MedTech Europe
from diagnosis to cure

MedTech Monthly

November 2025

Dear readers,

Welcome to this edition of MedTech Monthly — your regular update from MedTech Europe.

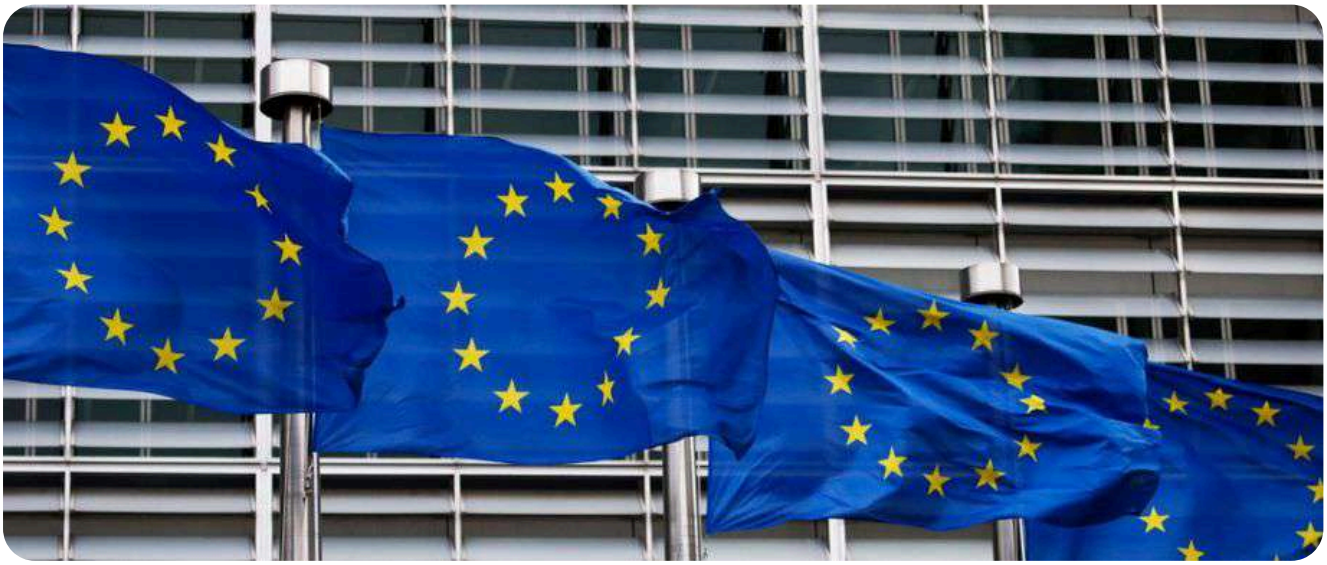
In this issue, we showcase MedTech Europe's active role in shaping European medical technology policies, including our recent responses to the European Commission's calls for evidence and consultations.

We also invite you to explore our new call to action and dedicated website on Antimicrobial Resistance (AMR) and Healthcare-Associated Infections (HAIs).

As we look ahead to the UN Climate Change Conference (COP30) in Belém later this month, don't miss our latest podcast featuring Sigrid Linher, Director of Sustainability & Environment, who shares insights on the importance of harnessing medical technolgy innovation for healthcare decarbonisation.

Read on to discover more.

