20 December 2023
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Highlights – Sixth EMA- Medicines for Europe bilateral meeting

6th December 2023 – Chaired by Marie-Hélène Pinheiro

1. Welcome and introduction

The EMA executive director and the Chair welcomed Medicines for Europe delegates to this 6th Medicines for Europe bilateral held in EMA premises, acknowledging the impact thatMedicines for Europe's members have on patients access to medicines.

Medicines for Europe welcomed the opportunity of this annual bilateral meeting to discuss and highlight topics of mutual interest.

2. New Pharma Legislation

Medicines for Europe presented their views on some aspects of the proposed reform of EU pharmaceutical legislation concerning in particular timely access and supply of generic and biosimilar medicines in Europe.

EMA welcomes the publication of the European Commission's legal proposal for the revision of the EU pharmaceutical legislation and EMA Executive director stated that this revision is a unique opportunity to reshape medicines regulation in the EU and make the EU regulatory framework fit for purpose for the next 20 years, taking account of advances in medicine and technology, to promote greater access to medicines for patients and to address the major public health challenges of the future. It was also clarified that EMAis not an official party to the legislative process and will therefore not comment on any of the proposals made but referred Medicines for Europe to the European Commission and thanked them for sharing their views.

EMA has not yet initiated any formal activities related to the implementation of future changes linked to the revision of the pharmaceutical legislation and has not yet started engaging directly with stakeholders. Once preparations for the implementation begin, EMA will involve relevant stakeholders as needed.

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3. Shortages

Medicines for Europe expressed overall positive support for the EMA/DG HERA antibiotic shortage preparedness exercise for winter 2023-2024, highlighting some challenges in collecting forecasts due to data confidentiality reasons and shared some suggestions on potential future improvements to simplify and gain efficiency.

EMA acknowledged the support from Medicines for Europe in encouraging their members to participate in the joint exercise and informed of the ongoing follow-up activities such as communication on avoiding stockpiling to all involved stakeholders through social media platforms and meetings with the relevant groups and working parties.

4. EU availability and access to biosimilar medicines over the next decade – the role of fit-for-purpose regulatory pathway

Medicines for Europe presented IQVIA biosimilar medicines development forecast to 2027 highlighting that a substantial decrease in biosimilar developments and a high concentration of biosimilar candidates covering few therapeutic areas is expected. Addressing economic and regulatory barriers, and in particular the streamlining of Comparable Efficacy Studies (CES) and tailored scientific advice with update of relevant guidance, were highlighted as key to revert this potential trend.

Important aspects related to global discussions and alignment on regulatory, technological and manufacturing flexibility with promotion of comparability and pipeline predictability were flagged.

EMA noted the comments made and clarified that shorter term forecasts were more optimistic with a record number of biosimilar submissions expected in 2023, and highlighting that these submissions still represent about 10% of EMA's annual centralised submissions on average over the past four years. EMA also highlighted the need for Medicines for Europe to take part in 2024 consultations and activities planned in the context of the Biosimilar Medicinal Products Working Party and any upcoming workshop organised at the international level as part of International Pharmaceutical Regulators Programme (IPRP).

5. EMA strategic priorities in the international arena

a. Global leadership in regulatory initiatives

Medicines for Europe emphasised the need for more global alignment in terms of regulatory convergence and streamlining of developments, biosimilarity, comparability requirements and for EMA to maintain its leadership role in that context in view of the experience gained over the last 20 years.

The EMA confirmed international dialogue with other regulators was taking place through IPRP, FDA clusters and bilateral activities were also still important and relevant.

b. Single global development on generic medicines

Medicines for Europe expressed some concerns about the potential complexity of the timely European implementation of ICH M13 A, B and C parts , and the need for industry stakeholder clarity on the status of the implementation progress.

The EMA acknowledged the challenges and confirmed that ICH M13 EU implementation planning was included as part of the Methodology Working Party (MWP) workplan and the latter is being discussed two days after this bilateral meeting also with Medicines for Europe.

6. PFAS

Medicines for Europe acknowledged that this topic is outside the direct scope of the European Medicines Agency, but acknowledged the importance and relevance of sharing with EMA the impact analysis sent to the European Chemicals Agency (ECHA) on the potential ban of the use of Per- and polyfluoroalkyl substances (PFAS) in the pharmaceutical sector in terms of potential impact on medicines availability and shortages in Europe.

EMA listened to the concerns and referred back to ECHA and the European Commission, for further discussion where and as appropriate.

7. AOB Nitrosamines

Medicines for Europe reported issues being experienced by their affiliated members in terms of heterogeneity of national implementation of the provision foreseen in the Questions and answers for marketing authorisation holders/applicants on the CHMP Opinion for the Article 5(3) of Regulation (EC) No 726/2004 referral on nitrosamine impurities in human medicinal products and highlighted the need for International convergences.

The need to bring these concerns to an upcoming meeting of the Nitrosamine Implementation Oversight Group (NIOG) with Interested Parties was flagged.

8. Summary of follow up items

Both parties welcomed the valuable and open dialogue and expressed mutual appreciation of such exchanges to be pursued in a bilateral next year.