Veterinary Medicines Division
EMA/273124/2023
June 2023

Union Product Database (UPD) - Volume of Sales webinar for UPD industry users held on 24 April 2023

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 24 April 2023. 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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Table of Contents

Acronym key and glossary terms

CAP	Centrally Authorised Procedures
CMS	Concerned Member State
CVMP	Committee for Veterinary Medicinal Products
DCP	Decentralised Procedure
EEA	European Economic Area
EMA	European Medicines Agency
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption
EU	European Union
HMA	Heads of Medicines Agencies
IG	Implementation Guide
MAH	Marketing Authorisation Holder
MRP	Mutual Recognition Procedure
NCA	National Competent Authority
NI	Northern Ireland
Q&A	Questions & Answers
RMS	Referentials Management Service
SPC	Summary of Product Characteristics
SRP	Subsequent Recognition Procedure
UK	United Kingdom
UPD	Union Product Database
VoS	Volume of Sales

1. General information about Volume of Sales (VoS)

1.1. Will this webinar recording be published on the EMA website?

The webinar supporting materials (recording and slides) have been published on EMA corporate website, on the event's page.

1.2. When will the updated Chapter 7 of the EU IG (Implementation Guide) be published?

The updated version of Chapter 7 of the Vet EU IG has been published on EMA corporate website.

1.3. Can EMA share the list of National Competent Authority (NCA) contact details and Annex 1 of Chapter 2 of the Vet EU IG?

The NCA procedural contact points for all countries can be found here. Annex 1 of Chapter 2 of the Vet EU IG can be found on the UPD landing page.

Information about the VoS submission deadline

1.4. Should 2022 data for National/Decentralised Procedures (DCP)/Mutual Recognition Procedures (MRP) authorised products be submitted according to the same deadline (30 June 2023) as centralised products?

As announced at the last EMA Veterinary Medicines InfoDay held on 16-17 February 2023 the submission deadline for annual VoS for 2022 data is end June 2023 and it will not be extended. Users are encouraged to submit as much and as complete data as they can for 2022 EEA sales, for both centrally and non-centrally authorised veterinary medicines.

1.5. From which month must the 2022 VoS data be submitted? From the beginning of the year (e.g., January 2022) or from the month of entry of the legacy data?

From January 2022 onwards.

1.6. Is it possible to submit Volume of Sales data for the previous 12 months on the due date for Signal Management? As users must collect the data from distributors anyway at that time.

The annual VoS for 2022 data should be provided by end of June 2023. The annual VoS for 2023 should be provided in 2024.

1.7. The UPD only contains products for UK(NI), but the sales data typically come from the entire UK. Is it acceptable to submit full UK data to UK(NI) entries in UPD? Doing otherwise might not be possible due to the way companies keep information.

Regarding UK(NI), users should submit to the UPD information concerning sales for CAPs/MRP/DCP/SRP products only. Where it is not possible to split out UK(NI) sales then it is possible to include all UK sales data, but the UK(NI) sales should be estimated. At this stage, we encourage users to continue to submit such data. In Q2 2023, a new functionality which allow products grouping will be introduced in UPD; this should simplify the submission process for non-EEA sales data.

1.8. As larger organisations will have to submit data for thousands of packages, is there any recommendation for automation?

Yes, some companies have already heavily invested in automation to fill in Excel documents, with the exception of any issues that may occur during the submission which are still being solved manually.

Information about VoS submission

1.9. Given the possibility to submit partial datasets for the 2022 Volume of Sales, how should this be clarified when submitting data, especially considering the need for comparability across years?

Users are encouraged to submit as much information and data as they can from the onset. Industry representatives' feedback indicates that large organisations are indeed able to submit data and that they are already doing so. In case of data gaps from 2022, these must be justified. A webinar for National Competent Authorities was held on 25 April 2023 in order to deal with data quality issues for products. Moreover, although the UPD product team is working with NCAs very closely to address issues as soon as they arise, users are kindly requested to be patient as it could take some extra time to address issues for certain data packages and for a small number of specific products.

1.10. When will users have access to all products in the Union Product Database? At present, there are some missing or incorrect.

Missing and/or erroneous product data should be reported to the relevant competent authority. For centrally authorised products, users should contact the Agency. For non-centrally authorised products, users should contact the relevant NCA. To correct common data, users should contact the RMS. To correct national data, the CMS. For more details on common/European data, please check Annex 1 of Chapter 2 of the Vet EU IG.

1.11. Will there be a list of standard body weights published for minor species to be able to calculate the dose factor (E.g., for gamebirds, geese, etc.)?

There is no foreseen guidance that would be further developed including body weights for minor species.

1.12. Do NCAs require users to report sales figures and ESVAC numbers separately?

No.