Highlights of the month



MedTech Europe's input to the Digital Simplification Package consultation

Domenico Sorrentino
Manager Public Affairs

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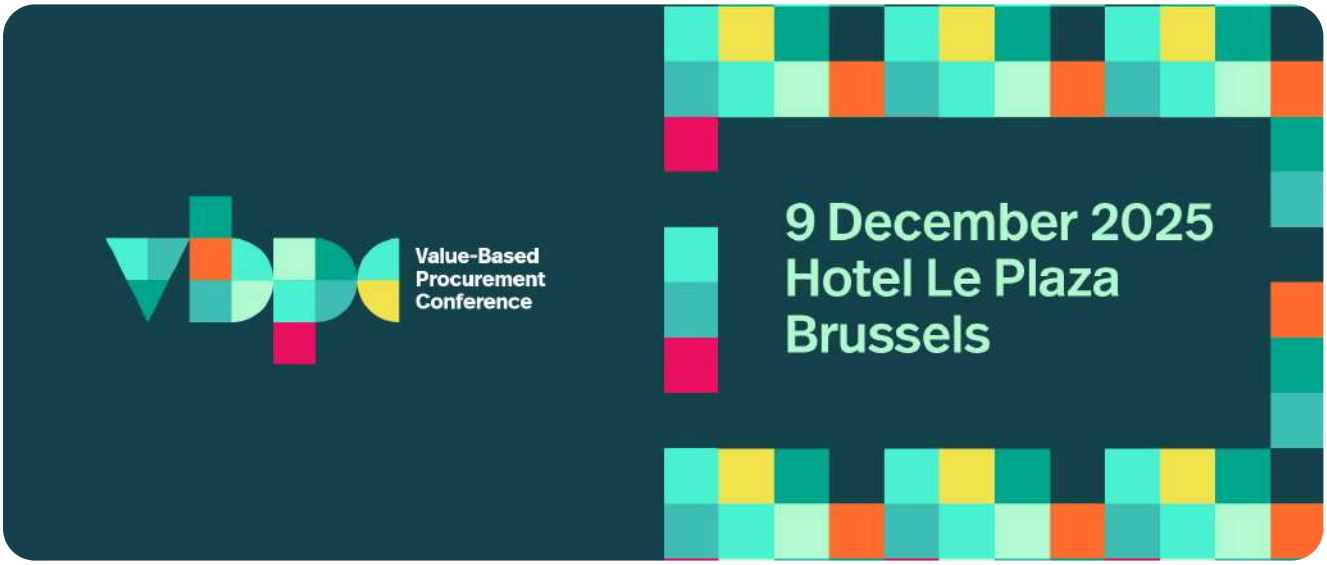
The European Commission opened a Call for Evidence on the Digital Omnibus.

The Digital Omnibus will include measures to quickly reduce the burden on businesses in the following areas: the data acquis (Data Governance Act, Free Flow of Non-Personal Data Regulation, Open Data Directive), rules on cookies and other tracking technologies laid down by the ePrivacy Directive, cybersecurity related incident reporting obligations, the smooth application of the AI Act rules, and other aspects related to electronic identification and trust services under European Digital Identity Framework.

The European Commission's presentation of the Digital Simplification package is expected on 19 November 2025, along with the presentation of the Data Union Strategy and a proposal for the revision of the Cybersecurity Act.

MedTech Europe submitted its response to the Call for Evidence on 14 October 2025.

The submission has been coordinated via the Digital Health Committee and was based on the previously published position paper on simplification of EU digital legislation.



One month to go: Seventh European Value-Based Procurement Conference

Hans Bax
Senior Adviser Value & Innovation-based Access

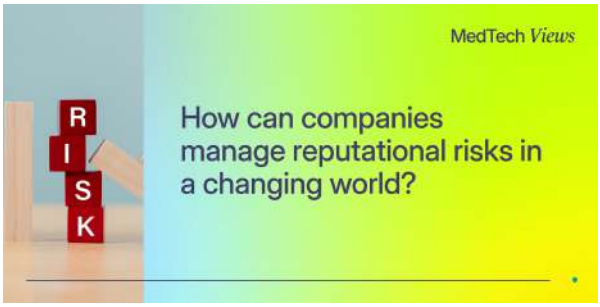
On 9 December 2025, stakeholders from the Value-Based procurement community will gather to discuss how Value-Based Procurement can improve patient outcomes while promoting sustainability in healthcare.

This year's theme will focus on "Driving Value in Healthcare – Scaling Up Value-Based Procurement across Europe".

Discover the full agenda on the official website.

REGISTER

Blogs & podcasts



Managing reputational risk is becoming increasingly critical in a world of constant change and heightened public scrutiny. Building and maintaining trust requires strong risk management strategies that address fraud, cybercrime, compliance, and data protection.

READ THE FULL BLOG

Health drives our lives, from our personal well-being to the health of our planet and economy. On the road to UN Climate Change Conference COP30 in Belém, we shine a critical spotlight on harnessing medical technology innovation for healthcare decarbonisation.

LISTEN TO THE PODCAST

In short

IHI 2026 Calls: draft text of call 12 now available – start building your proposal with your consortium

Jeroen Schuermans, Director Strategic Initiatives

Do you want to help shape the future of health through cross-sector research and innovation?

