The Future of Europe's Medical Technology Regulations

MedTech Europe's vision for an efficient, innovation-focused, and well-governed regulatory framework

POSITION PAPER

MedTech Europe
from diagnosis to cure

Contents

Executive Summary

MedTech Europe and its members fully support the objectives of the medical technology regulations, *In Vitro* Diagnostic Medical Devices Regulation 2017/746/EU (IVDR) and Medical Devices Regulation 2017/745/EU (MDR): to establish a "robust, transparent, predictable and sustainable regulatory framework for [*in vitro* diagnostic] medical devices which ensures a high level of safety and health whilst supporting innovation".[1] However, after almost six and a half years of implementation, the IVDR and MDR have still not fully achieved these objectives.

While considerable work has been done by all stakeholders to address the short-term implementation challenges, there are structural issues in the regulatory system which make it slow, unpredictable, costly and complex, and lacking in agile pathways for innovation. These structural issues cannot be solved through the implementation of IVDR and MDR alone.

MedTech Europe is calling for comprehensive reform to make the regulations work for patients and European health systems. Reform should address the three key areas of efficiency, innovation and governance, all while maintaining the regulations' high level of device safety and performance:

- **An Efficient CE Marking System:** We need a more efficient and resource-effective CE marking system that improves predictability, reduces administrative burden, and adapts to external changes.
- **A System that Works for Innovation:** We propose the inclusion of an innovation principle that swiftly connects the latest medical technologies to European patients and health systems through dedicated assessment pathways and early dialogues with developers.
- **An Accountable Governance Structure:** We suggest the establishment of a single, dedicated structure to oversee and manage the regulatory system, including the designation and oversight of Notified Bodies, with the authority to make system-level decisions.

We believe that discussion between all stakeholders must start now to realise a comprehensive reform with regards to the above three areas. At the same time we remain committed to working with all stakeholders to find short-term solutions to the implementation issues in the regulations, for example through implementing acts, guidance, best practice or other means. In this context, we urge the Medical Devices Coordination Group and stakeholders to fix issues without delay where solutions may be identified in the short-term.

Only together can we deliver on the original goals of the IVDR and MDR to develop a robust, transparent, predictable and sustainable regulatory framework that ensures a high level of safety and health while supporting innovation, for the benefit of European patients, health systems and society.

[1] See first and second preambles to IVDR and MDR. The objectives have been paraphrased.

Introduction

Europe takes great pride in its robust social security systems and the fundamental principles of equitable healthcare access. Medical technologies form an integral part of such quality healthcare and are crucial for all stages of the patient journey, from prevention and diagnosis, to treatment and cure.

Despite Europe's fundamental strengths in delivering the highest standards of care with the help of innovative medical technology, there are growing indications that new and existing products will struggle to reach European patients and health systems in a timely manner. Structural issues within the regulatory framework for medical technologies, IVDR and MDR, are resulting in unpredictability and delays, dampening innovation, and undermining confidence in the long-term viability of the framework. Left unaddressed, such issues will increasingly impact patients and health systems in Europe and erode the influence of Europe's valued CE-marking system.

In this position paper, MedTech Europe presents the challenges that medical technologies face under the European regulatory framework and comes forward with a 3-point vision for how a future system could look like. The vision is accompanied by recommended solutions to help start the conversation between all impacted stakeholders on the needed steps to reform the current system.

The situation

There are over 35,000 medical technology companies in Europe – 92% of them small and medium-sized enterprises (SMEs) – currently providing around 500,000 medical technologies to European patients.[2] At least 17% of today's IVDs[3] and 20% of the MD product portfolios[4] are expected to be discontinued in Europe due to the expectation that costs of the transition to the IVDR or MDR outweigh product revenue, particularly among SMEs. 28% of IVD manufacturers[5] and 48% of medical device manufacturers[6] are deprioritising the EU market (or plan to do so) as the geography of choice for first regulatory clearance of their new devices due to the unpredictability (time, cost, changes) of the IVDR and MDR.

