MedTech Europe
from diagnosis to cure

MedTech Monthly

February 2025

Dear readers,

I hope this year brings health, prosperity, and inspiration to you and your families. It is a pleasure to connect with you through this first edition of our newsletter for what promises to be a year of progress and positive change in the medical technology sector.

Medical technologies touch millions of lives everyday—helping to diagnose diseases earlier, enabling life-saving treatments, and supporting people in managing their health. They are essential to ensuring that healthcare systems can deliver the best possible care to everyone. While Europe has long been a global leader in medical technology, – thanks to a strong research ecosystem, advanced health infrastructure, and focus on value-based healthcare – we must take concrete steps to address the challenges that risk slowing our progress.

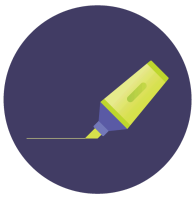
The upcoming Clean Industrial Deal presents a critical opportunity to reaffirm the role of medical technology in both Europe's future and people's lives. A thriving medical technology sector is essential for public health as well as Europe's long-term competitiveness. Achieving this requires a policy framework that fosters competitiveness through effective regulation, investment incentives. By creating the right conditions for innovation, we ensure that the entire healthcare ecosystem is strengthened —so that patients have faster access to cutting-edge treatments, healthcare professionals are equipped with the best tools, and health systems remain efficient and sustainable.

We are also pleased to share insights from the MedTech Europe 2024 Regulatory Survey. The findings highlight ongoing challenges under MDR and IVDR—barriers that can delay patient access to life-saving and life-enhancing technologies. Addressing these issues must be a priority. By streamlining processes, reducing unnecessary burdens, and improving the predictability of certification timelines, we can ensure that innovative medical technologies reach those who need them most.

MedTech Europe is dedicated to collaborating with all partners who share our vision of a healthier, more sustainable future. Together, we can shape a path forward that supports innovation, enhances healthcare systems, and most importantly, improves the lives of people across Europe.

Wishing you a healthy and inspiring year ahead.

-Miriam D'Ambrosio - Senior Manager Communications



Highlights of the month

Get ready for another exciting edition of The MedTech Forum

Claudia Peters
Events Manager

REGISTER HERE

Registrations for The MedTech Forum 2025 are now open! The largest health and medical technology industry conference in Europe will take place in Lisbon on 13-15 May 2025, gathering key stakeholders from across the sector. The MedTech Forum is a key event since 2007.

This year's edition will tackle the ever-evolving opportunities and challenges for our industry, from innovation and digital transformation to regulatory developments and sustainability.

By securing your spot early, you'll benefit from the exclusive Early Bird rate, available only for a limited time. Don't miss this opportunity to join experts and peers while exploring innovative sessions led by industry leaders.

EU Competitiveness Compass: MedTech Europe minds speed and unity for delivery

Sigrid Linher
Director Sustainability & Environment

READ THE STATEMENT

On 29 January 2025, the European Commission under the lead of President von der Leyen and Executive Vice-President Séjourné presented the EU Competitiveness flagship initiative, which will guide the Commission's work in the next five years. MedTech Europe welcomes its publication and the objective to "safeguard the EU's future as an economic powerhouse."

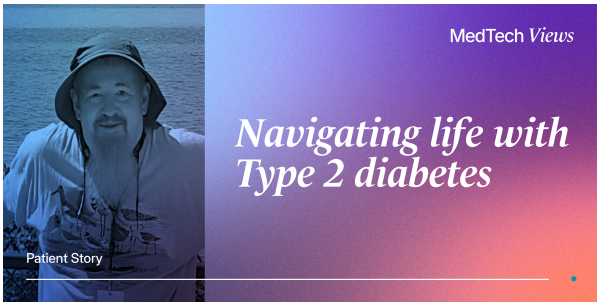
Turning this ambitious plan into tangible outcomes is the challenge now: speed and unity of all actors, including the Commission, Member States, investors, industry and other stakeholders will be of the essence. As the EU charts its course towards sustainable competitiveness and prosperity, MedTech Europe remains available to contribute constructively to shaping these policies for the benefit of people in Europe, and its healthcare systems.

Blogs & podcasts

A new bureaucratic challenge for manufacturers

The latest update to the medical device regulations aims to protect patients from supply interruptions, but this may eventually result in more red tape for companies.

READ MORE



Navigating life with Type 2 diabetes

After years of being overwhelmed by a Type 2 diabetes diagnosis, Mark Tiller stabilised his health with the support of medical technology. He shares his story with MedTech Views.

READ MARK'S STORY

In short

EU Prosperity and Competitiveness: MedTech Europe issues key recommendations on Clean Industrial Deal

Sigrid Linher, Director Sustainability & Environment

Climate, health and competitiveness are intrinsically linked. As the new EU Competitiveness Compass confirms the transformative imperative of a joint roadmap for decarbonisation and competitiveness, MedTech Europe published its recommendations on the Clean Industrial Deal and on how to implement the EU Green Deal in Healthcare.

READ THE FULL RECOMMENDATIONS HERE

MedTech Europe 2024 Regulatory Survey: key insights into the challenges facing manufacturers

Iana Slobodeaniuc, Manager *In Vitro* Diagnostics

MedTech Europe's 2024 Regulatory Survey reveals growing concerns over rising costs, unpredictable timelines, and inefficiencies in the regulatory system. Key improvements in regulatory processes are essential to ensure Europe remains an attractive and sustainable hub for medical technologies.

