

EC Call for evidence on the Life Sciences Strategy

MedTech Europe Response

17 April 2025

MedTech Europe, the European association of medical technology manufacturers, endorses the Commission's commitment to present a holistic Life Sciences Strategy. As medical technology's global competitiveness gap is widening and innovation dropping¹, designing the Strategy as a **comprehensive, cross-sectoral and forward-looking umbrella strategy for European life sciences** is without alternative. Medical technologies are an essential part of the life sciences sector and critical for the world-class performance and future resilience of European health systems as patients and healthcare professionals rely on medical technologies in each phase of care pathway (from prevention and detection to therapy and follow-up).

We urge policy makers to place **the medical technology sector as an integral part of the EU Life Sciences Strategy** and use the upcoming Strategy as an opportunity to reinstall Europe's attractiveness for medical technology innovation. MedTech Europe welcomes the broadening of the scope, from research-and-innovation-only, and urges policy makers to seize the opportunity of the Strategy by taking **seven Priority Actions**, ranging from the adoption of a structural reform of the medtech sector's regulatory system, better alignment and simplification of regulatory requirements across different policy domains, to allocating strategic investments to build a more efficient, sustainable, and resilient healthcare infrastructure.

(1) The medical technology industry is an engine of modern healthcare innovation and economic growth and competitiveness

The EU Competitiveness Compass explicitly acknowledges that "investing in life sciences holds significant potential for boosting competitiveness across multiple sectors", thereby emphasising that without health, no wealth can be generated.

Next to its crucial role in advancing human well-being and serving patients needs, the medical technology sector has indeed a substantial economic footprint in Europe² as it drives research, innovation and economic growth, creates high skill jobs and strengthens national resilience in the face of multiple global crisis. Besides, the sector has unique potential in support of safeguarding of the EU as an economic powerhouse.

- **Medtech has an important economic impact in Europe:** The sector consists of some 37,000 companies (90% of them being SMEs), offering 880,000 direct employments with an estimated value added of €177,000 per employee. On average, total healthcare spending amounts up to 11% of GDP with less than 1% attributed to medical technology and an average €304 per capita annual expenditure in Europe. In total, the European medical technology market is estimated at roughly €160 billion in 2023. The top five biggest markets are Germany, France, the United Kingdom, Italy,

¹ [Patent Index 2024 | epo.org](#)

² MedTech Europe [2024 Facts and Figures](#)

and Spain. Based upon manufacturer prices, the European medical device market is estimated to make up 26.1% of the world market. It is the second largest medical device market after the US (47.2%). Europe has a positive medical devices trade balance of 11 billion EUR in 2023. The main European medical device trade partners remain the same as in previous years: the US, China, Japan and Mexico

- **Medtech is a thriving, highly innovative sector with future growth, prosperity and competitiveness potential:** The medical technology sector files a patent every 30 minutes with the European Patent Office (EPO). In 2023, the medical technology sector still ranked 2nd highest in terms of number of total patent applications among all industrial sectors in Europe. The recent European Patent Office (EPO) 2024 Patent Index³, however, confirms that medical innovation is slowing down in Europe with a decline in patent applications in 2024. Action is needed urgently to course correct this alarming development.
- **Medtech is a highly diverse sector in support of health and competitiveness:** There are over two million different types of medical technologies to serve patients' very different needs (ranging from keeping them out of hospitals to providing the best standard of care to prolong the years of good life), including medical devices, *in vitro* diagnostic medical devices and digital health solutions.

Harnessing the sector's high innovative power to help address an aging population and increasing health threats, including from climate change, will only increase the strategic relevance for EU health and competitiveness. Without medical technology, there are no resilient, sustainable, digital healthcare systems.

(2) A strategically broadened scope to the Life Sciences Strategy

We strongly support the **expanded definition of "life sciences"** in the Call for Evidence, which now encompasses medical devices and *in vitro* diagnostics alongside biotechnology – in alignment with Denmark's comprehensive approach on the topic. This inclusive vision aligns with modern healthcare needs, where diagnostics, therapeutics, and digital health converge. Additionally, we welcome the Strategy's shift from a narrow focus on research and innovation (R&I) to a **broader framework that includes funding for healthcare infrastructure, hospitals, and other critical areas**. The Life Sciences Strategy is an opportunity to address key challenges and adopt concrete Priority Actions (see Point 3).

