EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31st July 2024
EMA/75640/2024

Highlights - Third EMA-MedTech Europe bilateral meeting

02 July 2024 – chaired by Marie-Hélène Pinheiro

1. Welcome and Introductions

The Chair and EMA Executive Director welcomed the MedTech Europe delegation and recognised the importance of collaboration between the medical device (MD)/in vitro diagnostic (IVD) and pharmaceutical sectors, given the impact of new technologies and Artificial Intelligence (AI) on innovation in both sectors.

Similarly, MedTech Europe recognised the importance of the engagement to address common challenges and promote opportunities in order to ensure timely access of innovative medicines and devices to patients in Europe.

2. MedTech Europe 2024-2029 key priorities and update on the MDR and IVDR implementations

MedTechEurope provided an overview of its roadmap and priorities for 2024-2029 highlighting the importance of constructively shaping the Europe's regulatory environment and taking into account the specificities of the medical device/in vitro diagnostic industry, especially for sectors related to digital health/AI, sustainability and crisis preparedness.

MedTechEurope presented the status and its vision for the Medical Device and In-Vitro Diagnostic Regulations implementation and efficiency optimisation in Europe.

The EMA noted MedTech Europe positions and invited them to share their views with relevant parties.

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3. MedTech Europe feedback on topics of common interest (e.g., EMA expert panel activities (inc. scientific advice), HTA, medical devices shortage management, combination product trials, artificial intelligence, etc.)

MedTech Europe presented and where relevant, provided feedback on MD/IVD related activities within EMA remit such as the Medical Device Expert Panels, the Health Technology Assessment (HTA) Regulation implementation, requirements for medical devices shortage reporting, AI act implementation and international collaboration.

MedTech Europe activities and challenges experienced were acknowledged. EMA provided an overview of the assessment done so far by the Medical Device Expert Panels for Clinical Evaluation Consultation Procedure (CECP) and Performance Evaluation Consultation Procedure (PECP) and, as announced during the last Industry Standing Group (ISG) meeting, it was clarified the intention to operationalise these activities upon conclusion of the current pilot phase.

EMA also clarified its limited role foreseen by the HTA Regulation and provided further insights on the future interface with the HTA coordination group through the secretariat for the technologies in scope. MedTech Europe was invited to participate to future meetings of the ISG where discussions on the HTA regulation implementation will be a recurrent topic.

The Agency's shortage reporting requirements for medical devices during public health emergencies were clarified. MedTech contribution to the development and further refinement of the Critical Medical Device Shortages IT system (CMDS), amongst other stakeholders, was acknowledged. MedTech Europe highlighted the high value of the information exchange with industry and close cooperation between EMA and HERA in the EMA-HERA Joint Industrial Cooperation Forum (JICF) Working Group on data collection on medical devices.

EMA updated on activities concerning AI (i.e. 2023 HMA/EMA workshop; the AI workplan to 2028; AI reflection paper) and encouraged MedTech Europe to participate to relevant discussions on this topic including a workshop planned for November 2024. The importance of global alignment was acknowledged.

4. Impact on combination products (incl. companion diagnostics) of the new pharma regulations

The activities undertaken under the EC led project COMBINE were acknowledged and MedTech Europe involvement confirmed.

5. Other legislative/policies EU proposals impacting the medical devices and pharma sector (e.g., Green Deal, European Health Union and European Health Data Space)

MedTech Europe views on several policy and legislation proposals (European Health Data Space; Green deal) were acknowledged. The impact of these proposals on the medical device as well as pharmaceutical sectors was highlighted and recognised. MedTech Europe was invited to participate to relevant public consultation activities in order to reflect their perspectives.

6. MedTech Europe feedback on international activities impacting EMA's remit

MedTech Europe presented the topics discussed at the International Medical Device Regulators Forum and Organisation for Economic Co-operation and Development considered to potentially impact and/or be of interest to EMA. The Agency welcome the information shared and asked to continue to be kept informed on these activities.

7. A.O.B MedTech Europe Stakeholder engagement on EMA activities overview and next steps

The Agency encourages MedTech Europe to participate as much as possible to stakeholder engagement activities such as topic specific events and the meetings of the Industry Standing Group (ISG) where medical devices related topics are being discussed and may affect MedTech Europe members.

8. Conclusions and next steps

The need to continue the already fruitful engagement was recognised in order to further strengthen the alignment on common areas of interests.