Veterinary Medicines Division
EMA/40218/2025
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Union Product Database (UPD) - Volume of Sales webinar for UPD industry users held on 5 December 2024

Questions and Answers

Disclaimer

This Questions and Answers (Q&As) document is for information only and it is based on questions raised during the UPD Webinar on the submission of Volume of Sales data held on 5 December 2024. Nothing in this document should be taken as an explicit commitment on behalf of the EMA, or the UPD product team. For convenience, many technical terms are explained in the table of abbreviations at the beginning of this document. For general queries on UPD, including questions on guidance, scheduled deployments, bug fixes, Volume of Sales, please contact the Agency via AskEMA: Send a question to the European Medicines Agency. For any UPD technical issues, errors in the system, inability to log in, and expired passwords, please submit a ticket via ServiceNow.

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Acronym key and glossary terms

API	Application Programming Interface
CAP	Centrally Authorised Procedures
.CSV	Comma-Separated Values
DCP	Decentralised Procedure
EEA	European Economic Area
EMA	European Medicines Agency
IG	Implementation Guide
MAH	Marketing Authorisation Holder
MRP	Mutual Recognition Procedure
NCA	National Competent Authority
NI	Northern Ireland
OPAD	Other Post-Authorisation data
PSMF	Pharmacovigilance System Master File
Q&A	Questions & Answers
RMS	Referentials Management Service
SRP	Subsequent Recognition Procedure
UK	United Kingdom
UI	User Interface
UPD	Union Product Database
VoS	Volume of Sales

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1. Is volume of sales cumulative?

No, Volume of Sales (VoS) data is not cumulative. Marketing Authorisation Holders (MAHs) have the flexibility to include any number of products in each submission and to make submissions as frequently as they choose (monthly, quarterly, or annually), provided the granularity remains at the monthly level. The frequency of submissions is at the discretion of the MAH, but submission timelines are expected to align with the calendar year. For new products, reporting in the first year should cover the period from the date the product is placed on the market up to 31 December.

2. Can products be combined into a single file for submission?

Yes, products can be combined into one file, ensuring all fields are correctly filled, especially species codes.

3. Is it possible to download sales data for more than one product at a time?

Under the OPAD menu – submenu *Download List of Packages*, selecting *Download* will generate a .CSV file containing all packages in your entire portfolio. Similarly, under the OPAD menu – submenu *Retrieve Volume of Sales*, you can download sales data for all packages associated with the Permanent ID and the selected reporting period, provided submissions have been made for that period.

4. What are the requirements for UK Northern Ireland submissions?

For UK (NI), users are required to submit to the UPD information relating to sales of CAPs, MRP, DCP, and SRP products only. If it is not feasible to separate UK (NI) sales, it is permissible to include total UK sales data, with an estimate provided for the UK (NI) portion. At this stage, users are encouraged to continue submitting such data.

5. Should non-EEA sales be reported as part of the submission?

Due to pharmacovigilance requirements, a Marketing Authorisation Holder (MAH) must also submit the annual volume of sales for non-EEA countries for each of their veterinary medicinal products. In this context, since the volume of sales is reported at the package level, a single consolidated value will be submitted for all non-EEA countries, mapped to an equivalent package in the UPD (either with the same pack size or adjusted to a comparable pack size). For further details, please refer to Chapter 7 of the EU Implementation Guide (Vet EU IG)

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6. Should VoS data from non-EEA countries be included when submitting EEA sales data for a specific country?

From Chapter 7 EU IG, it is recommended that for non-EEA countries, users submit a single (estimated equivalent) EEA package identifier representing the total volume of sales for all non-EEA countries

7. How should non-EEA VoS data be distributed or submitted if the same product is registered in multiple member states?

Chapter 7, section 2.1.5: "For non-EEA countries, the User shall submit only one (estimated equivalent) EEA package identifier for all non-EEA countries with the total volume of sales data."

MAH can use the .CSV file retrieved from UPD and manually change the country identifier to "100000000028"(correspondent to "non-EEA"). Country name values are not mandatory during submission on the contrary, country identifier is - please refer to section 2.2.2 of Chapter 7). When submitting sales for non-EEA countries the only code expected to be submitted is "100000000028"(correspondent to "non-EEA").

MAHs are strongly recommended to use the MAH product grouping functionality in this situation. Non-EEA sales data can then be submitted against the package identifier of only one member of the product group to apply to the whole product group.