However, while broadening the scope is essential, it must be **framed strategically**. Adjacent sectors such as chemicals, energy, raw materials, and rare earths – which are integral to medical technology manufacturing – must be explicitly recognised within the strategy as significant enablers. In tandem, when addressing competitiveness, it is vital to maintain a clear focus on healthcare companies such as medical technology, biotechnology, pharmaceutical, and health IT firms.

³ European Patent Office 2024 Patent Index: [Patent Index 2024 | epo.org](https://www.epo.org/patent/index)

(3) Key challenges that a comprehensive Life Sciences Strategy should address

Europe's attractiveness for medical technology innovation is hampered by insufficient investment in healthcare infrastructure and an often fragmented, misaligned and inefficient regulatory framework⁴. While aiming to ensure safety and quality, this regulatory environment stifles timely launch of innovation to the detriment of patients and healthcare practitioners and discourages investment in emerging medical technologies.

Europe is generally still attractive for its innovative medical technology research ecosystem, accessible healthcare systems and growing commitment to value-based healthcare. However, the sector loses out as the global epicenter for medtech innovation. As the Draghi Report correctly points out, Europe increasingly faces **an innovation launch gap**. For a long time medtech companies innovated in Europe and launched their innovation in Europe first. MedTech Europe's recent survey⁵ confirms that this has changed:

- In the medical devices (MD) sector the choice of the EU as the first launch geography has dropped by 33% for large and 19% for SME manufacturers since the Medical Devices Regulation became law.
- In the *in vitro* diagnostics medical devices (IVD) sector it fell even further by 40% for large and 12% for SMEs since the *In Vitro* Diagnostic Medical Devices Regulation became law.
- Many IVD and MD manufacturers have increased their R&D spending, however it remains uncertain whether these investments will lead to market innovations or if they are being diverted into regulatory compliance. This is because both sectors show significant negative impact from the regulatory situation on innovation activities including development of new products and improvements to existing products, raising concerns about the long-term availability of innovative devices.

A **dense regulatory environment** with the sector specific Regulations (EU) 2017/745 and (EU) 2017/746 at the core and horizontal legislation, notably on sustainability and digital health policy, lead to a significant cumulative regulatory burden, often insufficiently aligned and lacking legal coherence. This negatively impacts investor confidence, funding and therefore patients' access to innovation.

In addition, **healthcare systems** face severe austerity schemes, while reimbursement practices become increasingly complex, and the adoption of value-based procurement remains slow. We also observe downward pricing pressures, claw back schemes and other operational issues, such as chronic late invoice payments, with major long-term impact on the sector's competitiveness.

At the same time, **other regions of the world**, such as North America and the Asia-Pacific, **are becoming more competitive**, setting in place adapted systems that allow more timely access for patients, especially to breakthrough innovations that meet unmet needs. European policymakers must take key actions to preserve Europe's attractiveness for medtech innovation and take into account its significant contribution to the life sciences sector as a whole, specifically by focusing on the region's political, legislative, tax and regulatory climate.

In a world where healthcare demands and economic pressures are rising, we cannot afford to continue on the same path.

⁴ Medical Devices Regulation (EU) 2017/745 and *In Vitro* Diagnostic Medical Devices Regulation (EU) 2017/746), Artificial Intelligence Regulation (EU) 2024/1689, European Health Data Space (EU) 2025/327, Data Act (EU) 2023/2854, to name a few

⁵ [MedTech Europe 2024 Regulatory Survey: key findings and insights](#)

(4) Priority Actions and Specific Measures to be prioritised to bring tangible outcomes

a. Seven Priority Actions

MedTech Europe welcomes the shift from a narrow research and innovation only scope to a broader one and now urges policy makers seize the opportunity of the Strategy and take the following priority actions to bring the benefits of the Life Sciences Strategy to patients and the wider economy:

1. **A structural reform to each of the medtech sector's core regulations** (EU) 2017/745 and 2017/746 by latest early-2026 to ensure the regulatory system becomes efficient, innovation-friendly and well-governed.
2. **Better alignment and simplification of regulatory requirements across different policy domains** Ambitious and significant efforts are needed on (1) simplification and administrative burden reduction of the applicable digital, data protection and sustainability laws, and (2) bringing legal certainty in the interplay between MDR/IVDR and other legislation, be it General Data Protection Regulation (GDPR) or Product Liability Directive (PLD) and parallel safety legislation, such as the Artificial Intelligence Act (AIA).
3. **Introducing specific and tailored measures in the implementation of the European Health Data Space, data protection domain and HTA** (see dedicated Zoom in).
4. **Allocating strategic investments to build a more efficient, sustainable, and resilient healthcare infrastructure**, especially throughout the future Multiannual Financial Framework (MFF) and the next EU Framework Programme for Research and Innovation.
5. **Recommitting and strengthening the EU Single Market**
6. **Foster strategic procurement, by implementing innovative procurement and value-based procurement, joint decarbonisation and competitiveness planning** to bridge Europe's environmental and economic goals.
7. **Harnessing partnerships and ensuring a fair national, EU and global level playing field for companies.**

