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SCIENCE MEDICINES HEALTH

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Union Product Database (UPD) – Frequently Asked Questions Industry Use

Disclaimer

This document is for information only and it is based on frequently asked questions by Marketing Authorisation Holders (MAHs) on the usage of the Union Product Database (UPD). Nothing in this document should be taken as an explicit commitment on behalf of the EMA, or the UPD product team. This is a living document which is intended to be updated with additional questions and answers as and when they become available.

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, 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, bug fixes, 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	NP	National Procedure
ASU	Antimicrobial Sales and Use	SSO	Single Sign-On
CA	Competent Authority	OMS	Organisation Management Service
CAP	Centrally Authorised Products	OPAD	Other Post-Authorisation Data
CMDv	Coordination group for mutual recognition and decentralised procedures for veterinary medicinal products	PSMF	Pharmacovigilance System Master File
CMS	Concerned Member State	PSUR	Periodic Safety Update Report
CP	Centralised Procedure	Q&A	Questions & Answers
CSV	Comma-separated values	QRD	Quality Review of Documents
CVMP	Committee for Veterinary Medicinal Products	QPPV	Qualified Person Responsible For Pharmacovigilance
DCP	Decentralised Procedure	RMS	Referentials Management Service
EDQM	European Directorate for the Quality of Medicines & HealthCare	SPC	Summary of Product Characteristics
EEA	European Economic Area	SPOR	Substances, Products, Organisations and Referentials
EMA	European Medicines Agency	SRP	Subsequent Recognition Procedure
ENTA	Estimated number of treated animals	UAT	User Acceptance Test
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption	UI	User Interface
EU	European Union	UK	United Kingdom
EVVet3	EudraVigilance Veterinary	UK(NI)	Northern Ireland
HMA	Heads of Medicines Agencies	UPD	Union Product Database
IG	Implementation Guide	VMP	Veterinary Medicinal Product
MAH	Marketing Authorisation Holder	VNeS	Veterinary Non eCTD Electronic Submission
MRP	Mutual Recognition Procedure	VNRA	Variations not requiring assessment
MVP	Minimum Viable Product	VoS	Volume of Sales
NAP	Nationally Authorised Products	VRA	Variation requiring assessment
NCA	National Competent Authority		

1. General information about the UPD & access management

1.1. Why should MAHs use the UPD?

As required by the Veterinary Medicines Regulation ([Regulation \(EU\) 2019/6](#)), which became applicable on 28 January 2022, MAHs must submit the following to the Union Product Database:

- Volume of Sales (VoS) data;
- Availability status of the product;
- Changes to the authorisation status (in case of revocation or suspension);
- Variations not requiring assessment;
- Third country product names;
- MAH product grouping (optional but recommended).

For further guidance, please refer to the '[Guidance for marketing authorisation holders](#)' section of the [EMA's UPD webpage](#).

1.2. How can Industry user register for a UPD account?

Industry users with an existing account for other EMA-hosted systems (such as Eudralink, IRIS, SPOR, etc.) can use the same credentials, but will need to apply for the relevant UPD role(s) for their account on the EMA Account Management Portal first.

Users can check whether they already have an EMA account and get more information about EMA SSO (Single Sign-on) by visiting <https://register.ema.europa.eu>.

1.3. How does user management work for Users and Super Users?

UPD user management is similar to other EMA systems (SPOR, IRIS, etc.), where one of the Users is appointed as the Super User to manage other users belonging to or representing the specific MAH.

Users do not have to be staff members of the specific organisation, as the Super User of that organisation can give access to individuals external to the organisation (e.g. to a consultant or staff member of another MAH in the group).

UPD Industry Super Users can grant/revoke UPD rights to users, in addition to viewing and submitting data.

1.4. Is it possible to limit access rights of a user?

Yes, the Super User of each organisation shall be able to approve user roles requests from specific users for their organisation only. A user having distinct roles for different organisations shall request the roles as needed, and they will be reviewed and approved by the Super Users of the relevant organisation. However the approved role will grant rights (view and/or submit) to the whole product portfolio, because it is not possible to grant access on product basis. For further details please see below questions 1.5 and 1.6.

1.5. In case multiple MAHs are involved in one procedure, will all MAHs be able to enter/change data? Or will only the MAH product owner have access to these products?