MedTech Europe strongly believes the underlying reasons for these challenges are structural deficiencies within the IVDR and MDR. Despite concerted efforts of all stakeholders to make the system work[7], such structural deficiencies make the regulatory framework unpredictable[8], complex, slow and costly and create a growing vacuum for medical technology innovation within the EU market. In short, the IVDR and MDR are

[2] MedTech Europe (2023): Facts & Figures for 2022.
[3] MedTech Europe (2021), MedTech Europe Survey Report analysing the availability of In vitro Diagnostic Medical Devices (IVDs) in May 2022 when the new EU IVD Regulation applies
[4] MedTech Europe (2022), MedTech Europe Survey Report analysing the availability of Medical Devices in 2022 in connection to the Medical Device Regulation (MDR) implementation
[5] MedTech Europe (2021), MedTech Europe Survey Report analysing the availability of In vitro Diagnostic Medical Devices (IVDs) in May 2022 when the new EU IVD Regulation applies
[6] MedTech Europe (2022), MedTech Europe Survey Report analysing the availability of Medical Devices in 2022 in connection to the Medical Device Regulation (MDR) implementation
7 For example, the extensions to the transitional provisions of the IVDR and MDR, Joint Implementation and Preparedness Plans, MDCG 2022-14, and various MDCG guidance documents, to name but a few areas.
[8] For example, variation in conformity assessment timelines for both IVDR and MDR may be see in the European Commission Notified Bodies Survey on certifications and applications (MDR/IVDR) (Survey results with data status 31 March 2023)

not measuring up to their stated objective of establishing a robust, transparent, predictable and sustainable regulatory framework which ensures a high level of safety and health whilst supporting innovation.[9]

Upstream from the care setting, an unpredictable process makes it highly difficult for medical technology companies to adequately plan, prepare, and allocate resources effectively for regulatory clearance, production and communication to their supply chain and end users. Yet this ability for companies to operate is critical for ensuring availability of devices and allowing first-launch innovations. There is a lack of transparency regarding the information that will be expected of companies during the certification process;[10] also the timelines for conformity assessments and requirements over the certificate lifetime are often unpredictable and inefficient, posing a financial and resource challenge for companies. Many iterative innovations in medical technology typically have a lifecycle of 18 to 24 months before an improved product becomes available – with some technologies moving slower, but others even more quickly – while regulatory clearance under the current framework can take 12 to 24 months or longer[11]. There are inconsistencies in the implementation of the regulatory framework, such as variance among the Notified Bodies, as well as variance between official guidance and the legal basis of the regulation.

Medical technology continuously improves through innovation to meet the needs of patients and society. 'Innovation' in this context refers to breakthrough and disruptive technologies, as well as iterative changes which enhance functionality and performance of existing technologies, such as software updates, improved service time, more interoperable services, and offering a technology used in a clinical setting for home or point of care use. Innovation is necessary to ensure that the EU effectively combats emerging health crises, such as antimicrobial resistance, new strains of infectious disease, and non-communicable diseases. Innovation in medical technology design is critical if our industry is to respond to the calls of the EU and society at large for more environmentally sustainable healthcare. Finally, it is innovation that enables the benefits of digital healthcare to empower patients, and support care teams and the chronically overburdened health systems.

This range of innovation is the result of continued research and development investment by the industry (the average is estimated to be around 8% in the sector[12]) in close cooperation with healthcare professionals, patients and health systems to identify unmet needs.

The current regulatory framework for medical technology simply does not match the innovation dynamics of developing and offering new or improved products. Certification timelines are too slow compared to the innovation cycle speed, compounded by delays, unpredictability and procedures which are significantly more resource-hungry, costly and complex than under the previous medical devices directives. There are layers of oversight requirements by Notified Bodies and other entities which result in an overly formalistic assessment approach. Resource and cost challenges particularly impact products whose revenue is not

[9] See first and second preambles of IVDR and MDR. The objectives here have been paraphrased.
[10] MDCG 2022-14 allows Notified Bodies and manufacturers to have 'structured dialogues' before submitting applications for conformity assessment; today it is not clear what can be discussed during these dialogues.
[11] See European Commission survey on applications and certifications (July 2023)
[12] Evaluate MedTech, 2018, World Preview 2018, Outlook to 2024.

expected to cover the cost of acquiring and maintaining CE-marking under the IVDR and MDR. This can particularly pose a problem for commercially mature, niche or orphan devices. SMEs can also face significant challenges in resourcing regulatory compliance. The higher cost may result in manufacturers choosing either to downsize their European portfolio, refrain from 'updating' products (optimisation activities) or move their investment to other markets.