1.13. Is it possible to submit several products in one go?

Yes.

1.14. In case of multiple distributors across the EU, users' aim is to get data from each of them. Are users allowed to submit multiple files to the system?

MAHs are required to collect all the relevant information related to their sales. Users can choose how to submit the information to the UPD: for products, distributors, themes. Users are not expected to submit a unique, compete file including all sales, information can be split. **Please note that if users have two distributors for a given country, they must submit one figure for that pack / country / year-month combination which relates to the total for both, otherwise the second figure will overwrite the first. The UPD does not total up different figures for the same package / country / year-month.**

Information about data editing/corrections

1.15. What is the correct procedure to request the edit of incorrect data or to add missing data in the UPD?

EMA understands the concern behind this. A webinar for National Competent Authorities was held on 25 April 2023 aimed at highlighting some data issues to be addressed by the NCAs, but at the same time it is necessary to contact the NCA's. on the HMA website, there is a list of procedural contact points for each Member State, with a series of email addresses users should reach out to request an update to the data. In case of doubts as to who to contact, whether the RMS or the CMS, users should look at Annex 1 of Chapter 2 of the EU IG which makes a clear distinction between common data and national data. To correct common data, users should contact the RMS. To correct national data, the CMS.

1.16. What happens if users submit data for a given month, they already uploaded data for in the past? And if one submitted wrong data for a given month, can users submit an updated CSV file to replace the previously submitted one?

In both the above scenarios, the new CSV file will overwrite the information that already exist in UPD.

1.17. In the future, will changes to existing data in the complete package list be visible to users? Currently, it is only possible to see whether a record is newly created, but not if its data changed since it was first created in the UPD.

Currently, the download file for Volume of Sales only incorporates the "Creation Date of the Product". In the future, the file will incorporate two new columns with information related to the "Creation Date of Package" and the "Deletion Date of Package". Changes to existing data in the packages will be communicated to users through the notifications as well.

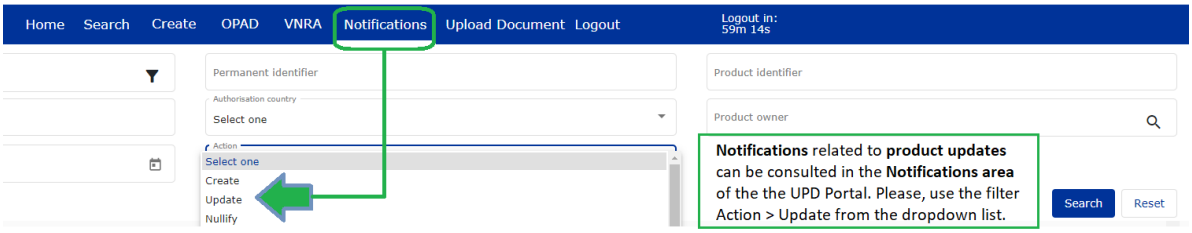

Figure 1 - Notifications related to product updates

Information about species/doses

1.18. Can you please provide the link to the Species List?

The terms for Species are listed on the Species list in RMS. Note: while SPCs use terms form the RMS Target Species list, VoS data must be submitted using RMS Species list identifiers.

1.19. For the species that are not mentioned in Vol 9B - standard weights - which sources will be accepted in order to calculate the dose factor?

In relation to this matter, users should raise the question through AskEMA. Moreover, colleagues in the CVMP Pharmacovigilance working party have regular meetings with stakeholders who have the possibility to raise questions via these forums.

1.20. Chapter 7 of the EU IG refers to "the average number of animal species that can be treated with one package", whilst in the presentation reference is made to "the amount of packages that can treat 1 single animal". Can you please clarify the correct interpretation of this?

The interpretation given about the dose factor during the demonstration on the webinar was incorrect, apologies for that. Please, check the Chapter 7 of the Veterinary EU Implementation Guide for the correct approach.

1.21. What is the right course of action for when the species from one's sales are not included within the RMS terms in the Species list? As an example, the mentioned list includes "Indian hen" but does not include the general term hen.

While SPCs use terms form the RMS Target Species list, VoS data must be submitted using RMS Species list identifiers. If Indian hen is a specific breed and sex of the species chicken, then the term *Chicken* from the Species list shall be used.