b. Translating the Priority Actions into Concrete Measures

1. A structural reform of the medtech sector's regulatory system

As an immediate outcome of the European Commission's ongoing targeted evaluation running until end-2025 – **a package of legislative reforms for each of the two sector specific regulations (EU) 2017/745 (Medical Devices) and 2017/746 (In Vitro Diagnostic Medical Devices) should be developed** to ensure that these regulations deliver on their original objectives and enable innovation. It is imperative that the improved regulatory systems meet three criteria: being **efficient, innovation-friendly** and **well-governed**, while

providing a high level of product safety and performance. Immediate targeted measures also are needed to support device availability and the viability of the medical technology industry by increasing the predictability and accessibility of the regulatory system.

Reforming the regulatory system will help the European Commission to meet its competitiveness and simplification goals.

2. **Better alignment and simplification of regulatory requirements across different policy domains**

The cumulative impact of overlapping or overly complex requirements, for example in health data, artificial intelligence and environmental restrictions – can hinder innovation and delay progress. To tackle this challenge, we believe the Strategy should aim to build a more systematic approach to **evaluating regulatory impact, including competitiveness checks and retrospective assessments** and ensure an efficient interplay between MDR/IVDR and other legislation (be it GDPR or PLD and parallel safety legislation, such as AIA).

We call for the EU to systematically address and debunk **environmental, food, packaging, and chemical legislation** that affects the manufacturing and supply of medical devices in Europe. For example, the EU Packaging and Battery Regulations' implementation should be fully synchronized with the EU Medical Device Regulation and the *In Vitro* Diagnostics Regulation.

The **pending / upcoming Simplification Omnibuses Packages on Sustainability, Investment, Mid Size Cap and Paper Requirements, Digital and Healthcare** can further support patient access to medical technology while upholding agreed goals.

As part of the structural reform mentioned above, a single accountable governance structure of our regulatory system is needed, which will promote and ensure coherence between all EU legislation applicable to medtech.

3. **Introducing specific and tailored measures in the implementation of the digital package and HTA**

Zoom in: European Health Data Space

The European Health Data Space (EHDS), if implemented effectively, with sufficient funding and alignment across Member States, represents a **once-in-a-generation opportunity to unlock real-world data and evidence (RWD/RWE) for innovation and more personalized treatment**.

The Life Sciences Strategy should explicitly promote:

- harmonized implementation across Member States with secure and interoperable access to health data as well as effective stakeholder involvement and consultation throughout the implementation process
- adequate funding for infrastructure to ensure that we can implement the regulation and tap into data insights at scale
- address concerns about the protection of trade secrets and IP rights, particularly regarding alignment with existing laws on undisclosed know-how and business information. To safeguard

confidentiality and ensure competitiveness, clearer rules and safeguards in the context of secondary data use are needed.

Zoom in: GDPR and Product Liability Directive

With respect to digitalisation, **enhancing cybersecurity and data protection in European healthcare systems** is essential to safeguard patient data and ensure the availability of safe and top-tier innovations across the EU. Sector-specific regulatory frameworks should align with the needs of digital and AI-driven transformation, which will strengthen Europe's position as a global leader in medical technology innovation while maintaining high safety and ethical standards.

Divergent interpretation of **GDPR** in combination with overly risk averse approach among hospitals make it extremely difficult to implement digital solutions. We would suggest building in instead a positive message around support for harmonised implementation of GDPR which could serve as an important enabler for digitalisation of healthcare.

The EU should also consider clarifying specific aspects of the newly adopted **Product Liability Directive** to limit the unclarity of how its newly introduced presumptions interact with safety regulations, extra costs, and risks for business in litigation. For example, it would be helpful to:

- (1) narrow the scope of the rebuttable presumptions and/or create a de minimis threshold for their application and
- (2) clarify in what situations non substantial changes, as per MDR/IVDR, which do not materially impact patient safety or functionality are excluded from liability unless proven otherwise.