Finally, the current regulatory framework for medical technologies does not have a single clear and accountable structure governing the oversight of the regulatory framework. Instead, a combination of 27 national Competent Authorities, the Medical Device Coordination Group, the European Commission, and individual National Competent Authorities (responsible for supervising Notified Bodies) are responsible for its governance, with many assessment and oversight responsibilities delegated (and in some cases, relegated) to the Notified Body system.

The challenges posed by such dispersed authority are becoming increasingly apparent. During the COVID-19 pandemic, for example, EU institutions were unclear on who to turn to in order to shore up crucial medical technology.

It is important to note that within the current regulatory framework, the conformity assessment process for receiving CE marking is decentralised by design. Having multiple Notified Bodies aims to ensure that numerous medical technologies are effectively assessed, and available to European patients and health systems. However, as there is no single structure with a mandate to govern the oversight of this decentralised system, this results in the following gaps:

- A lack of system-level governance – including for taking system level decisions, spotting and addressing inefficiencies, designating and managing Notified Bodies, managing dedicated and/or fast track pathways, adapting the system to rapid technological development, coordinating and ensuring smooth functioning in the system, ensuring timely accountability and operating an appeal mechanism.
- No driver of a healthy ecosystem – including for taking responsibility for fostering Europe as an innovation hub, linking to the research agenda in the EU, ensuring regulatory coherence with other product legislation, educating the public and setting standards for the system.
- No functioning single provider of guidance within the decentralised system to support competent authorities and Notified Bodies – such as in issuing guidance on interpreting relevant laws which balances concepts of safety and access to innovation, setting clear timelines, framing and overseeing structured dialogue before filing and during assessment.
- No single representative of the system – who can communicate and interface with other jurisdictions and agencies, both within Europe and in a wider global context.

All these challenges risk widening a gap in access to medical technology that is already starting to appear.

To address these challenges means allowing the system to meet its core objectives and thus to work for patients.

MedTech Europe's vision

MedTech Europe has developed a vision for the future regulatory framework in Europe – one that will foster access to innovation and ensure timely availability of safe and performing medical technologies for patients and health systems in Europe. This vision builds on what works well in the current CE marking system and calls for reform in three key pillars:

1. Ensuring efficiency – establish clear, lean, dedicated and predictable processes for conformity assessment and across the certificate lifetime;
2. Embracing innovation – incorporate an innovation principle to ensure the latest medical technologies swiftly reach patients and health systems;
3. Effective governance – ensure ownership through an accountable structure which is responsible for driving a healthy ecosystem for medical technologies, taking system-level decisions, managing the decentralised network of Notified Bodies and representing the system both within Europe and globally.

Implementing this vision, and thus reaching the objectives of the IVDR and MDR in full will require comprehensive structural reform that addresses efficiency, innovation, and governance – all while maintaining the highest standards of patient safety.

For this, MedTech Europe is ready to work with everyone involved to address the system-level challenges of today while preparing for the opportunities of tomorrow, ensuring that innovative medical technology reaches more people and help healthcare systems become more viable.

Ensuring efficiency

While there are some requirements specific to device risk classes, often the regulatory framework takes a 'one size fits all' approach to the extremely diverse array of medical technology products without clear, predictable, dedicated and efficient pathways for regulatory clearance and oversight over the certificate lifetime. These inefficiencies in the short-term create a gap between medical technologies and the patients and medical professionals who need them, while in the long-term undermine trust in the regulatory framework and its long-term viability.

Europe needs a more efficient and fit-for-purpose CE marking system, which guarantees access to devices and innovations which live up to their safety and performance claims. We envision a regulatory framework that is modern, sustainable, agile and functions seamlessly to ensure medical technology rapidly reaches patients, healthcare professionals and health systems by taking the best of the current process and building in greater efficiency, predictability and convergence.

Principles for success

Improvements to the current system should enable all actors to plan, prepare, and allocate resources efficiently. They should also result in reduced administrative burden and costs. The system should be lean and able to react and adapt as needed to external changes.

