22 January 2026

Highlights of the 8th EMA-Medicines for Europe bilateral meeting

15/12/2025 – chaired by Melanie Carr, Head Stakeholders and Communication

1. Welcome and introduction

The EMA Executive Director welcomed the delegation from Medicines for Europe, emphasizing the vital role of the generic and biosimilar medicines sector in strengthening the European healthcare system. The continued and constructive dialogue on key topics present in the agenda, such as the implementation of new legislative requirements and related acts, was appreciated.

Medicines for Europe delegation welcomed the opportunity to bring the views and challenges experienced by its members to the attention of the Agency.

2. Medicines for Europe expected pipeline trends and submission predictability

Medicines for Europe provided feedback from its members on initiatives to improve submission predictability and discussed some proposals for improvement.

The Agency welcomed the proposals regarding the Centralised Procedure and reaffirmed its ongoing engagement with both industry and the network (including CMDh) through the established focus group on submission predictability. The need for applicants to reconfirm their submission timelines three months prior to filing and to promptly inform the Agency of any unforeseen delays was emphasised.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

3. Medicines for Europe priorities for the implementation of the pharmaceutical legislation

Medicines for Europe provided its position on the key priorities to consider when implementing the revised pharmaceutical legislation. The need to ensure stakeholders engagement and clarity on the Agency's implementation roadmap was highlighted as key to allowing for companies preparedness.

The EMA welcomed the proposals and confirmed that, as presented during the 15th meeting of the Industry Standing Group (ISG), more details will be communicated to stakeholders via the ISG as well as the established industry stakeholder platforms and dedicated events. Additionally, it was noted that a dedicated webpage on the Agency corporate website will be published as well as an industry newsletter to provide regular updates.

4. Biosimilars in the international context

Medicines for Europe flagged the importance of ensuring clarity and guidance to streamline the global biosimilar development and to ensuing a future-proof, science-based biosimilar regulatory approach.

The Agency confirmed its continued commitment to to supporting biosimilar development and provided an update on recent activities, which included a public consultation on the reflection paper on a tailored approach in biosimilar development, a workshop on a tailored clinical approach in biosimilar development and contribution to the activities related to the ICH M18, the IPRP (International Pharmaceutical Regulators Programme) and the clusters with partner authorities.

Medicines for Europe was asked to encourage its members to take advantage of the already available procedures, specifically the parallel scientific advice with US FDA. Companies were also encouraged to contribute to the dedicated survey on this procedure, expected to be launched next year, as presented during the 15th industry stakeholder platform on research and development support.

The EMA also invited Medicines for Europe companies to engage in an early dialogue on a tailored approach for the product development.

5. Single global development

Medicines for Europe outlined challenges experienced by its members when sourcing the reference product. The findings from the IGBA (International Generic and Biosimilar Medicines Association) report were also acknowledged.

The Agency confirmed the current mandatory EU legislative requirements for bioequivalence studies (generic) and bridging studies (hybrid), to use of EEA sourced comparator. Possible modernisation of the requirement may be provided by the reformed pharmaceutical legislation. It was also confirmed that the use of non-EEA authorised comparator is already envisaged for certain studies.

6. Medicines for Europe views on EMANS Strategy implementation

Medicines for Europe views on priorities when implementing the European Medicines Agency Network Strategy to 2028 through the EMA's single programming document and HMA multi-annual workplan were noted.

7. Conclusions and next steps

The meeting provided an opportunity to gain a better understanding of the specific challenges and opportunities presented by the generics and biosimilars sector.