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European Medicines Agency

Highlights - 2nd EMA-COCIR Bilateral meeting

07 October 2024 Chaired by Marie-Hélène Pinheiro, EMA Industry Stakeholders Corporate Liaison

1. Welcome and introductions

The Chair and Executive Director of the EMA welcomed the COCIR delegation and recognised the important contribution made to ensure alignment between the medical technology sector and relevant activities of the EMA and the European Commission.

The need to further clarify possible links between the sector represented by COCIR and EMA activities was acknowledged and COCIR's input in the upcoming public consultation on the European Medicines Authorities Network Strategy to 2028 was highlighted, in that context.

2. COCIR priorities for the next 3-5 years and pipeline trends

COCIR outlined the key priorities for the next 3-5 years and provided an overview of emerging trends for its sector. The promotion of innovation and competitiveness was identified as crucial to the attractiveness of innovative development in the European Union. The need to ensure fit-for-purpose legal and regulatory framework was highlighted. COCIR collaboration in the activities of the Health Emergency Preparedness and Response Authority (HERA) to ensure availability of critical medical devices was acknowledged.

Emerging trends were outlined in several areas including Artificial Intelligence (AI), environmental sustainability and the extension of hospital care settings to patient's premises through wearable solutions.

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3. Discussion on EMA medical device related activities

The EMA provided an update on activities within the Agency's remit related to high-risk medical devices, medical devices and companion diagnostics used in combination with medicines, digital health solutions used in the development, use or monitoring of medicinal products and the monitoring of critical medical device shortages during a public health emergency (PHE).

- More specifically in relation to EMA medical Device expert panels activties, an overview of EMA activities related to class IIb active devices destined to administer or remove a medical product that have undergone a clinical evaluation consultation procedure (CECP) with the Medical Device Expert Panels and on the ongoing pilot where medical device manufacturers can ask for advice on an a possible orphan device status and the sufficiency of clinical data/clinical strategy, was also provided

  Additionally, EMA informed COCIR that it will reopen in early 2025 the possibility for manufacturers of class III or the above-mentioned class IIb active devices to ask for advice from the Expert Panels on their clinical strategy development / proposals for clinical investigations.

- The Agency's growing experience in scientific advice and qualification for digital health technologies was highlighted and COCIR/COCIR members invited to participate in the upcoming public consultation on the first draft qualification opinion of an AI based histology assessment tool to be used in registration studies. The Questions and answers: Qualification of digital technology-based methodologies to support approval of medicinal products, the published article Evolving regulatory perspectives on digital health technologies for medicinal product development and the action plan Future-proofing Qualification of Novel Methodologies (QoNM) were also highlighted. In addition, COCIR was invited to participate to the HMA/EMA multi-stakeholder workshop on artificial intelligence (AI) - enabling the safe and responsible use of AI where the use of AI in medicinal product lifecycle and the EMA/HAM AI Road Map will be discussed.

- Scientific and regulatory advice activities to ensure identification of the appropriate development pathway of both medicines and medical device/companion diagnostics were highlighted, with a forthcoming publication of an analysis of 9 scientific advice cases were highlighted.

Early consultation tools were welcomed by COCIR and seen as particularly important for small-, medium size companies, although it was recognised that so far no COCIR members have applied.
The need to consider the contribution of new actors in digital health solutions (e.g., software providers) and cybersecurity considerations was acknowledged.
COCIR presented its views on the implementation of the medical device regulation, outlining challenges and proposing recommendations to ensure clarity of responsibilities and availability of innovative devices on the European market. The EMA noted the points raised and advise COCIR to refer to the European Commission for further discussions.

Regarding shortages of critical medical devices during PHEs, COCIR's support and contribution in the development of the Critical Medical Device (CMDS) IT system was acknowledged.

Ongoing discussions with industry stakeholders through the EMA-HERA JICF subgroup on medical devices on data analysis were outlined.

COCIR acknowledged the cooperation and highlighted the need to recognise the specificities of the medical devices/Technology sector which includes different actors and components (in particular in

terms of the numbers of involved supply chain actors which might in individual cases exceed 1000 involved actors.

The multiple, sometime (perceived) overlapping requests for device reporting within the EU and globally, is becoming more and more complex for companies to understand and comply with. It will be important that clarity is given so that if a future public health emergency was to occur, all actors can react/comply timely and as efficiently as possible.

4. COCIR's EHDS impact analysis and feedback

COCIR presented its views on the European Health Data Space (EHDS) regulation, highlighting the positive intent of the legislative proposal to reduce barriers and facilitate access to health data for the benefit of research and innovation in Europe. The need for well-defined vision, workable frameworks and reduced fragmentation through alignment and early engagement with stakeholders was highlighted as a key factor for the success of the implementation of such new Regulation.

The EMA shared similar views on opportunities and risks represented by the EHDS regulation in its activties. Early dialogue with different stakeholders and data specialists in order to ensure appropriate implementation of the regulation was considered fundamental. Pilot activities exploring the DARWIN EU® interface with EHDS were noted.

5. COCIR specific position on EU AI Act implementation

This specific item was not taken due to time constraints. COCIR was encouraged to participate to the HMA/EMA multi-stakeholder workshop on artificial intelligence (AI) - enabling the safe and responsible use of AI (05th November 2024).

6. Summary of follow up items and close of the meeting

The chair thanked COCIR delegation for the interesting exchange and encouraged to keep an open dialogue on this important sector.