Examples of solutions can include:

- **Considerably cut down on unnecessary bureaucracy in conformity assessment**, allowing Notified Bodies to take a more efficient and "benefit-risk based" approach, focusing their efforts on maintaining a high standard of device safety & performance rather than on producing numerous and lengthy assessment reports,
- **Put in place a 'pay for procedure' model** where the total cost for delivery of the certificate and other procedures is known and agreed up front. The total expected cost for all necessary procedures should be publicly available. This would greatly enhance predictability and efficiency of the system and support investment in medical technologies,
- **Fully digitise the EU system** including setting up a platform for upload of summary technical documentation, Summary of Safety and (Clinical) Performance and Periodic Safety Update Reports (PSURs). This should replace the current practices, including submission via paper, email or upload of pdf. The platform should support a harmonised approach between Notified Bodies, allowing for machine-to-machine communication and intelligent review tools to support for example, agile change notification procedures,
- **Permit digital labelling**, to enable reliant, agile and flexible supply chains, while at the same time supporting a more carbon-neutral environment. Digital labelling should be allowed for all medical technologies in principle, following a risk-based assessment by the manufacturer,
- **More differentiation should be made between IVD class B and class C professional laboratory devices** which are under EU QMS conformity assessment (risk based approach), for example, less frequent submission of technical documentation during conformity assessment, with less frequent or no review of the technical documentation during annual surveillance visits (unless a need to do so arises from the post-market system).
- **Remove the limited validity of certificates**, making it more efficient and risk-based. Instead of requiring re-certification every 5 years, certificate validity should be based on the continuous assessment of the Quality Management System, device post-market system, safety and event reporting, change notification and other post-market activity evaluation,

Embracing innovation

Safety and performance are rightfully the guiding principles for the regulatory framework for medical technologies in Europe. It is not sufficient, however, for connecting medical technology to patients and health systems. Innovation is critical to drive positive changes across health and to meet societal objectives such as more environmentally sustainable healthcare. Imagine if innovation had stopped 20 years ago – what technologies would patients and health systems be missing, and what would the impact be? Together, safety

and innovation are critical pillars for a regulatory framework that delivers medical technology to address unmet needs and improve outcomes.

When the regulatory framework was updated to the IVDR and MDR, the innovation principle was not sufficiently prioritised. As the gap in access to innovative technologies increases for European patients and health systems, we expect that Europe will continue to fall behind comparable frameworks around the world where regulators develop specific tracks for innovative devices that address unmet needs to reach their market. In fact, this trend is already starting to happen, with countries ranging from Switzerland to Australia for the first time considering recognising the regulatory decisions taken in non-EU jurisdictions.

Principles for success

Europe needs a regulatory system for medical devices and IVDs that embraces innovation. We envision a regulatory framework that rests on the principles of safety, performance and innovation – ensuring all and compromising on none – to swiftly connect the latest medical technologies to European patients and health systems. A reform of the current system should incorporate an explicit innovation principle which both provides for specific pathways that lead to a CE-mark and is future proof for the innovative products of tomorrow.

Examples of solutions can include:

- **Early / pre-filing / pre-market dialogues** are essential to set the level of evidence expectations. This should include the ability to ask for scientific advice outside – as well as part of – the certification process. Such early dialogues also would greatly improve the quality/correctness of submissions for conformity assessment and support Notified Bodies in managing their efficiency. Early engagement with regulators and Notified Bodies is key for supporting innovation in medical technologies.
- **Create dedicated and accelerated assessment pathways** within IVDR and MDR for medical technologies innovations that address unmet medical needs, life-threatening or highly debilitating conditions, and orphan and niche indications. Also include dedicated pathways to accelerate the uptake of emerging areas for medical technology such as gene sequencing, proteomics, customisable devices, breakthroughs in design for environmentally sustainable applications, etc. Eligibility should be monitored at EU level.
- **Improve the EU emergency use pathways** (derogations) so that they work to bring needed devices quickly onto the EU (rather than just an individual country's) market. The process for doing so should be clear and harmonised at EU level.
- **Adopt "pre-certification" access models** where appropriate, for example to provide initial access to niche products in selected hospitals in different countries rather than the EU market. Such models provide limited but early access to patients while supporting CE-marking later.
- **Adopt evidence requirements**, including to increase the use of real-world data for product certification and post-market clinical follow-up, recognize "early feasibility" studies and develop an adaptive approach to clinical evidence.