Zoom in: Health Technology Assessment

Specifically linked to the Lifesciences sector too, is the newly entered into force of the **Regulation (EU) 2021/2282 (HTA-R)** which will set an EU approach to health technology assessment. To ensure the development of timely and equitable access to safe, effective and high value innovations, an adapted approach will be critical. This will allow to adapt the timing and methods to the nature of the technology, its potential impact on and contribution to health outcomes and care delivery, the nature of information needed by patients and health service decision makers, the urgency and the level of certainty required.

4. Allocating strategic investments to build a more efficient, sustainable, and resilient healthcare infrastructure

Strategic investments in more efficient, sustainable healthcare systems, supported by digital health and medical technologies, including innovative breakthroughs, would not only reduce the cost of care but also help secure Europe's position as a global leader in healthcare innovation and its wider sustainability and digitalisation ambitions.

Concretely, the EU can:

- Leverage the **Multi Annual Financial Framework** for digital health and innovative medical technologies to ensure equitable, timely, and affordable patient access to care, and reduced burden on hospital and healthcare systems. This will foster a resilient and innovative medical technology ecosystem, contributing to health, growth, jobs and wider sustainability and digitalisation ambitions.

This should be complemented by targeted investments into interoperable IT infrastructure at both EU and Member State levels.

- Ensure the next **EU Framework Programme for Research and Innovation**:
 - o maintains health as a priority;
 - o safeguards the strong research culture including public-private partnership programmes; and
 - o makes improvements based on learnings and good practices in EU Member States, to continue strengthening EU global leadership in health research and innovation, and preserve its world-class health research ecosystem.

5. Recommitting and strengthening the EU Single Market

We call on policy makers to promote the upcoming EU Single Market Strategy as a critical opportunity to reinforce the simplification, coordination, and efficiency needed to strengthen Europe’s healthcare ecosystem.

MedTech Europe calls for **recommitment to and strengthening of the EU Single Market**. On the one hand, we observe increasing fragmentation in the internal market with respect to product requirements, divergences in the national transpositions of EU Directives, public procurement, remuneration practices or the capital market. On the other hand, the free movement of healthcare workers across national borders can help manage critical workforce shortages. Most importantly, however, patient access to medical technologies is increasingly under strain following, among other, overly complex regulation, “national blending” and insufficient coordination when implementing the sector’s safety and performance, i.e., Regulations (EU) 2017/745 on Medical Devices and (EU) 2017/746 on In Vitro Diagnostic Medical Devices. A well-functioning Single Market is not just an economic necessity—it is essential for improving diagnosis, treatment, and overall patient well-being.

6. Foster strategic procurement, by implementing value-based procurement, joint decarbonisation and competitiveness planning

As approximately **70% of all medical technologies are purchased through procurement**, an efficient (public) procurement process is essential for all healthcare actors e.g., patients, clinical staff, healthcare providers, society and the medical technology industry. Better public procurement can help to reduce the pressure on health budgets in EU Member States, deliver better value to patients, sustain healthcare systems and foster the development of high-quality medical technologies.

Moving beyond volume- and price-based procurement, **Value-based Procurement** is an innovative procurement approach that supports patient-centric, high quality and affordable healthcare and is an enabler of Value-based healthcare. VBP awards a supplier’s contract on the basis of what matters to patients and care providers and aims to have an impact on the outcomes of health care delivery and management of the total cost of care delivery.

As climate, health and competitiveness are intrinsically linked, **joint decarbonisation and competitiveness planning is key**. MedTech Europe promotes accelerating the roll out of clean energy and infrastructure, designing a supportive sustainable framework, leveraging the synergies with digitalisation for efficiency and

enabling increased circularity in healthcare. The design of realistic, patient-centric and economically viable transition pathways for medical technology manufacturers and their supply chains will ensure that patients and practitioners can rely on uninterrupted access to medical technologies during the transition.

(5) A call to joint and well-coordinated action

Few industries have greater growth potential than life sciences, but that potential only matters when it is realised and touches people's lives. We all have a role to play to ensure that Europe's regulatory and investment landscape continues to enable the potential of innovative healthcare, to save and improve people's lives, while contributing to the resilience and sustainability of our environment, our healthcare systems, and our economies. With that said, it is time for health stakeholders and policymakers – at all levels – to engage collaboratively and proactively to unlock the full potential of medical technology innovation and sustain its substantial contribution to the healthcare ecosystem.

