certification significantly postpones the availability of new products in Europe, unlike with the quicker process under the previous MDD.

AVERAGE INCREASE IN TIME SPENT FOR MDR COMPARED TO ALTERNATIVES

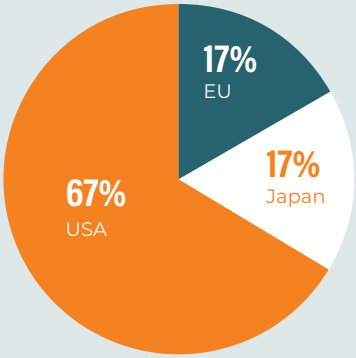
Figure 5.
Average increase in time (and therefore increased associated costs) experienced by COCIR Members for MDR certification, compared to MDD and US FDA certification.



[13] COCIR Members largely anticipate that the procedure for medical device certification under the US FDA will be shorter than under the MDR, as shown in Figure 5

PRIMARY JURISDICTION FOR INNOVATION LAUNCH

Figure 6.
First jurisdiction when applying for certification of a new innovative product.

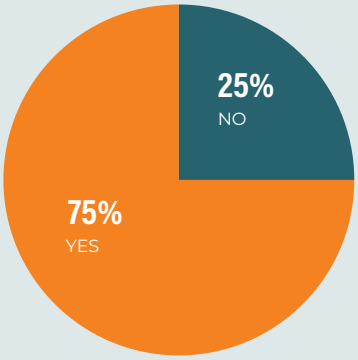


02 IMPACT OF ADMINISTRATIVE BURDEN ON BUDGET FOR R&D AND LAUNCH OF INNOVATIVE PRODUCTS ONTO THE EUROPEAN MARKET

The additional administrative burden imposed by the MDR has forced companies to reassess their budgets for research and development[14] **(FIGURE 7)** and the launch of innovative products in Europe. While the European market remains important, some companies have had to revise their market targets to accommodate MDR-related delays. That has resulted in delays to both the development of innovative products and the modification of existing ones.

HAS BUDGET FOR R&D BEEN REDUCED DUE TO ADMIN BURDEN OF MDR?

Figure 7.
R&D budget reduction among COCIR Members



03 LACK OF SUITABLE REGULATORY PATHWAYS FOR INNOVATIVE DEVICES

Existing regulatory pathways are not suitable for the efficient and timely introduction of innovative devices within the EU medical device system. That delay contrasts with the quicker approval process in the US[15], resulting in European patients waiting longer for access to potentially life-saving technologies.

04 INSUFFICIENT AVAILABILITY OF HARMONISED STANDARDS

European manufacturers face challenges due to a lack of harmonised MDR standards and the lengthy timescale for adopting the remaining ones. The absence of harmonised standards adds complexity and uncertainty to conformity assessment procedures, making it difficult for companies to navigate regulatory requirements and hindering timely access for innovative medical devices.

[14] In some cases, it accounted for a reduction of up to 50% in the R&D budget.
[15] US FDA Breakthrough devices program, website: https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program

RECOMMENDATIONS

Closer collaboration between regulatory authorities, industry stakeholders and policymakers is essential to identify and address regulatory barriers effectively, ensuring a supportive environment for innovation and timely access to innovative medical technologies for patients across Europe. To promote a regulatory framework conducive to competitiveness and innovation on the European medical device market, COCIR recommends the following measures:

- **Streamline regulatory processes:** That means providing detailed guidelines and standards for compliance, ensuring consistency in interpretation across regulatory bodies and offering support to companies with regard to understanding and fulfilling regulatory obligations.
- **Ensure suitable pathways for innovative medical technologies and devices that address unmet clinical needs:** Supporting the timely and efficient introduction of innovative medical devices onto the EU market is crucial in order to enhance EU competitiveness. Steps may include ensuring that existing pathways are suitable for innovative technologies or creating dedicated pathways for new technologies and devices that address unmet clinical needs. Furthermore, promoting the increased use of real-world data and early feasibility studies in health technology development can accelerate the regulatory process. Regulatory sandboxes could serve as valuable tools to facilitate those objectives, providing a controlled environment for testing and refining innovative approaches.
- **Eliminate backlog in citation of harmonised European standards:** Addressing the backlog in the citation of harmonised European standards in the Official Journal is crucial. A swift citation process should be ensured to allow for the timely use of those standards by the industry for presumption of compliance. That will streamline conformity assessment procedures and provide clarity and certainty to medical device manufacturers navigating the regulatory landscape.

About COCIR

COCIR is the European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries. Founded in 1959, COCIR is a non-profit association headquartered in Brussels (Belgium) with a China Desk based in Beijing since 2007. COCIR is also a founding member of DITTA, the Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association. Our industry delivers innovative, data-driven, safe and efficient diagnostic imaging, radiotherapy and digital health solutions.

COCIR's core objectives are:

To support the transformation of European health systems, enabling better health outcomes and better experiences for patients and professionals.

To promote the critical role of our industry as providers of essential or life-saving products and solutions for patients.

To strive for the best innovation climate for our industry in Europe.

COCIR aisbl | Bluepoint Building
Boulevard A. Reyerslaan 80
1030 Brussels | Belgium

Tel +32 (0)2 706 89 60
info@cocir.org
www.cocir.org | @COCIR

COCIR
Advancing Healthcare