13 December 2022
EMA/88147/2022
Stakeholders and Communication Division

Second EMA – Affordable Medicines bilateral meeting

16 November 2022

Chair: Marie-Helene Pinheiro (EMA), via WebEx

1. Welcome and introduction

The Chair welcomed participants to the 2nd bilateral meeting and highlighted the importance these bilateral meetings have to streamline communication between EMA and Affordable Medicines (AM) from Corporate level perspective.

2. Metrics

EMA presented metrics on Parallel Distribution (PD) procedures from January 2022 until October 2022. The rate of processing notifications matches the current submissions received with >70% processed around two weeks and >90% submissions processed within 30 days. This was acknowledged by Affordable Medicines and positively received.

EMA PD team is implementing improvements in the IRIS system that manages the submission and processing of PD notifications. EMA is also developing a new tool for document comparison. Any changes impacting Parallel Distributors will be timely communicated by email and in IRIS Forum.

The FAQs and checklists are being updated regularly and EMA is open to suggestions for improvement of these documents in case additional information is needed.

Upon request from AME, EMA clarified that the recently launched functionality in IRIS linked to financial company information is currently available, but not applied for applications drafted before the launch of the feature. This one-off situation explains some issues reported by some Parallel Distributors.

3. UPD on VET

Parallel Distributors are not requested to record any parallel distribution of Veterinary Medicinal Products in the Union Product Database (UPD).

Product information on Parallel-Traded medicinal products is recorded in UPD by the corresponding NCA following approval. Wholesalers are not involved in recording (neither at destination nor source), but they can contact relevant NCA for amendments if they identify errors.

Although UPD refers to parallel-traded medicinal products, AME highlighted a misalignment with the information provided in the current 'intent-to-distribute' notifications to MAHs by Parallel Distributors.

4. Communication with EMA

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Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

- Feedback from EMA webinar

The EMA 2021 **Webinar on Submissions of Parallel Distribution Notifications for Centrally Authorized Products (CAPs)** was positively received by AME that highlighted its usefulness as a training material. AME highlighted the limited question time during the webinar and proposed new sessions in the future more focused on questions.

- Attaching documents to AskEMA queries

Current AskEMA system does support attachments. AskEMA will move in the future to a new system that supports this functionality. Procedural queries via IRIS require uploads to Sharepoint (not attachments) due to security protocol.

5. Regulatory check of notifications for parallel distribution

- Anti-tampering device

The topic was raised due to a specific case that was solved ahead of the meeting. AME appreciated EMA clarification that a letter of acceptance of the ATD from the supervisory authority was no longer required in that particular case.

- New EPARs being published during assessment

For initial notifications, EMA asks Parallel Distributors to update the product documents when the EPAR is updated during the regulatory check of the PD notification. EMA has a legal obligation to check that the submitted materials are in line with terms of marketing authorisation at the time of the issuance of the notice, not at the time of submission. Considering the current processing times of notifications which is below two weeks, this situation is very infrequent.

- EMA requirements for additional text on the product packaging

AME supplied specific visuals of a case where the information was already on a pack, but the PD was requested to add the information regardless. This was a case-specific issue which was clarified outside the meeting.

6. Other

- Specific mechanism (SM) Q&A

Although only Croatia falls under the specific mechanism, AME reported that some NCAs may still ask at national level for the SM notifications. Although individual NCAs can apply their own regulations with regard to SM, EMA may consider adding a reference in the specific mechanism in the EMA guidance.

- Sunset clause

AME noted divergencies in the application of Sunset clause among MS and the need to strengthen harmonisation, since some NCAs are applying the Sunset clause to parallel-traded products. Sunset clause applies to the marketing of authorised medicinal products by the Marketing Authorization Holders, not to products that are parallel-distributed within the EU. Parallel imports are under the remit of the NCAs and are subject to national legislation, so no update of EMA guidance is deemed necessary.

7.A.O.B

Topics not discussed in this meeting: fees and shortages.

8. Conclusions and next steps

Follow up action

A meeting highlight will be prepared and circulated to all participants before publication.