- Consider where devices can be brought through the European CE-marking system more quickly, **based on regulatory decisions taken by other jurisdictions**. Identify on which criteria such decisions should be based to ensure the required level of safety and performance. The EU should join the Medical Device Single Audit Programme, which will reduce duplicative audits from multiple jurisdictions for the same quality management system.

Effective governance

The current regulatory framework for medical technologies does not have a single clear and accountable structure governing the oversight of the regulatory framework which is empowered to course-correct systemic issues.

In the past, industry and other health stakeholders had not seen a need for a central structure governing the oversight of the decentralised system. However, the system has since become more complex, new domains in medical technologies continue to develop quickly, and new challenges have emerged – all of which make this need increasingly clear.

Principles for success

To be successful, the governance structure should be specific to medical technologies. It is vital that there be empowerment for the structure to be able to take the right decisions fast (i.e. agility to carry out its mission). The structure should not engage in authorisation of devices; certification (where required) should remain with the Notified Body system. At the same time, it should replace the roles of other currently existing structures, including management of Notified Bodies and expert panels. There must be a net gain in efficiency for the system from incorporating such a structure, the principle of which should be enshrined in its mission. There also must be a reduction in cost either directly or indirectly to the manufacturer and the system.

Examples for what the structure could be responsible for:

- **Taking system level decisions** – it should drive everything that has to do with governance of the system, ensuring efficiency and agility in the system and providing for an effective, transparent, pragmatic and resource-efficient Notified Body system. It should ensure the system remains technology-neutral so that it stays relevant and fit-for-purpose over time as our technologies evolve.
- **Driving a healthy ecosystem for medical technologies** – it should identify accelerated pathways for innovative products introduction in the market. This could include setting evidence requirements or providing for regulatory sandboxes which consider the limited evidence of risk-benefit which has been gathered with these products prior to their launch. The structure also should manage controlled access to needed technologies through other means such as emergency use pathways or reliance on decisions taken in other jurisdictions. It should interact with healthcare professional and patient associations to identify their needs and inform them about innovation ready to enter the market.
- **Managing the decentralised network of Notified Bodies** – it both should designate Notified Bodies and promote efficiency and best practice in the Notified Body system. It would work with Notified Bodies so that they recognize a unique system without local requirements. It would

harmonise practices between them to avoid discrepancies in the assessment and certification process as well as costs. It would also ensure each company (especially SMEs) can have access to a Notified Body in a timely fashion.

- **Authoring guidance documents** – it should have a final say on EU-level guidance and other documents to verify their compatibility with and support implementation of the IVDR and MDR. It should ensure and verify that there is a harmonized application of guidance, common specifications and other elements which are needed to support implementation of the IVDR and MDR. It also would take classification decisions, grant exceptions regarding application of the UDI-system and EUDAMED and determine the list of well-established technologies.
- **Representing the system both within Europe and globally –** it should promote regulatory coherence in the EU legislative ecosystem where there is an impact on the medical device or IVD; this includes digital, green and other EU legislation.
- **Creating a structured, on-going stakeholder dialogue mechanism to identify needs for adapting the system** – it should coordinate on disputes, e.g. providing manufacturers with an opportunity to appeal Notified Body and authority decisions and allowing for the challenge of decisions in front of an appropriate court.

Conclusions

Medical technologies form an integral part of healthcare systems and are crucial for prevention, diagnosis, treatment, and cure. If medical technologies do not reach health systems in a timely manner, patients pay the highest price. It is therefore crucial that the framework regulating access of medical technologies to European health systems is fit-for-purpose.

MedTech Europe's vision for the future of the medical technology regulations in Europe aims to be a starting point for a discussion that should address existing system issues and craft lasting solutions.

MedTech Europe looks forward to working closely with all stakeholders to achieve the original goals of the IVDR and MDR and to develop an effective and fit-for-purpose system that benefits European patients, health systems and society.

* * *

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

For more information, visit www.medtecheurope.org.

For more information, please contact:

Petra Zoellner
Director IVD Regulation and Medical Devices Regulation
MedTech Europe
p.zoellner@medtecheurope.org

Judith Kalina
Senior Manager - External Affairs
MedTech Europe
j.kalina@medtecheurope.org