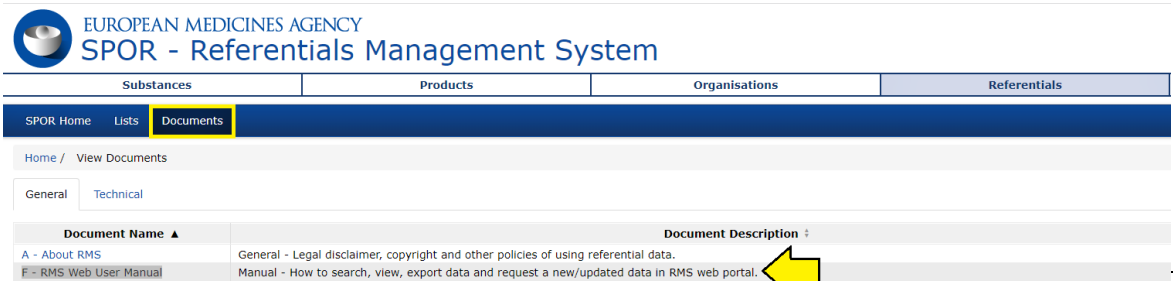

Figure 2 – Documents description

2. Questions related to the Demo

2.1. What is the reason for using a comma "," as a separator despite in most European countries the standard separator being a semicolon ";"? This makes creating a valid CSV file difficult using standard Office programs (e.g. Excel).

The use of comma as a separator was defined by the UPD group together with the technical team and has been implemented on this basis. This decision was taken being conscious that some of the users who would work with Excel would have to change the settings in their systems, but this was not considered as a problem in any way.

2.2. The Excel sheet used in the demo only contains the "Pack size Numeric value" for "Tablets" but not for the Solution. For the Solution it contains "1". As users often handle large data, is it possible to add the "Pack size Numeric value" for Solutions other than tablets?

First, as stated during the webinar, the demonstration was performed in the test environment, therefore we cannot rely on the quality of all the data contained in the Excel file. Secondly, we know that the way data has been entered for some products in the UPD has been somewhat inconsistent in relation to description of the package. We believe for nearly all products either the download file alone, or use of the download file and the UPD will enable MAHs to identify precisely what the package is. In the situation where this is not possible the appropriate Competent Authority (or RMS for MRP/DCP/SRP product) should be contacted and corrections to the package information requested.

2.3. Is it possible to upload the Volume of Sales data to the UPD if our CSV-file contains more columns than the given 1-19 ones, e.g. users include data in column 20 for internal purposes, or will this prompt an error message?

When submitting Volume of Sales, if the number of columns differs from the ones specified in the Chapter 7 of the Veterinary EU Implementation Guide, the system will display the following error: *ER.04: The number of columns provided is not correct according to Vet EU IG Chapter 7.*

2.4. In the demo, while importing the CSV file, all identifiers were transformed to a form that does not appear to represent any valid identifier e.g. 6,0001E+11. Can you please clarify what is the correct format?

Please note, the identifiers with scientific notation were converted to numbers during the DEMO session.

2.5. In the demo file, columns A to M are fixed, but users must add 12 rows for each pack size for each month. Are users allowed to copy one line for the rest of the 11 lines?

Yes, this is possible.

2.6. On the provided documentation, not all the columns downloaded are mandatory, but on the example followed these were indeed kept. Should users include all of them or only the ones detailed as mandatory?

The system will validate only those columns specified as mandatory in the Chapter 7 of the Veterinary EU Implementation Guide, therefore providing these would be sufficient. Optionally, users can provide the information for the rest of the columns if this facilitates their work in any way, but please note that this information will be ignored by the system.

2.7. If there is no Volume of Sales for certain months but a user already entered the respective months in the columns, is it possible to enter a "ZERO" value or alternatively delete such months for products with no sales?

Marketing authorisation holders 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.

2.8. In the demonstration, a number of packages were deleted. Can you please explain why? Perhaps there were no sales for those packages?

It is up to the user to decide how the Volume of Sales data are going to be submitted to UPD. In the example illustrated during the demonstration, the user's decision was to submit the Volume of Sales in different batches, but it could also have been that there were no sales for those packages.

2.9. Should users download the packages file every time they wish to submit Volume of Sales data, or can users have their own version based on a previous download?

It is not necessary to download the Volume of Sales file each time a user is going to proceed with a submission. As correctly stated in the question, users can have their own version based on previous downloads. However, if there are new packages in their portfolio, users will be able to obtain their identifiers by downloading the file.

2.10. In the demo's example, the dose factor was 0.5 and it was mentioned it represented "0.5 packages used to treat a cat". According to the description of the "dose factor" in Chapter 7, would it be correct to say that 2 cats can be treated with a package, hence the dose factor would be 2?

Indeed, the correct dose factor should be 2, we apologise for the mistake in the webinar. Chapter 7 of the Veterinary EU Implementation Guide describes the correct approach.

2.11. How often in a given period of 12 months should MAHs download the packages Excel file before submitting Volume of Sales data?

The download file for Volume of Sales contains the information that will help marketing authorisation holders to map packages in UPD with the ones in their own systems. Because in the course of a year this information may change (e.g. addition of new packages), our recommendation is to download it several times a year to ensure consistency between the two systems.