8. Will a blank "deletion date of package" column cause errors?

The column is included for user convenience, as packages deleted in the UPD remain in the download file for 24 months post-deletion. It is optional to fill in during submission, and a blank column will not cause errors. However, the column should not be deleted as the system checks for the number of columns during submission.

9. How is the "creation date of package" defined?

The creation date of package is the date when the package was created in UPD.

10. Where can I find information about country columns in the submission file?

"Country" and "Country Identifier" are in columns 10 and 11, respectively, in the downloaded file. The "Country ID" column is mandatory and must align with the RMS list to avoid submission failure. Removing this column will result in submission failure.

11. Is it possible to pre-fill the downloaded file with products species and months for the whole calendar year?

It would be challenging to provide all months in a single download as it would result in a much larger file, hindering the submission process. However, providing species-specific data per package might be feasible, pending internal discussions.

12. How can we access the UPD Validation environment?

The link is provided in Chapter 7 of Vet EU IG page 21: The URL is https://upd-portal-prod-validation.azurewebsites.net/updwebui/home.

13. Can .CSV files from the previous year be reused for following years sales submissions?

There are three aspects to this. Firstly, you must ensure that the number of columns matches the latest CVS file format. For 2024, two new columns have been added, and submitting a file that contains less columns would result in submission errors. Second, you must ensure that you are not missing any product or any product update, we are encouraging you to download the .csv file containing your whole portfolio. Thirdly, before making any other amendments, it is recommended you delete all of the previous year's sales data to avoid inadvertently submitting incorrect data for the current year.

14. Is it still necessary to format .CSV files or remove empty rows?

Yes, removing empty rows is still necessary.

15. Where can I find the link for the species RMS list?

Please note that the SPOR RMS Species list (200000000019) is not the same as the SPOR RMS Target Species list referred to in the QRD template.

16. Will commas in fields like package descriptions be removed to prevent .CSV issues?

Previous improvements to VoS formatting columns addressed comma issues, and package descriptions can now contain commas, which the system will treat as text and enclose in quotes when downloading.

17. If a MAH only has one authorised product that has not been sold, is the VoS submission necessary?

MAHs are not obliged to submit information on packages that were not sold, therefore in these cases, they will either remove the rows corresponding to those packages or will provide the value '0' with all the mandatory information in the .csv file.

18. Can months with zero sales be skipped?

Yes, months with zero sales can be omitted from submissions.

19. Is the dose factor the number of animals that can be treated with 1 package, i.e. per package ID (e.g. Carton x 10 vials x 100ml) and not per unit (e.g. 1 vial).

The dose factor represents the average number of animals of a particular species that can be treated using one package.

20. Will there be an API for volume of sales data submission??

Yes, an API is planned for release in late 2025. Documentation and endpoints will be provided in due course.

21. Will submitted sales data be shared with NCAs?

Yes, the data is accessible to NCAs and used for reporting purposes.

22. Will the VoS submitted to the UPD replace the parallel submission of antibiotic sales?

Please note this guidance is provided in respect of obligations arising from Regulation (EU) 2019/6, especially Article 58 (12) - *Responsibilities of the marketing authorisation holders*; 12. The marketing authorisation holder shall record in the product database the annual volume of sales for each of its veterinary medicinal products.

Therefore, MAHs should consider directly contacting any body requesting data which has already been entered in the UPD.

23. Will the number of columns in the submission format change in the future?

No changes to the number of columns are anticipated.

24. Regarding the dose factor, should it be prepared in a separate sheet and included in PSMF Annex 4, or does it need to be submitted separately?

The dose factor for each species / package combination should be submitted in the .csv file. MAHs should also maintain their justification for each calculated dose factor in their PSMF.

25. Will there be enhancements to volume of sales functionality?

The only enhancement expected for the next year regarding VoS submissions is the MAH availability to submit VoS data via API.

26. Will EMA use sales data to address product availability issues?

No, volume of sales data is not used for product availability issues. Industry users can update product availability via the UI.

27. Are NCAs advised not to create new UPD package IDs when updating existing ones?

NCAs have been advised to edit existing entries rather than create new IDs. Guidance for updating without deletion is available on the agency's website.

28. Could further clarification on special permits sales submission be provided?

The UPD does not contain information relating to special import permits. Ideally, and where reasonably practical, such sales should be recorded against the origin (i.e. exporting or source country).

29. What if errors are discovered after the February deadline?

Corrections can be made by submitting updated data, which will override previous submissions. Notify EMA if significant corrections are required or have been made.