MedTech Europe response to the Call for Evidence on the European Innovation Act

October 2025

MedTech Europe welcomes the European Commission's initiative to develop a European Innovation Act to promote and accelerate the deployment and diffusion of technology of today and of the future to create an innovation-friendly level playing field for cutting edge companies, including SMEs, within the EU Single Market.

MedTech Europe represents the European medical technology industry, including diagnostics, medical devices and digital health. The sector is a cornerstone of Europe's health resilience and competitiveness, operating with more than 2 million medical technologies across 7,000+ device groups, but the sector is increasingly affected by regulatory complexity, market fragmentation, investment gaps, and procurement practices that undervalue innovation and outcomes.

The European Innovation Act should be a catalyst to address these barriers, enabling faster translation of research into market uptake, and reinforcing Europe's global leadership in health innovation.[1]

Our key messages

- **Create an enabling framework without hampering sectoral reforms:** MedTech Europe strongly supports that the European Innovation Act should serve as an enabling framework and not substitute or delay urgently needed reforms of sectoral legislation such as MDR/IVDR, digital, or environmental simplification measures. Targeted sectoral legislative proposals remain the dedicated channels for those critical reforms.
- **Keep health and medical technologies at the core of EU competitiveness:** Strong healthcare systems and a thriving innovation ecosystem strengthen patient outcomes, system efficiency, and Europe's economic resilience.
- **Prioritise simplification, coherence, and governance**: Regulatory fragmentation and complexity, overlapping horizontal/sectoral rules, and capacity bottlenecks are eroding Europe's attractiveness for innovation and delaying patient access. We call on the European Commission to engage in inter-departmental dialogues to ensure that the European Innovation Act further enables existing

[1] In the context of the medical technology sector, we consider 'innovation' to refer to breakthrough, disruptive medical technologies, as well as iterative changes which enhance the functionality and performance of existing technologies, such as software updates, improved battery life, more interoperable services, and offering a technology used in a clinical setting for home or point of care use. 'Medical technologies' refers to medical devices, IVDs, medical equipment, medical services, medical software (incl. medical apps, artificial intelligence, etc.), surgical procedures, new or extended Indications, new technology, new or alternative materials or components, etc.

simplification efforts (digital, environmental) and planned sectoral reform (MDR/IVDR planned for late 2025) to deliver concrete mechanisms which reduce burden and align frameworks.

- **Strengthen collaborative R&I and market uptake**: Europe needs better pipelines from research to adoption, leveraging public–private partnerships (PPPs), innovation-friendly value-based procurement and public procurement of innovation, access to infrastructures, a strong IP framework, and a robust, outcome-oriented Single Market.

Our recommendations

1. European Innovation Act - Framework-level recommendations

1.1 Recognizing medical technologies as a critical sector for Europe's future

The medical technology (medtech) sector is one of Europe's most dynamic and innovative industrial ecosystems, playing a vital role in strengthening Europe's health resilience, economic competitiveness, and technological leadership. The sector is comprised of more than 38,000 companies, 90% of which are small and medium-sized enterprises (SMEs), and directly employs over 900,000 people across Europe. Medtech innovation supports life-saving and life-improving solutions, enhances health system capacity, and drives the shift towards value-based, efficient, and sustainable healthcare. The sector consistently leads in research and patenting activity, contributing to 8% of all European patent applications, and maintaining a positive trade balance of €11 billion annually.

Therefore, MedTech Europe calls on policymakers to explicitly recognise medical technology as a strategic sector in the European Innovation Act. This recognition is essential to ensure that policies and frameworks for innovation reflect the sector's strong contribution to innovation activities as well as its importance for citizens' health, economic opportunity, technological sovereignty, and the overall resilience of the EU.

1.2 Facilitating access to finance, and supporting access to EU/national funds

MedTech Europe supports measures that close the 'scale-up finance' gap in Europe and enable medical technology companies to commercialise and grow in the EU.

Recommendations

1. Expand access to EU and national funds for market implementation and innovation uptake:
   - Funding gaps are particularly acute in the critical 'translation phase' between research validation and market implementation. The Act should prioritise support for late-stage validation, evidence generation, regulatory readiness, and first-of-a-kind deployments in health systems that demonstrate real-world clinical value.
   - Preserve and strengthen public–private instruments (e.g., Innovative Health Initiative) with adequate budgets and predictable multiannual pipelines in FP10 (the successor of Horizon Europe that will run from 2028 on) and beyond.
   - Strengthen EU support to member states to support investments into medtech innovations that reduce the burden of disease, improve patient outcomes, and support efficiencies of healthcare and hospital systems.
2. Ensure funds to support SME participation: Simplify application and reporting, reduce duplications across programmes, and provide technical assistance for regulatory and clinical evidence requirements.

