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Highlights of the 7th EMA-Medicines for Europe annual bilateral meeting

29 May 2024 – chaired by Marie-Hélène Pinheiro

1. Welcome and introductions

The chair and the EMA Executive Director welcomed Medicines for Europe delegation and highlighted 2024 as being a special year for Medicines for Europe as it is celebrating its 30th years anniversary.

2. Medicines for Europe views on the revision of the Pharmaceutical legislation

Medicines for Europe shared their positions on the European Commission's legal proposal for the revision of the EU pharmaceutical legislation remarking the importance of ensuring the adoption of a flexible, pragmatic and harmonised approach that takes into account the constraints experienced by generics and biosimilar medicines manufacturers.

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 Medicines for Europe was referred to the European Commission.

3. Repurposing

Medicines for Europe highlighted the importance of continued dialogue to support companies interested in repurposed medicines applications. Repurposing is considered a high-risk investment given the multifactorial barriers and uncertainties. More clarity on regulatory requirements and expectations was flagged.

The EMA acknowledged the challenges reported and highlighted the several initiatives established at EU level involving stakeholders with the aim to explore solutions (i.e. Safe and Timely Access to Medicines for Patients -STAMP, Remedi4all). Medicines for Europe was invited to participate in the

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dialogue with relevant groups (i.e. Repurposing Observatory Group (RepOG) in order to raise awareness on the specific challenges experienced by the sector represented.

4. Union list of critical medicines: selection of products and implementation hurdles

Medicines for Europe provided its comments on the recently published union list of critical medicines and the ongoing stakeholders consultation. The importance of a common list and approach across all Member States was flagged and clarifications regarding the interlinks with the European Shortages Monitoring Platform (ESMP) were asked.

The EMA highlighted the ongoing collaboration with all Member States through the Medicines Shortages Single Point of Contact working party (SPOC WP) in compiling the list and provided relevant clarifications on interlinks with ESMP, Product Management Service (PMS) and reporting relevant requirements.

Medicines for Europe was encouraged to participate to the upcoming webinar on European Shortages Monitoring Platform Essentials and Industry Reporting Requirements scheduled for the 24th of June 2024 and to the next Industry Standing Group meeting scheduled for the 28th of June 2024, where additional clarifications will be provided.

5. European Medicines Agencies' Network Strategy to 2028

Medicines for Europe was informed of the new timelines for the public consultation on the European Medicines Agencies Network Strategy (EMANS) update to 2028. The timelines now set for Q4 2024 (October-December 2024).

6. Nitrosamines

An overview of a recent survey done to assess the risk of medicines shortages caused by the identification of N-nitrosamines impurities and regulatory actions taken at member state level was provided by Medicines for Europe.

EMA asked to obtain more insights on the survey as well as concrete examples of impacted product. The issues highlighted by the survey from Medicines for Europe were noted, and EMA emphasised that such product recalls, withdrawals or shortages due to Nitrosamines, were not reported in the EU regulatory network. EMA advised that all concerned companies approach the relevant regulatory authorities with the impacted products as well as scientific data in order to allow adequate case assessment.

All available mechanism established in the context of the implementation of CHMP Opinion for the Article 5(3) of Regulation (EC) No 726/2004 referral on nitrosamine impurities in human medicinal products were pointed out. Medicines for Europe was asked to encourage its affiliated members to keep an early and open dialogue with relevant authorities, as well as through established groups for nitrosamines (i.e. the NIOG and its Interested Parties meeting), in order to identify suitable solutions avoiding any unnecessary shortages.

7. Biosimilars

Medicines for Europe provided its views on the Biosimilar Medicines Working Party (BMWP) workplan flagging the need to have a technical discussions in order to make the plan fit for purpose and discuss on streamlining of biosimilar development.

In terms of tailored scientific advice pathway on biosimilar medicines, it was suggested to increase live interactions in order to better inform guideline revision and allow discussions for future developments, in addition to increase publication of available data.

EMA noted Medicines for Europe's proposal for a technical meeting upon conclusion of the planned public consultation (Q4 2024) on the future need for comparative efficacy studies reflection paper and would considered it, as appropriate, with BMWP.

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8. Summary and follow up items

The chair closed the meeting thanking all attendees for the important exchanges occurred and flagged the importance of keeping an open dialogue and collaboration in order to promote development and availability of generic and biosimilar medicines for European patients.