17 April 2024

Highlights: 3rd annual EMA-Affordable Medicines Europe bilateral meeting

10 April 2024

Chair: Marie-Helene Pinheiro, EMA

Item	Agenda and outcome points
1.	**Welcome and Introductions** After a round of introductions from all participants, EMA welcomed the participants to this 3rd annual EMA-Affordable Medicines Europe meeting which was held at EMA premises. This annual bilateral meeting is organised between the European Medicines Agency (EMA) and Affordable Medicines of Europe (AME) in line with industry stakeholder Framework. Its objective is to exchange views and promote dialogue on topics of common interest in an open and direct manner.
2.	**Affordable Medicines 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 trade flows amongst European Member States (EU/EEA) and presented their views on the new Pharma Legislation proposal, highlighting its strong support to EU EMA shortages management coordination. AME also shared some concerns about some of the transparency proposals to potentially be introduced into the legislation by the legislators.
3.	**Windsor framework agreement implementation** EMA presented the practical implications for parallel distribution trade from/to Norther Ireland and the European Union (EU/EEA) Member States after the date on which Regulation (EU) 2023/1182 becomes applicable, expected on 1 January 2025 (tbc). From that date, parallel distribution notices that only have United Kingdom (Northern Ireland) as a member state of origin/destination will no longer be valid. A communication with instructions on how to withdraw the notices and the

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	timeframe to do so will be sent to parallel distributors holding such notices once the formal implementation date is published. United Kingdom (Northern Ireland) will need to be removed from parallel distribution notices including multiple countries of origin/destination with the annual update procedure once the Regulation enters into force. The parallel distribution notice will remain valid for the remaining Member States of origin/destination on the notice. For this latter case, AME questioned whether EMA could automatically remove the United Kingdom (Northern Ireland) as a member state of origin/destination from all notices. The feasibility of this approach will be considered by EMA and feedback provided in due course. AME was informed that the EMA PD FAQs (Frequently asked questions about parallel distribution | European Medicines Agency (europa.eu)) will be updated and additional communication will be sent to parallel distributors closer to the date, once the implementation date is known.
4.	**Update on the safety update procedure** EMA presented an update on the way safety updates will be reviewed. Submission of stand-alone safety updates will no longer be required. It was highlighted that Parallel distributors are still required to implement safety-related changes to the product information within three months of the publication of the updated annexes, and within six months for non-safety-related changes. These changes will be reviewed as part of the annual update procedure. It was clarified that the abolishment of the safety update procedure does not affect the timelines of the annual update nor the birthday date of the product. EMA will consider continuing providing the safety update list until a suitable alternative is in place. The FAQs will be updated in the next months and further communication will be sent to parallel distributors.
5.	**New fee regulation implementation for parallel distribution** EMA presented the implications for parallel distribution of the new fee Regulation, coming into force 1 January 2025. The key changes are: • Six charges for parallel distribution procedures will be reduced to three. • Implementation of a new pre-payment system. Currently an invoice for a parallel distribution procedure is triggered in parallel to the service being delivered by EMA. After implementation of the new pre-payment system, the invoice for a parallel distribution notification will need to be paid prior to the start of the procedure.
6.	**Performance update and EMA lead times** EMA presented the metrics for the volumes and handling time of parallel distribution notifications. The Agency receives and processes an average of 1000 cases per month, with around 94% of the cases being handled within 30 days. Data indicates that 58% of initial notifications require corrections, which is an improvement compared to previous years, but remains a high percentage. Industry was reminded of the latest PD guidance documents, webinar for Industry, and checklists available to support companies and facilitate the application process. AME key role in facilitating information sharing amongst its members was highlighted.

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7.	**Published Annexes and Risk Minimization Measures materials: how to choose the correct ones?** AME took the opportunity to ask what action to take in case a discrepancy is found between product information published on the European Commission webpage and the Agency's EPAR webpage. EMA highlighted that it handles a vast number of variations and that a course of action should be determined on a case-by-case basis. EMA advised AME/its affiliated Members to reach out via an Ask-EMA query if these instances occur in order to be able to investigate in advance and avoid delays during the assessment. AME also took the opportunity to highlight that for pharmacovigilance reasons and traceability purposes, it is often not possible to deviate from the revision date on sourced RMM material. EMA noted the comment and will consider whether FAQs will need to be updated in that respect.
8.	**Suggestions from Industry on IRIS improvements: withdrawals, corrections, others** Affordable Medicines Europe highlighted points of improvement in IRIS from the perspective of the industry user. All comments are welcomed and noted by EMA and considered as appropriate.
9.	**A.O.B** No other business to be discussed.
10.	**Conclusions and next steps** EMA and AME mutually benefited from the level of interactions and dialogue exchanged during this third annual bilateral meeting and agreed to continue such engagement in the future.