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European Medicines Agency

Highlights- 4th EMA- Affordable Medicines Europe bilateral meeting

1. Welcome and Introductions

The European Medicines Agency (EMA) welcomed Affordable Medicines (AME) delegation to the 4th annual bilateral meeting recognising the ongoing cooperation and welcoming an open dialogue on the topics identified in the agenda.

2. Affordable Medicines Europe priorities for the next 3 to 5 years and position on the new Pharma Legislation proposal

AME shared the current overview of the parallel distribution market and sales trends, highlighting challenges and concerns on certain supply restrictions.

Additionally, AME presented their priorities for 2025 – 2026 and highlighted their position on certain elements of the proposed reform of the EU pharmaceutical legislation and the Critical Medicines Act.

3. Statistics on PD submissions 2024 - 2025

An overview of the metrics related to the volumes and time taken by the Agency to process parallel distribution notifications was presented, flagging that an average of 1000 requests per month are processed.

The EMA flagged the need for AME to raise awareness among its affiliated members on the published Parallel Distribution (PD) guidance documents and availability of recorded dedicated webinars and checklists. Companies are encouraged to use them in order to ensure correct submissions and to facilitate the application process.

An update on the implementation of the Windsor Framework was also provided.

4. QR codes and E-leaflets

The EMA explained the purpose and differences between mobile scanning technologies, the electronic product information (ePI) project, and the electronic package leaflet (e-PL) pilot projects run at national level. Additionally, the EMA emphasised that the use of QR code on the product packaging is

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optional for the Marketing Authorisation Holders (MAHs) however, it is mandatory for parallel distributors if it appears in the approved Product Information of the sourced product.

AME shared their experience and challenges in complying with the use of QR codes and agreement on the need to revise the related questions and answers (FAQ about Parallel distribution) document to better clarify requirements was reached.

5. Batch handling requirement

The EMA presented an overview of the current Q&A on good manufacturing practice and good distribution practice and re-iterated that, in accordance with this guidance, parallel distributors are required to comply with national legislation and guidance for batch handling requirements. In absence of specific national legislation or guidance, parallel distributors are required to refer to the mentioned Q&A and request to the relevant National Competent Authority (NCA) the possibility to deviate from the general recommendation. AME discussed several challenges encountered at National level when applying the provisions of the Q&A.

6. Retention samples

The EMA confirmed that the GMP annex 19 is expected to be published soon.

7. Prepayment method and direct debit system

The EMA confirmed stabilisation of the pre-payment process and that all relevant systems are performing in line with expectations. Additionally, the EMA provided the highlights of the preparation for implementation of the SEPA Direct Debit scheme and encouraged AME to participate in the preliminary call for expression of interest.

8. IRIS and other technical issues

EMA provided updates on IRIS technical improvements impacting Parallel Distribution.

AME expressed interest in participating in the consultation prior to implementation of a technical solution replacing the publication of the safety update list.

9. A.O.B

No other businesses were discussed.

10. Conclusions and next steps

The EMA and AME welcomed the open interactions and dialogue exchanged during this fourth annual bilateral meeting and agreed to continue such engagement in the future.