The relevant MAHs will have to agree on that on a case-by-case basis. The relevant Super Users of each MAH can assign roles to anyone inside or outside their organisation to perform actions on their behalf. Please note that a user can only make changes to products where s/he has the relevant role for the organisation owning that product. However, if access is given by the Super User to a user outside the organisation, they would be able to perform the permitted actions within the role on the whole product portfolio of that organisation. Careful consideration and explicit agreement of the processes is strongly recommended.

1.6. Can consultants perform submissions on behalf of MAHs in the UPD?

Consultants must request access rights (i.e., a role on behalf of an organisation, e.g., submit variations on behalf of organisation XY) through the [EMA Account Management Portal](#). The Super User of the respective MAH will approve and subsequently administrate the access rights in the [EMA Account Management Portal](#).

The Super User of the respective MAH must be aware that the approved role will grant rights (view and/or submit) to the whole product portfolio of the given MAH, including confidential data.

1.7. Is there a maximum number of accounts per MAH?

No limit to the number of user interface (UI) accounts per MAH is foreseen. For the application programming interface (API), only one account per MAH is available (as this is a machine-to-machine interaction).

1.8. Is it a concern if a company has slightly different names in various countries or even within one country compared to the Marketing Authorisation Holder (MAH)? Will National Competent Authorities (NCAs) view this as a discrepancy, or will it be treated as equivalent names for one organisation?

Just like OMS, each legal entity equals one organisation. MAHs can verify the accuracy of their organisational data in OMS. It is important to request roles for UPD access separately for each organisation, especially if multiple affiliated organisations are designated as MAHs in different countries for the same MRP/DCP product. In such cases, individuals handling activities for the entire product group must have the relevant role for each MAH involved.

1.9. Can distributors of a VMP/procedure view/enter/change data?

Access and permission are governed by the UPD Access Policy, which foresees Level 2 access for MAHs. If a distributor/consultant is appointed as a user by a MAH, that distributor will have the same view/permissions as the respective MAH.

2. General information on data available in the UPD

2.1. Is sales data submitted to the UPD available to the public?

Submitted sales data are not public data and will not be disclosed to the public or other MAHs. This data is only accessible to CAs and the individuals with Super User / User access affiliated to the individual MAH.

2.2. Are parallel traded products in scope of the UPD?

Parallel traded products fall within the UPD scope and are entered into the database by the NCAs of the destination country as stand-alone products, with reference to the source product and wholesaler and the destination reference product and wholesaler.

The provisions set in Regulation (EU) 2019/6 can be found in Article 102. For guidance on national implementation of parallel trade provisions, we recommend contacting the relevant competent authority.

2.3. Are parallel distribution products in scope of the UPD?

Parallel distribution products are already included in the UPD as products authorised in all EU Member States under the centralised procedure. The parallel distribution activities are not reflected in the UPD, i.e., it is not possible to see which products are parallel distributed. For further details see the [EMA website](#).

2.4. What data related to the PSMF shall be included in the UPD?

As stated in Chapter 2 of the Vet EU IG, the PSMF reference number and location are not mandatory for legacy data. The PSMF is mandatory for new VMP for which marketing authorisation is granted under Regulation (EU) 2019/6. For legacy data, MAHs should provide the PSMF code and PSMF location as soon as possible, via a variation not requiring assessment.

2.5. What is the format of the PSMF reference number and location?

MAHs will set the reference number themselves as free text (it is not set automatically, nor does it need to be requested). The PSMF reference number must be unique for the company and products it covers – for example, if a company has two PSMFs in place for two groups of products, the two respective numbers must be different and unique within that company.

The recommended format is the following: prefix “PSMF” followed by a reference number allocated by the MAH/QPPV. Please note that for some NCAs the use of prefix “PSMF” is a must.

The PSMF location is organisation data from OMS, same as for the product owner and manufacturing site information.

3. General information about functionalities

3.1. What information are MAHs responsible for, in terms of uploading and updating in the UPD?

Via UPD the MAHs are responsible for submission of variations not requiring assessment, updating information on availability status, placing on the market date*, marketing authorisation status (in case of revocation/suspension), product grouping and third country product names, and submission of Volume of Sales.

*Please note that this attribute is derived from the availability status date when the product was first set to marketed.

