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European Medicines Agency

Highlights - 6th EMA-EuropaBio bilateral meeting

01 October 2024 – Chaired by Marie-Hélène Pinheiro, EMA Industry Corporate Liaison

1. Welcome and introductions

The Chair welcomed EuropaBio delegates highlighting the interest in learning more on 2024 developments and position on key legislations concerning biotechnological medicines including EuropaBio priorities and vision for the coming years.

2. EuropaBio priorities and vision for future Biotechnology industry and pipeline trends in Europe

EuropaBio provided the results of a study detailing the Impact of the EU's General Pharmaceutical Legislation on Europe's innovation ecosystem and biotechnology companies. According to EuropaBio, certain provisions included in the revised pharmaceutical legislation proposals may reduce incentives for innovators and decrease the attractiveness of the EU for development and investment in innovative life sciences . The impact to small innovators, rare diseases and Advanced Therapy Medicinal Products (ATMPs) developers were flagged. The same risks were recognised by the recently published "The future of European competitiveness" (Draghi report) as well as by the European Commission with the proposals to boost biotechnology and biomanufacturing in the EU (Biotech act). Key priorities addressing the concerns reported were discussed.

It was clarified that EMA, not being an official party to the legislative process, was not in position to comment on any of the proposals made. Therefore, EuropaBio was referred to the European Commission for any specific follow-up discussions in relation to the new pharmaceutical legislation. EuropaBio was encouraged to provide more examples and details on areas where more support and guidance would be strategically essential or gaps identified within the current pharmaceutical framework and future proposals to foster biotechnology medicines in Europe.

EuropaBio was also encouraged to incentivise its members to engage at the level of the Quality Innovation Group (QIG), which is an operational expert group set up to support the translation of

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innovative quality approaches to the design, manufacture and quality control of medicines, to ultimately bring new therapies and help improve the supply of existing medicines to patients.

EuropaBio also emphasised the importance of recognising biotechnology as a critical technology for the EU and asked for consistency and clarity across all legislative pathways. According to the presented pipeline trends, expected increase in biological share especially for rare disease and oncology areas was identified. The EMA outlined the ongoing activities in supporting to innovation and helping building expertise on new technologies (such as the QIG expert group, Innovation Task Force, Biologics Working Party, Biosimilar Medicines Working Party (BMWP), other early interaction mechanism, reliance activities under the Mutual Recognition Agreement, and ICMRA pilot for collaborative assessment) and encouraged EuropaBio and its affiliated members to keep engaging and bringing for discussions their innovative developments..

3. Specific EuropaBio Clinical Trial Regulation (CTR) implementation and ACT EU position

EuropaBio generally recognised the successful implementation of the Clinical Trials Regulation (CTR) and the role played by regulators in providing support to companies, particularly in relation to transition of clinical trials from EudraCT to CTIS, and revision of CTIS transparency rules.

The remaining operational challenges slowing down clinical trials approval in Europe were outlined, asking to ensure more flexibility and alignment between all parties involved. The points raised were acknowledged and it was mentioned that in relation to CTIS functionalities prioritisation of items for resolution is in place. On the operational side, several activities including CTR collaborate and MedEthicsEU EU will contribute to achieve harmonisation.

EuropaBio participation to the ACT EU Multistakeholder Platform Advisory Group (MSP AG) and MSP annual meeting was encouraged.

4. EuropaBio Variation Regulation and Guideline specific feedback

EuropaBio provided sector specific considerations on the proposed revision of the Variations Guidelines. The revision was welcomed but amendments ensuring further simplification and flexibility for MAHs with medicinal products in EU and non-EU were also suggested.

The EMA confirmed the close dialogue and cooperation with the European Commission and member states in drafting/updating guidance to prepare for the application of the amended Variations Regulation (Regulation (EU) 2024/1701 of 11 March 2024) from 1 January 2025. It was further confirmed that guidance is expected to be published in the coming weeks.

EuropaBio was encouraged to participate to the discussions of the next meeting of the Industry stakeholder platform on the operation of the centralised procedure for human medicines, scheduled for the 22nd of November 2024, and on the interested party meeting with the Co-ordination group for Mutual recognition and Decentralised procedures – human (CMDh), scheduled for the 20th of November 2024, where additional insights on the transition period may be discussed.

5. EMA SME office support activities

The EMA provided an overview of the specific incentives and support for micro, small and medium enterprises (SMEs) including a dedicated contact point, regulatory assistance and SME briefing meetings, and encouraged EuropaBio to promote such activities within their SMEs members. In particular, EMA encouraged EuropaBio to raise awareness of its members on a feedback survey on early development support, including SME briefing meetings. As presented during the July meeting of the R&D platform, the survey is targeting early engagement support platforms and aims at monitoring the implementation of the framework for interaction between EMA and industry stakeholders. The survey is targeting all pharmaceutical irrespective of size, which benefitted from such support between 1 January - 15 December 2024. EuropaBio was also asked to encourage its SME members to participate to the upcoming SME info day (18 October) and contribute to the ongoing EMA SME survey 2024. EMA highlighted a SME roundtable to be organised in late 2025 in the context of the 20-year anniversary of the SME regulation. EuropaBio will be invited to the roundtable and EMA invited to EuropaBio to collect information from their members on experience with the SME regulation.

6. Summary of follow-up items

Close of meeting

Specificities of the biotech sector were recognised as pivotal to enhance innovation in Europe. Further engagement on key areas were welcomed.