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Highlights of the second EMA-MedTech Europe bilateral

11 April 2023– chaired by Marie Helene Pinheiro

1. Welcome and Introductions

The EMA executive director welcomed MedTech Europe representatives highlighting the importance of collaboration and strategic discussion to address the challenges linked to the complex sector of medical device technology. The importance of the growing interplay between EMA and MedTech Europe to ensure Europe's access to safer and more effective medical devices/IVDs was also recognised.

In this context MedTech Europe contribution to the activities of the Industry Standing Group (ISG) and the EMA-HERA Joint Industrial Cooperation Forum working group on data collection was highlighted and valued.

2. MedTech Europe update on the medical devices/IVD implementation status impacting EMA's activities

The intrinsic diversity of medical technologies means also higher complexity in terms of regulatory and operational aspects. Europe is considered an important market for this sector, the second largest world market after the US[1].

MedTech Europe provided an overview of the current status and challenges experienced for implementing the medical device and in vitro diagnostic Regulations.

For drug-device combination products (i.e. medicinal products forming an integral part with the medical devices and co-packaged medicinal products, or co-packaged with a medical device or with medical device referenced in the product information but not supplied together), although the approval of such configurations were already encountered before the new medical device/IVD Regulations, new requirements were introduced in particular for medicinal products forming an integral form with medical devices i.e. introduction of oversight by notified body for the device component in such combination.

[1] 27,3% of the market in value, the US standing for 43.5% (In: The European Medical Technology Industry in figures 2022)

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The need for a more streamlined and coordinated approach was flagged also for the approval of medicinal products clinical trials that include the use of a medical device in terms of the implementation of requirements and parallel processes required on the medical devices side.

Another area that was also identified as in need of a more integrated development approach was the field of health digital solutions, a growing area in terms of business and complexity.

3. Update on EMA role(s) in medical devices and *in vitro* diagnostic medical devices' regulation

EMA provided an overview of the activities falling under the Agency's responsibilities which have been extended following the publication of Regulation (EU) 2022/123. It was highlighted how most of the topics are being addressed in other fora and in particular through the meetings of the ISG.

EMA clarified responsibilities in relation to:

- Provision of advice to the European Commission and to the Medical Devices Coordination Group on scientific, technical and clinical aspects related to medical devices.
- Provision of scientific advice on clinical development and/or clinical investigation proposals of high-risk medical devices through the Expert panels currently being developed in a pilot project. MedTech Europe members were encouraged to participate as much as possible and present their proposals for selection during the pilot phase.
- Activities related to evidence generation for digital health technology capacity building, scientific advice and qualification, publication of related guidance and organisation of dedicated workshops. At this regards the upcoming multi-stakeholder workshop on qualification of novel methodologies was flagged. It was stressed the fact that for digital health technology EMA relies on notified bodies for the assessment linked to General Safety and Performance Requirements (GSPR) while questions are asked directly to the applicants for benefit/risk considerations.
- On-going discussion on the possibility for scientific advice pilot for medicinal products used in combination with medical devices or companion diagnostic specifically in prospective evidence generation plan and procedural aspects Upcoming discussion at the July 2023 R&D platform was flagged.
- Activities linked to EC/HMA/EMA ACT EU initiative, specifically entailing the setting up of a multi stakeholder platform, and methodology guidance facilitating aligned clinical trial guidance development including medicinal products used in combination with *in vitro* diagnostic medical devices within clinical trials (Guidance on the interface between Regulation (EU) 536/2014 on clinical trials for medicinal products for human use (CTR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)).
- Activities linked to drug-device combination products evaluations and its interlinks on assessment between medicines regulators and notified bodies (Article 117 applications). Challenges and inconsistencies were discussed on establishing the correct device classification and establish the responsibilities of lifecycle management requirements. Overview of activities addressing such challenges was provided.
- Consultation by notified bodies on suitability of the companion diagnostic with a concerned medicinal product as part of the conformity assessment for certification purpose. It was highlighted that data on the test used in the clinical trials is also reviewed during marketing authorisations

where a biomarker is used. Details on submission pipeline were considered helpful to receive for planning purposes as the transitional period approaches.

- For the already established process for Consultation procedures on medical devices incorporating ancillary medicinal substance by notified bodies on quality and safety aspects of the medicinal substance incorporated in the medical device, it was mentioned that further implementation is needed on information sharing and its analysis of relevant serious incidents of an ancillary medicinal substance incorporated in a medical device for which (substance) the EMA has been consulted in the past.
- Activities of medical devices Expert panels related to the clinical/performance evaluation consultation procedures (CECP/PECP).
- Activities related to monitoring and mitigating shortages of critical medical devices in the context of public health emergencies. The importance of these activities was highlighted.

4. Conclusions and next steps

Both parties agreed on the need to foster collaborating to further enhance common understanding of the increasing identified cross sectors activities, role and responsibilities. MedTech Europe participation to the ISG and any other fora was encouraged.