The draft text of IHI call 12 is out, offering early insights into the first 2026 call. With the new calls on the horizon, now is the perfect time to activate your network and start shaping strong proposals.

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Waste as a resource: how updated waste shipment rules can support more circularity in healthcare

Sigrid Linher, Director Sustainability & Environment

Modernised waste shipment rules play an essential role in the mission of accelerating the EU's transition to a circular economy.

By 31 October 2025, the European Commission consulted stakeholders on harmonising the classification of certain waste types (so-called “green-listed” waste) to facilitate their shipments across borders.

In its consultation response, MedTech Europe recommends upholding the green-list status for non-hazardous intra-EU e-waste shipments beyond 1 January 2027, including the exemption for shipments under 20kg.

Besides, we outline general improvement suggestions to support more circularity in healthcare.

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Greener, Smarter Healthcare: time to digitalise near-patient testing

Vaida Jukneviciute, Manager *In Vitro* Diagnostics

For healthcare professionals, near-patient (point-of-care) testing is an essential tool – enabling faster decisions, improved patient outcomes, and streamlined workflows.

Yet current EU regulations still require paper Instructions for Use (IFUs) with each test, even when healthcare professionals would choose electronic version.

MedTech Europe has released a new booklet – “Greener, Smarter Healthcare: Electronic Instructions for Near-Patient Tests” – highlighting how digital transformation can make clinical practice more efficient and sustainable.

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Joint industry paper calling for digital label for importer and authorised representative information

Jana Russo, Manager Medical Devices

Recently, mandatory requirements for additional product information for medical devices (MDs) and *In Vitro* diagnostic medical devices (IVDs) have exponentially increased.

MedTech Europe, AESGP, COCIR and EUROMCONTACT call on the European Commission to allow via the upcoming targeted revision of the EU rules for medical technologies, as a first step, that the importer and authorised representative information may be provided via a digital label

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Safeguarding Europe's future – new call to action and website on Antimicrobial Resistance (AMR) and Healthcare-Associated Infections (HAIs)

Vivien Reinhardt, Officer Public Affairs

MedTech Europe has issued a Call to Action on policymakers to take rapid, targeted action on AMR and Healthcare-Associated Infections (HAIs).

Curious about the role of the sector in addressing AMR/HAIs? Our newly updated mini-site on the role and health economic benefits of our technologies is now live here.

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Join MedTech Europe at the Politico Healthcare Summit

Melanie Wahl, Head of Public Affairs

MedTech Europe will sponsor the Politico Healthcare Summit on 18–19 November 2025 in Brussels.

Oliver Bisazza, CEO of MedTech Europe, will spotlight how medical technologies advance access, innovation, and sustainability across Europe. Join our Opening Remarks (18 November at 9:05) and In Focus session (19 November at 10:15) - and visit our booth to meet the team and continue the conversation!

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MedTech Europe supports the European Patients Forum congress

Dominika Suchonova, Manager Communications

MedTech Europe officially supports the European Patients Forum congress, which will take place on 26 and 27 November 2025 in Brussels.

The event is the largest European congress focused on patient involvement in healthcare.

We look forward to taking part in the discussions, with Pierre-Yves Brevet, Senior Manager IVD at MedTech Europe, speaking in the session "COVID-19, 5 Years Later: *Have Our Healthcare Systems Recovered?*" on 26 November 2025.

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Refresher webinar on the Conference Vetting System (CVS) and e4ethics

Dhana Ong, CVS Compliance Officer

Whether you are a new or experienced submitter, or simply check the status of events, we invite you to join our upcoming webinar on the Conference Vetting System (CVS) and e4ethics.

This training is designed to provide clarity and practical guidance for all users.

The session will be divided into two key parts: understanding the Conference Vetting System (CVS)/e4ethics assessment criteria and the event submission process.

You can register here.

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Bringing a global regulatory perspective to AfriSummit 2025

Clare Birmingham, Manager International Affairs

MedTech Europe's International Affairs team contributed to AfriSummit 2025 in Cairo, Egypt, sharing insights on how global regulatory frameworks, including the EU Medical Device and *In Vitro* Diagnostic Regulations, can help inform regional approaches and contribute to discussions on medical technology regulation in Africa.

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MedTech Europe
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