MedTech Europe
from diagnosis to cure

MedTech Monthly

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Don’t let tariffs & export restrictions block access to medical technologies

The European Commission has recently closed its public consultation on a list of EU countermeasures that could be applied to both imports from and exports to the United States, paving the way for a second package of retaliatory measures. MedTech Europe is deeply concerned that this draft package targets a broad range of finished medical devices, *in vitro* diagnostic medical devices, and a variety of essential components used in their manufacture.

We urgently call on European policymakers to exempt medical technologies from any trade tariffs or export restrictions. We also call for medical technologies to be included and prioritised in a “Zero for Zero” tariff agreement on industrial goods or as part of any negotiated settlement seeking to eliminate tariffs on both sides of the Atlantic. Action is needed now to protect patients and preserve access to critical healthcare solutions.

Medical technologies are indispensable to patients and healthcare systems. Diagnosis, treatment, and recovery heavily depend on them. Because of their direct impact on patient health, medical devices have historically been exempted from many trade restrictions, and we urge to continue this responsible approach. No trade strategy should come at the expense of patients’ health.

The medical technology sector is also a strategic driver of Europe’s economic strength and industrial resilience. Trade disruptions and tariffs risk undermining access to these crucial technologies. The recently proposed EU package of countermeasures includes over 800 trade codes related to medical technologies, covering finished goods as well as a variety of core components necessary for the functioning of medical devices and diagnostics.

Medical technologies depend on complex global supply chains and advanced material sciences. Some devices require up to a thousand components sourced from various regions, e.g., patient monitoring, dialysis systems, *in vitro* diagnostic analysers, magnetic resonance imaging machines and many more. Raw materials and semi-finished parts are often moved between international production sites for specialised processing. Tariffs or restrictions would disrupt these intricate chains and create ripple effects throughout the healthcare system.

Replacing components is not a simple option. In some cases, no alternative exists. Where substitutes are possible, the process of revalidation is lengthy and resource-intensive to ensure the same high standards and safety are met. Delays to access to medical technologies ultimately affect patients.

MedTech Europe continues to urge policymakers to consider the real-world implications of tariffs and export restrictions on medical technologies. Patients must not become collateral damage in a trade dispute. Safeguarding their access to the technologies they depend on must remain a shared priority.

Diana Kanecka, Director International Affairs I **Miriam D’Ambrosio**, Senior Manager Communications

Highlights of the month

MedTech Europe welcomes ambitious EU Life Sciences Strategy

Melanie Wahl
Senior Policy Advisor

READ OUR STATEMENT

On 2 July 2025, the European Commission released its much-anticipated Life Sciences Strategy (LSS), setting an ambitious vision to make the EU the world's most attractive region for life sciences by 2030. MedTech Europe welcomes this comprehensive strategy, which recognises the essential contribution of medical technology alongside pharmaceuticals and biotechnology.

Europe's medical technology sector is one of its most dynamic and innovative, with over 37,000 companies, 880,000 employees, and 8% of all European patent applications. The sector delivers 11 billion € in positive trade balance annually and plays a vital role in strengthening healthcare systems and patient outcomes.

MedTech Europe supports the LSS's focus on regulatory reform but stresses the urgent need for further simplification—not only within the sector's framework but also across digital, data, and sustainability regulations. Streamlined, predictable, and innovation-friendly rules are essential to ensure timely patient access and global competitiveness.

We stand ready to contribute to the successful implementation of the LSS, including through the future Coordination Board, and call for bold action to position Europe as the global leader in MedTech innovation.

Strengthening MedTech Europe's voice: highlights from recent EU engagements

Melanie Wahl
Senior Policy Advisor

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MedTech Europe continues to provide members with unique opportunities to engage at the highest levels of EU policymaking.

On 10 June 2025, a delegation of MedTech Europe members met with EU Health Commissioner Olivér Várhelyi to discuss the urgent need for structural reform of the Medical Devices Regulation and *In Vitro* Diagnostics Regulation framework and the impact of US tariffs on European medical technology. The meeting reinforced our call for a predictable, innovation-friendly regulatory environment to support Europe's competitiveness and patient access to new technologies.

On 23 June 2025, MedTech Europe members met with EU Commissioner for Startups, Research and Innovation, Ekaterina Zaharieva, to explore how public and private investments—particularly through the Horizon Europe Programme—can strengthen the EU research and innovation ecosystem. We emphasised the importance of fostering collaboration among patient organisations, SMEs, competent authorities, and industry, and attracting global investment to ensure Europe remains at the forefront of health innovation.

