08 December 2025

Highlights of the fourth EMA-MedTech Europe bilateral meeting

21 November 2025 – chaired by Alberto Ganan Jimenez, Head of Committees and Quality Assurance Department

1. Welcome and introduction

The Chair welcomed the MedTech Europe delegation, highlighting the timing of the bilateral exchange in light of the ongoing targeted revision of the Medical Devices Regulation (MDR) and In Vitro Diagnostic Medica Devices Regulation (IVDR) by the European Commission (EC), and the initiatives taken by the Agency to support this sector.

2. MedTech Europe key priorities and strategy

MedTech Europe presented its priorities for the period 2025–2030, emphasising the importance of making Europe a more attractive location for medical technology innovation while maintaining high quality standards and ensuring patient safety.

The need for a consistent approach to regulatory reporting requirements across several bodies, and the importance of securing funding for the medical device sector and relevant health programmes (particularly for public health emergency activities) were discussed.

The Agency confirmed that innovation and competitiveness are shared priorities, within the scope of its mandate, as reflected in the European Medicines Agencies Network Strategy to 2028. Several activities are being further enhanced to provide support to the med tech sectors (such as the early dialogue opportunities via Innovation Task force, Qualification of Novel Technologies) and strengthen the engagement with key players (such as the establishment of Combination Products Operational Group, COMBO). The Agency is also actively participating in the COMBINE initiative looking at the interfaces between the MDR/IVDR, Clinical Trials regulation and the regulatory framework for medicinal products.

It was further clarified that the Agency's remit under Regulation (EU) 2022/123 is to coordinate urgent actions within the Union in relation to the management of supply and demand issues of critical medical devices during declared public health emergencies (PHE). This has resulted in the establishment of the Executive Steering Group on Shortages of Medical Devices (MDSSG) and of the supporting Medical

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Device Shortages Single Point of Contact Working Party (MD SPOC WP), in addition to the development of the Critical Medical Device System (CMDS). The MDSSG, the MD SPOC WP and the CMDS are required to be activated only in case of a declared PHE. Agency's cooperation with Health Emergency Preparedness and Response Authority (HERA) was also confirmed.

With regard to concerns relating to preparedness activities and funding, MedTech was invited to also raise these with the relevant European Commission services and other relevant bodies, as appropriate.

3. MedTech Europe position on legislation

MedTech Europe's position on the upcoming revision of the MDR/IVDR and the AI Act, as well as its proposals to increase system efficiency and strengthen the EU's innovation capacity were presented and noted.

It was clarified that, as it is not an official party to the legislative process, EMA is not in a position to comment on any of the proposals made. MedTech Europe was invited to also share its position and proposals with the EC.

The Agency confirmed its willingness to continue providing support and take appropriate action within its remit to ensure that innovative medicines and medical devices reach patients in a timely manner.

4. MedTech Europe feedback on the expert panels and HTAR interface

MedTech Europe shared positive feedback from its members on their experience with the expert panel advice on orphan and paediatric use medical devices and provided some clarity on the reasons for the limited use of this supportive mechanism so far.

The possibility for extending the scope of activities and pilots of the expert panels (e.g. breakthrough designation, broadened types of medical devices and in vitro diagnostics), the need for clear oversight of authorised devices across Europe and the need to establish formalised pathways with clear incentives were briefly discussed.

MedTech Europe also outlined the challenges associated with the Joint Scientific Consultation (JSCs) envisaged under the Health Technology Assessment Regulation (HTA) and asked for enhanced alignment between scientific advice expert panels, HTAs and notified bodies.

The Agency confirmed the importance of process alignment and confirmed the positive experience in including of HTA observers in the expert panel advice process.

5. Update from the EMA on scientific advice activities

MedTech Europe confirmed that members had a positive experience when interacting with the scientific advice expert panels. The need for an interlinked regulatory pathway to enhance predictability, and concerns regarding confidentiality, were highlighted.

The Agency noted these points and clarified that no confidential information will be published following scientific advice. The legal nature of the conformity assessment advice was also emphasised.

6. Combination product regulatory pathway optimisation

MedTech highlighted the challenges faced by combination products and the need for streamlined approval pathways.

The EMA acknowledged the points made and confirmed the establishment of the COMBO, a group that aims to facilitate the dialogue on regulatory challenges at the intersection of pharmaceutical and medical device (including in vitro diagnostics) frameworks.

It was confirmed that the COMBO group intends to hold ad hoc meetings with industry stakeholders and will it publish meetings agendas and highlights.

7. Conclusions and next steps

The group agreed to continue the dialogue on how best to support the medical device sector, with the aim of enhancing speed and predictability to deliver innovative medical devices to patients.

MedTech Europe was encouraged to continue engaging with the Agency, raising guidance needs and concerns, and participating to relevant activities, including the meetings of the Industry Standing Group.