For further information see: Towards an EU Single Market Strategy; FP10 joint statement; Europe's Attractiveness; MFF response [attached].

1.3 Enabling talent attraction and retention, including employee ownership

MedTech Europe supports measures that help medical technology companies attract and retain interdisciplinary talent (engineering, clinical, digital, regulatory, sustainability). This is a growing challenge for the sector: a MedTech Europe survey showed that 86% of large and 91% of SME manufacturers find it difficult to find staff in regulatory affairs.

Recommendations

3. Invest in skills for health innovation: Expand EU-supported training in regulatory science, clinical evidence, AI/data, cybersecurity, and sustainability specific to medical technology; align with the Union of Skills and recognise sectoral needs.

For further information see: Towards an EU Single Market Strategy; Europe's Attractiveness.

1.4 Coordinating innovation policies among Member States and with the EU

MedTech Europe supports a stronger EU–national coordination framework that reduces Single Market fragmentation. This is particularly important in healthcare, where fragmentation hinders the scaling of innovations and access of patients to new solutions.

Recommendations

4. Establish a health innovation coordination platform: Bring together Member States, EU institutions, regulators, HTA/procurement authorities, patients, healthcare professionals (HCPs), industry and academia to identify barriers, monitor fragmentation, and share best practices on procurement, reimbursement, regulatory implementation and operations.
5. Introduce a "5th freedom" for research and innovation: Advance the Letta recommendations to promote free movement of knowledge, research, and education, with FP10 as a core instrument to drive collaborative R&I and industrial competitiveness in health.

For further information see: Towards an EU Single Market Strategy

1.5 FP10 and the Innovation Act: mutually reinforcing pillars

In addition to the areas of intervention detailed above, MedTech Europe would like to further stress the need to coordinate the European Innovation Act with FP10.

Recommendations

6. Ring-fence health within FP10, preserve a stand-alone programme, and support PPPs like IHI with sufficient budgets for collaborative, cross-border, multi-stakeholder R&I spanning basic to implementation research.
7. Reduce administrative burden, clarify calls and topic design, balance basic and applied research, and prioritise projects with implementation pathways to patients, HCPs, and health systems.
8. Ensure systematic scaling pathways for successful uptake of PPPs results like IHI, with fast tracking options in joint procurement pilots.

For further information see: FP10 joint statement

2. Nurturing medical technology innovation through sectorial reforms and simplification

Regarding areas of intervention:

- *Simplifying and making the regulatory framework more innovation-friendly*

- *Supporting access to research and technology infrastructures and regulatory sandboxes*
- *Facilitating deployment and diffusion in the market, including innovation-friendly public and private procurement*
- *Improving commercialisation of publicly funded R&I*

Recommendations

9. The European Innovation Act should act as a catalyst, complementing, not replacing, dedicated reforms underway for medical technology regulations (MDR/IVDR) [2], digital, and environmental legislation. MedTech Europe calls for the Act to focus on its core function: streamlining the path from research to uptake, promoting interoperable frameworks for innovation support, and creating an enabling environment, while targeted regulatory simplification and technical alignment should remain within the remit of ongoing sectoral & simplification legislative reviews (e.g., MDR/IVDR, artificial intelligence, data, environmental, product safety, cybersecurity, procurement).
10. We urge the Commission to establish formal coordination mechanisms between relevant Directorates-General to ensure horizontal policies reinforce and do not duplicate or create obstacles for specific sectoral innovation pathways in healthcare, also covering topics such as:
    - Regulatory sandboxes fit for medical technology, especially breakthrough innovations
    - Interoperable testbeds for digital health
    - Accelerate and harmonize standards and guidance for emerging technologies
    - Certification capacity and predictability
11. Access to Research and Technology Organizations (RTOs) and clinical infrastructures: Create a "single-door" access mechanism to public R&I infrastructures, with transparent terms, fair pricing, and IP frameworks that encourage uptake and follow-on investment, ensuring that medical technology innovators can benefit equally from public infrastructures.
12. As regards the commercialisation of publicly funded R&I, we support the promotion of collaboration between academia, industry, and healthcare providers, with frameworks that simplify technology transfer and intellectual property rights (IPRs) management. IPRs are fundamental to fostering an environment where creativity and innovation can thrive, and have been key in shaping the European medical technology industry's leadership in R&I. For the medical technologies sector, it is important that standardisation and certification pathways are streamlined to accelerate the safe introduction of innovations to the market.
13. Innovation policy should pay stronger attention to ensuring continuity: R&I programmes should not only support early-stage research but also facilitate the transition to later stages of development, including regulatory preparedness, evidence generation, and alignment with health system needs. Funding mechanisms should explicitly factor in these downstream challenges and equip companies, particularly SMEs, with the tools to navigate them. Otherwise, Europe risks subsidising innovations that ultimately reach patients elsewhere.

