Coordination Group for Mutual Recognition and Decentralised Procedures for Veterinary Medicinal Products

Amsterdam, 28th September 2023
EMA/CMDv/393434/2023

Dear applicants,

Subject: Union Product Database: Deadlines for the Submission of Annual Volume of Sales data for veterinary medicinal products

As per Article 58(12) of Regulation (EU) 2019/6, Marketing Authorisation Holders (MAHs) are required to submit in the Union Product Database (UPD) the annual **volume of sales** for each of their veterinary medicinal products.

As announced previously by the European Medicines Agency (EMA) (both at the last Vet Medicines Info Day held on 16-17 February 2023, and the Webinar on the submission of Volume of Sales data for Industry users held on 24 April 2023), **the submission deadline for the Marketing Authorisation Holders to provide annual Volume of Sales for the 2022 calendar year has been set to 30 June 2023**.

As of 1 August 2023, **the submission of Volume of Sales data is still incomplete and its rate lower than expected.** Sales data are missing for ¾ of the products registered in UPD i.e. data have not been provided for 31,000+ medicinal products.

All MAHs must submit 2022 sales data without further delay! We advise users to focus on and undertake any necessary testing related to the **submission of EU/EEA sales**.

T**he deadline for submitting the data for the 2023 calendar year has now been set for end of February 2024.** Thereafter the deadline to provide annual volume of sales will be set as the end of February the following year. For example, the deadline for submitting the data for the 2024 calendar year will be February 2025; for the 2025 calendar year will be February 2026, and so on.

Should users identify any inconsistencies with VMP data in UPD, they are urged to proactively liaise with the relevant responsible Competent Authority without delay.

Failure to provide Volume of Sales data by the specified deadlines poses a significant risk to Veterinary Pharmacovigilance and Antimicrobial Sales and Use activities. In such a scenario with unmet obligations, non-compliant MAHs could face regulatory or legal actions as deemed necessary by the European Commission or relevant National Competent Authority, according to article 130 of Regulation (EU) 2019/6.

In order to effectively support Industry stakeholders in the data submission, the UPD product team would like to signpost the below informative materials:

- **Webinar on the submission of Volume of Sales data**, recording available **here**.
- **Video tutorial on how to submit Volume of Sales data,** available here
- **Q&As on the submission of Volume of Sales data,** available here
- **EU Implementation guide,** available here

Another webinar is scheduled for 18th September 2023 (registration available here), focusing on the MAH User Interface functionality to group essentially similar products together and the MAH possibility to match a non-EEA product name with a product authorised within the EEA. These two functionalities will facilitate users to submit **non-EEA sales data** for similar/same products in the EU/EEA only once (as opposed to submitting against every individual product that is similar/same in the EU/EEA). For your convenience, a recorded video will be accessible post-event on the event's page and EMA YouTube Channel.

Yours sincerely,

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Chair of CMDv

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