READ THE FULL SURVEY RESULTS HERE

Boosting Europe's attractiveness for medical technology innovation through a revitalised EU Single Market

Sigrid Linher, Director Sustainability & Environment

MedTech Europe has responded to the European Commission's call for evidence on a new Single Market Strategy, set to be proposed in Q2 2025, in alignment with the EU Competitiveness Compass (published on 29 January 2025). Europe's greatest strength has reached a critical turning point. An increasingly complex and fragmented regulatory environment has made the region less attractive for medical technology manufacturers to

invest, innovate, produce, commercialise, and scale up, ultimately leaving patients in Europe without timely access to vital medical technologies.

A renewed Single Market Strategy represents an opportunity to reinforce the Single Market for innovation, health resilience and competitiveness.

READ THE FULL STAMENT HERE

Joint medical technology industry's feedback to the XpanDH project

Verena Thaler, Manager Data Governance

As the European Health Data Space (EHDS) takes shape, MedTech Europe and COCIR actively participated in the XpanDH project to share industry views and highlight challenges. The recently published paper emphasises the input from industry side. Both organisations affirm their commitment to supporting the successful implementation of the EHDS by addressing key challenges.

READ THE FULL JOINT POSITION PAPER HERE

MedTech Europe co-signs statement calling for the withdrawal of the Artificial Intelligence Liability Directive

Pablo Rojas Abad, Legal & Compliance Senior Manager – Senior Legal Counsel

MedTech Europe, along with 11 other associations, has today issued a joint statement urging EU policymakers to withdraw the Artificial Intelligence Liability Directive proposal. The directive risks increasing legal complexity, undermining EU competitiveness by adding regulatory burdens, and deterring investment in AI innovation.

READ THE FULL JOINT STATEMENT HERE

MedTech Europe contributes to the European Data Protection Board public consultation on Article 48

Mirella Kavadaki, Junior Legal Counsel

MedTech Europe has submitted its contribution to the European Data Protection Board public consultation on the Guidelines on Article 48 of the General Data Protection Regulation (GDPR). The consultation, open from 3 December 2024 to 27 January 2025, aimed to clarify conditions for transferring personal data to third countries in

response to legal requests from non-EU authorities. MedTech Europe took part in the consultation to reflect the perspective of the medical technology sector.

READ THE FULL STATEMENT HERE

The Innovative Health Initiative's calls for proposals 9 and 10 have launched

Estefanía Cordero, Manager Communications

The Innovative Health Initiative's (IHI) latest calls for proposal are now open. Call 9, is an applicant driven approach aligned with the IHI's key objectives; Call 10 covers diverse topics, including digital labelling for medical technologies.

Find the full details, deadlines, and supporting resources below.

MORE INFO

Get ready for Japan: registrations for the 27th International Medical Device Regulators Forum Management Committee Meeting are now open

Diana Kanecka, Director International Affairs

The 27th International Medical Device Regulators Forum (IMDRF) Management Committee Meeting, hosted by the Japanese Pharmaceutical and Medical Devices Agency (PMDA), will be held in Tokyo, Japan, from 10-14 March 2025. This year, Japan will chair the IMDRF Management Committee, which is foreseen to tackle the IMDRF Strategic Plan 2026-2030 as one of its main topics of discussion.

Registrations for both in-person and online attendees are now open.

REGISTER HERE

Value-Based Procurement Conference report

Hans Bax, Senior Adviser Value & Innovation-based Access

The post-conference report of the 6th European Value-Based Procurement Conference is now available, summarising some of the key discussions addressed during the event. The conference was held on 2 December 2024 in Brussels.

READ THE FULL REPORT HERE

Highlights from recent events from the Conference Vetting System team: Webinar success and major Conferences

Dhana Ong, CVS Compliance Officer

Discover the latest updates from Conference Vetting System (CVS), including highlights from our successful webinar held on 21 January 2025 with over 375 attendees, the introduction of exciting new features in the CVS/e4ethics 2.0 platform and participation in major conferences.

READ MORE

Key update on SARS-CoV-2 IVD (EU) classification

Iana Slobodeaniuc, Manager *In Vitro* Diagnostics

The European Commission's *In Vitro* Diagnostics expert panel has concluded that SARS-CoV-2 no longer presents a life-threatening risk with significant mortality for the general European population. This decision will impact the classification of SARS-CoV-2 tests under the *In Vitro* Diagnostic Medical Devices Regulation 2017/746/EU (IVDR).

READ MORE

Nathalie Virag takes up role as Chair of the Governing Board of the Innovative Health Initiative

Estefanía Cordero, Manager Communications

MedTech Europe is proud to announce that Nathalie Virag, Chair of the MedTech Europe Research and Innovation Committee and Senior Director and General Manager at Medtronic, has begun her mandate as Chair of the Innovative Health Initiative (IHI), marking the first time a MedTech Europe representative assumes this position.

READ MORE

New year, new factsheets

Dario Belluomini, Manager International Affairs

The European Commission has published the new version of the Factsheet for authorities in non-EU/EEA states on medical devices and *in vitro* diagnostic medical devices. The document aims to provide a high-level overview of the transition to the EU Medical Device Regulation and *In Vitro* Diagnostic Medical Device Regulation, including reviewed timelines and conditions for authorities in third countries to be fulfilled to benefit from the extended transition periods.

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In the media

COCIR, MedTech Europe confirm support for EU regulation - *Read on* AuntMinnieEurope

CONTACT US

MedTech Europe
from diagnosis to cure

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

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