As **Life Sciences Strategies are also building up in different EU Member States**, MedTech Europe expresses its support to the Danish Recommendations on the Life Sciences Strategy. We also call on the Commission to adopt a mechanism to ensure a coordinated approach to the set up and implementation of the Strategy. We suggest **setting up a European Life Sciences Council** inspired by the Danish Life Science Council to bring together all healthcare ecosystem actors pool resources and means to unlock the transformative power of medical technology for all.

Investing in the medtech sector isn't just smart policy – it is imperative for the functioning of society and the future competitiveness of Europe across sectors. A vibrant and competitive life sciences landscape with Medtech at its core is how we build a healthier, more hopeful tomorrow. We strongly encourage the EU institutions to tap into this unique potential.

In the annex, we provide an illustrative list of underlying evidence confirming the need for a comprehensive, multi-disciplinary Life Sciences Strategy that

- boosts competitiveness and prosperity.
- Invests in modern, efficient, digitally enabled, resilient and sustainable healthcare infrastructure.
- ensures patient centric green and digital transitions that take Medtech sector specificities into account.
- creates new jobs and wellbeing.
- Increases overall resilience and economic security of our health systems and wider economy.
- rapidly develops, translates and markets innovative ideas and solutions in the EU.

MedTech Europe remains available to partner and share sector specific expertise to guide this important initiative and build together a stronger, resilient, more innovative and sustainable healthcare sector that contributes significantly to Europe's economic strength and citizens' health and wellbeing.

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.

www.medtecheurope.org.

ANNEX: Underlying evidence concerning the need of a comprehensive life sciences strategy to boost Europe's attractiveness for Medtech innovation

Key studies, data and facts:

- MedTech Europe [2024 Facts and Figures](#)
- Deloitte Report, 2023 [Europe's MedTech Attractiveness](#)
- [MedTech Europe 2024 Regulatory Survey: key findings and insights](#)
- [Danish Government Strategy for life science English 2025.01.23.pdf](#), January 2023
- European Patent Office 2024 Patent Index: [Patent Index 2024 | epo.org](#)
- [EUIPO and EPO study on the impact of intellectual property rights on firm performance in the EU](#)
- Draghi Competitiveness Report: [The Draghi report on EU competitiveness](#)
- Report [Enrico Letta - Much more than a market](#), April 2024
- Heitor Report [Align, act, accelerate - Publications Office of the EU](#)
- MedTech Europe [Manifesto 2024-2029](#)

MedTech Europe policy papers:

- On EU attractiveness for MedTech innovation and competitiveness:
 - MedTech Europe position paper on [Europe's Attractiveness for Innovation](#), June 2024
 - [Relaunching European competitiveness: a joint European industry manifesto](#), April 2024
- On regulatory system reform:
 - MedTech Europe [position](#), The Future of Europe's Medical Technology Regulations
 - MedTech Europe [position](#) "Smooth transition to the mandatory use of EUDAMED"
 - [MedTech Europe response to the consultation on Targeted Evaluation of In Vitro Diagnostic Regulation and Medical Devices Regulation](#), March 2025
- On Adaptive HTA:
 - [Setting High Quality Standards in EU Regulation on HTA: Applying an Adaptive Approach to assess the value of medical technology innovation along the lifecycle, 2024](#)
- On revitalising the EU single market:
 - [MedTech Europe recommendations on the Single Market Strategy](#), February 2025

- **On sustainability and environment:**
 - [MedTech Europe recommendations on the Clean Industrial Deal](#), January 2025
 - [Circular Economy Act: MedTech Europe recommendations, January 2025](#), January 2025
 - [Chemicals Industry Act: MedTech Europe recommendations, January 2025](#), January 2025
 - [MedTech Europe position paper on EU Prosperity and Competitiveness: Implementing the EU Green Deal in Healthcare](#), November 2024
- **On digital health:**
 - [Vision for Strengthening Cybersecurity in Europe's Future Healthcare Systems](#)
 - [Charting the path forward: Joint stakeholder statement on the implementation of the EHDS](#)
 - [Medical technology industry perspective on the final AI Act](#)
 - [Stakeholder coalition calls for legislative refinement of the EHDS](#)
 - [Joint COCIR and MedTech Europe Vision for Strengthening Cybersecurity in Europe's Future Healthcare Systems](#)
- **On the revision of the public procurement directive:**
 - [MedTech Europe position-paper on revision of public procurement directive.pdf](#), March 2025
- **On research and innovation:**
 - [Joint Statement for an Ambitious FP10: Investing in Europe's Future Competitiveness through Collaborative Research, Development, and Innovation](#)
 - [Medtech Europe contribution to Heitors Expert Group on FP10.pdf](#)