For further information see: Four urgent targeted measures; Report on Administrative Burden; Simplification of EU digital legislation.

Public procurement

[2] Regulations (EU) 2017/745 and 746

14. Public procurement is pivotal for first adoption and scale-up of medical technology, remaining an underused driver of innovation in healthcare. Europe needs consistent value-based procurement and innovation-enabling procedures across Member States.
15. Value-based procurement as the default: Reinforcing the use of Most Economically Advantageous Tender (MEAT) as the default criterion (above EU thresholds) is essential. Detailed EU-level guidance and capacity building should support procurement authorities to apply MEAT criteria to include clinical and patient outcomes, thereby avoiding price-driven awards and limiting the weight of price to 10% with 90% minimum quality criteria.
16. Most Economically Advantageous Tender (MEAT) criteria: Make innovation-friendly strategic procurement procedures the default for complex solutions. Promote negotiated procedure, competitive dialogue, and innovation partnerships; ensure contracts allow iterative upgrades reflecting rapid tech cycles; require structured open market consultations and stakeholder dialogues pre-tender. Set **a dedicated process for procurement of breakthrough innovations,** aligned with the Medical Device Regulation (EU 2017/745), the *In vitro* Diagnostic Medical Devices Regulation (EU 2017/746) and the Health Technology Assessment Regulation (EU 2021/2282).
17. Reduce administrative burden and fragmentation: Standardise qualification documents and e-certification across the EU; improve TED functionalities to support full e-tendering; set maximum timelines from bid close to award; define minimum submission periods for below-threshold tenders.
18. Strengthen SME participation: Require lotting for high-value tenders, enable SME consortia for larger contracts, and avoid excessive bundling that restricts competition.
19. Avoid origin-based preference in medical technology: Do not introduce rigid EU-preference rules for medical technologies given globally integrated supply chains, risk of access disruption, higher costs, trade retaliation, and negative impact on innovation and patient care; if introduced horizontally, exempt medical technology. Keep procurement centred on outcomes and value for patients and health systems.

For further information see: Position on Public Procurement.

Concluding remarks

The European Innovation Act presents a valuable opportunity to empower Europe's innovation ecosystem and reinforce competitiveness, health resilience, and technological leadership. For this to be realised, the policy framework must be clear in its purpose: enabling and accelerating the translation of innovative solutions, such as those from the medical technology sector, into real impact for patients, society, and Europe's economy.

MedTech Europe reiterates that while the Innovation Act can and should support simplification, coherence, and better governance at the horizontal framework level, core reforms of sectoral regulations (such as MDR/IVDR), as well as simplification efforts around digital, data and sustainability legislation, must remain the focus of dedicated, separate processes and legislative proposals. The Act should act as an enabler, facilitating coordination, knowledge-sharing, and the removal of practical bottlenecks, while respecting the critical role and autonomy of sector-specific reforms to ensure effective patient safety, innovation, and regulatory clarity.

Recognising medical technology as a strategic sector for Europe's future and enabling an innovation-friendly environment that accelerates the journey from research to market uptake, will be the foundation of Europe's global leadership in health and long-term prosperity. MedTech Europe stands ready to work with policymakers and all stakeholders to help shape and successfully implement the European Innovation Act and all related efforts.

Further information

- Facts & Figures 2025
- Towards an EU Single Market Strategy: Reinforcing the EU Single Market for Innovation, Health Resilience and Competitiveness (31 Jan 2025)
- MedTech Europe Position Paper on the EU Public Procurement Directive consultation (24 Mar 2025)
- Europe's Attractiveness for Innovation: State of Play and Recommendations
- Joint Statement: Healthcare Stakeholders' Priority Areas and Recommendations on FP10
- Simplification of EU digital legislation: MedTech Europe proposal to ensure coherent implementation (28 Aug 2025)
- Report on Administrative Burden under IVDR and MDR (18 March 2025)
- Four urgent targeted measures to enhance rapid access to safe medical technology while safeguarding innovation (May 2025)

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 that research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

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