29 January 2025
EMA/5433/2026
European Medicines Agency

Highlights – 7th EMA-EuropaBio bilateral meeting

20 January 2026 – Chaired by Juan Garcia Burgos, Head of Public and Stakeholder Engagement Department

1. Welcome and introduction

The Chair and Executive Director welcomed the EuropaBio delegation, encouraging an open dialogue to collectively explore how the current and future legislation could support innovation and competitiveness in Europe, as well as the transformation of the regulatory system.

2. EuropaBio update on pipelines and emerging biotechnologies

EuropaBio provided an overview of global trends in the biopharmaceutical industry, focusing on clinical trial applications and the authorisation of new active pharmaceutical substances. They also highlighted areas in which Europe could specialise, such as CAR T cell therapy, gene therapy, in vivo treatments and radioligands.

The importance of supporting small innovative companies and enhancing the EU's attractiveness to global scientific experts was emphasised.

The activities of the Agency activities conducted under the Accelerating Clinical Trials in the EU (ACT EU) initiative were recognised as important mechanisms for improving the clinical trials environment in the EU and attract more companies to conduct clinical trials in Europe.

3. EuropaBio position and proposals on securing innovation in the EU

EuropaBio shared its views on the key priorities for implementing the revised pharmaceutical legislation and the Biotech Act, emphasising the importance of coherence across legislation, transparency regarding the implementation activities, and close collaboration with stakeholders.

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The update presented at the 15th meeting of the Industry Standing Group was welcome, as was the publication of a dedicated webpage for updates on the implementation of the revised pharmaceutical legislation. The activities of EMA with international partners were also highlighted, including the recent extension of the scope of the OPEN framework. There was a call for more transparency on artificial intelligence-related activities and the use of AI tools.

The Agency acknowledged the importance of transparency regarding the new legislation implementation activities and confirmed that additional details and engagement activities will follow the publication of the final legislative text. EMA is also planning a workshop to discuss some aspect of the implementation of the pharmaceutical legislation.

Support to the European Commission (EC) in the medical device sector was confirmed by the EMA and details were shared on the Agency's activities linked to the COMBO (Combination Products Operations Group) and COMBINE initiatives.

It was also confirmed that more guidance on AI would be explored with the recently established AI industry focus group. Clarifications were provided on the use of certain AI tools by EMA and EU Network, such as scientific explorer, in support to Agency's and network activities. Inclusion of the EC AI office in the activities of the Network Data Steering Group (NDSG) and EMA compliance supervision from the European Data Protection Supervisor (EDPS) were briefly discussed.

4. International cooperation and EU global leadership

EuropaBio shared some reflections, highlighting the importance of maintaining all activities already in place with global partners, and emphasising the Agency's key role in promoting international reliance and providing training to countries worldwide.

The Agency confirmed its support for current initiatives and stressed the importance of EuropaBio members to take advantage of supporting activities involving international authorities such as the ICMRA PQKM collaborative assessment and the collaborative hybrid inspection pilots , OPEN and the EMA-WHO pilot on post approval changes. For development support, in addition to the parallel FDA-EMA scientific advice, the Agency highlighted that the QIG meetings are observed or can be done jointly with Int. Partners upon company request. (Quality Innovation Group

5. Global supply chain disruption

EuropaBio shared its views and recommendations on ensuring global resilience, as well as its thoughts on the use of targeted measures for procurement and stockpiling. They welcomed the approach taken by the Agency to date and emphasised the importance of continued dialogue on areas in which the industry can contribute.

The EMA confirmed its approach to consulting stakeholders on the vulnerability assessment methodology and Union list of critical medicines and said it would continue to provide updates as required.

6. Closing

The meeting was a valuable opportunity to share views and learnings on key aspects related to the biotech sector.