A highlight of 2 July 2025 was the keynote speech by Lorena Boix Alonso, Deputy Director General for Health at DG SANTE, at our CEO Summit in Brussels. Her intervention underscored the strategic importance of medical technology for Europe's health and competitiveness.

These engagements reflect our commitment to shaping a future-ready, innovative, and resilient medical technology sector in Europe.

Blogs & podcasts

The targeted evaluation of EU regulations on *in vitro* diagnostics (IVDs) is a second chance to develop a system that works for patients, health systems and manufacturers. Key concerns centre on the efficiency of the system, timelines and predictability.

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Our special two-part MedTech ON AIR series, recorded live at the MedTech Forum 2025, are now available. In these episodes, we capture key takeaways from the largest gathering of our industry in Europe. And we explore how the MedTech Forum is helping our sector align on regulatory priorities.

LISTEN TO THE PODCAST

In short

Just published: amending electronic Instructions for Use regulation for medical devices

Jana Russo, Manager Medical Devices

MedTech Europe welcomes the official publication of the amending electronic Instructions for Use (eIFU) regulation. The publication follows the European Commission adoption of 25 June 2025 and a positive vote by Medical Device Committee on 6 June 2025. This crucial amendment allows all devices used by professionals – all professional use of medical devices and devices for aesthetic/non-medical purposes - to be provided with eIFU.

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Joint industry call for preserving the functioning of the internal market when implementing new packaging waste rules

Sigrid Linher, Director Sustainability & Environment

Preserving the functioning of the internal market when implementing new packaging waste rules matter: for the environment and the economy. MedTech Europe joint forces with industry colleagues across the packaging value chain to call for a future EU labelling system that aligns with the goals of EU-wide harmonisation, large-scale recyclability, and protection of the Single Market.

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MedTech Europe joins the European Framework for Advanced Medical Technology Evaluation and Follow-up Stakeholders Forum

Petra Zoellner, Director Regulatory Affairs (IVDR & MDR)

MedTech Europe joins the European Framework for Advanced Medical Technology Evaluation and Follow-up (EU4MEDTECH) Stakeholders Forum – a platform working on developing pre-and post-market methodologies for clinical and performance evaluation. Our participation reinforces our commitment to shaping an efficient, innovation-friendly legal framework that ensures timely access to medical technologies across Europe.

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How can Robotic Assisted Surgery help solve Europe's healthcare challenges?

Sophie Koettlitz, Senior Expert Research & Innovation

MedTech Europe has recently published a position paper examining how Robotic Assisted Surgery (RAS) can transform healthcare across Europe. In addition to highlighting the benefits of RAS, the paper outlines several challenges that this innovative technology faces. It further provides recommendations for coordinated policy measures to help address these challenges and support the adoption of RAS in clinical practice.

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Healthcare Ethics & Compliance Conference 2025: save the date

Marta Paci, Junior Legal Counsel

Following the success of the previous editions, the third Healthcare Ethics & Compliance Conference (HETHICO 2025) will take place on 7–8 October 2025 at The Hotel, Brussels. Jointly organised by EFPIA, ETHICS, and MedTech Europe, the conference will convene industry leaders, legal experts, compliance professionals and key stakeholders to promote integrity and build public trust in therapies and innovations.

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The European Commission publishes the International Procurement Instruction measure legal text and FAQs

Diana Kanecka, Director International Affairs

As expected, the European Commission has officially published the International Procurement Instruction (IPI) measure restricting access to its public procurement for EU tenders equal or above five million € for economic operators originating in China. In addition, EU contracting authorities will need to ensure in their tenders that they do not source more than 50 percent of medical devices originating in China.

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Revision of Standardisation Regulation 1025/2012

Carlos Pérez Barrionuevo, Manager Medical Devices

The EU is set to revise its Standardisation Regulation 1025/2012, as announced in the 2025 EU Competitiveness Compass. This revision aims to accelerate and simplify standard-setting processes, particularly for SMEs and startups, aligning with the 2022 EU Standardisation Strategy's focus on global standard-setting for EU competitiveness and technological sovereignty.

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A strategic turn in U.S. Anti-Bribery Law: the Department of Justice releases new Foreign Corrupt Practices Act Guideline

Marta Paci, Junior Legal Counsel

Following President Trump's executive order pausing enforcement of the Foreign Corrupt Practices Act (FCPA) for 180 days, the US Department of Justice (DOJ) released the awaited guidelines on 9 June 2025 to govern its application.

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MedTech Europe is the European trade association representing the medical technology industries, from diagnosis to cure.

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