3.2. Do MAHs have to provide data on third country product names?

Yes, MAHs are required to link third country product names to their EU/EEA name. For further information, please consult the ["Product grouping and 3rd country product names Webinar for UPD Industry users"](#).

3.3. Who should the MAHs contact to address data quality issues of their products?

According to Article 18(9) of the Commission Implementing Regulation (EU) 2021/16, if MAHs identify data or document quality issues in their UPD products, they shall immediately notify the relevant Competent Authority which shall correct the data. For products authorised via MRP/DCP or NP we recommend contacting directly the UPD national contact points listed in the [HMA website](#). The quick link to the document can be found [here](#). For CAPs please submit a ticket via [ServiceNow](#).

3.4. Which functionalities are available for MAHs in the UPD?

The following functionalities are available for MAHs:

- Search and View product data;
- Edit availability status (marketed or not);
- Edit marketing authorisation status (in case of revocation/suspension);
- Download, Submit or Edit Product grouping and Third country product names;
- Download, Submit or Edit Volume of Sales;
- Submit variations not requiring assessment (VNRAs);
- Search for Notifications.

3.5. Are updates and expanded functionalities expected? By when? For which functionalities?

Additional functionalities and improvements will be made available at every iterative release, approximately every 3 months. Please refer to the below roadmap for further information on features planned to be developed and those who are currently being analysed. Moreover, users can refer to the [EMA's UPD webpage](#) for guidance (EU IG, release notes, video tutorials, webinar recordings).

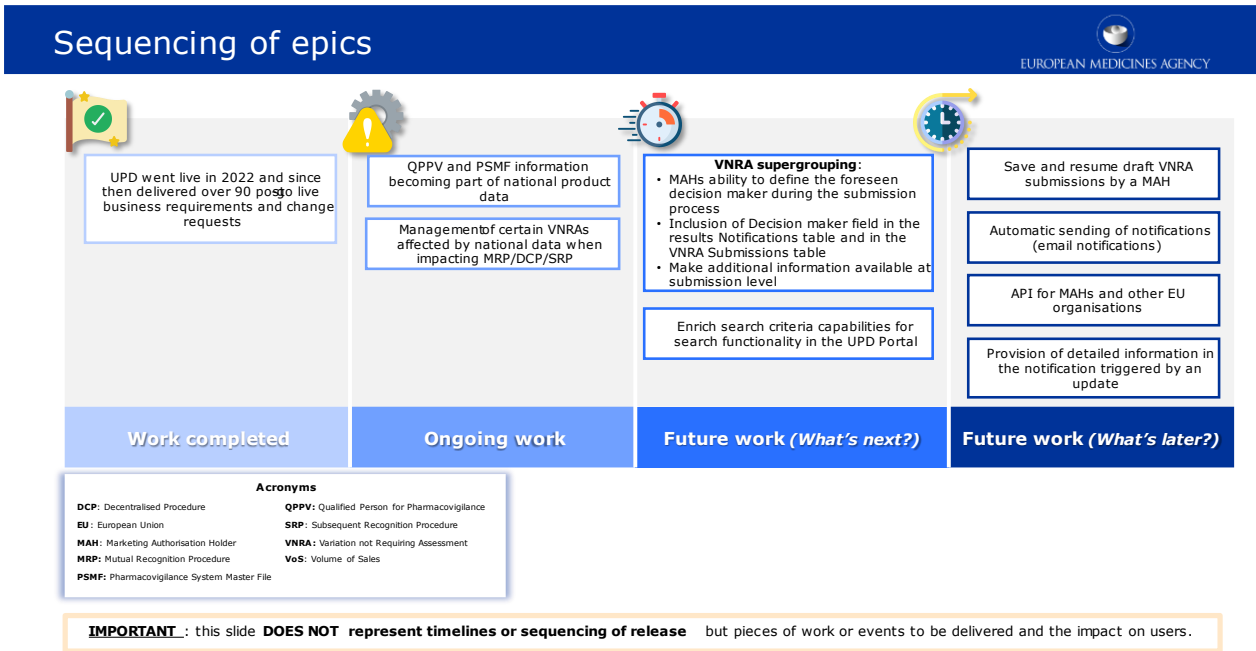


Figure 1 - UPD roadmap

3.6. Do notifications for MAHs contain the exact change in the product data?

This has not yet been implemented although it is in the pipeline to be delivered in future releases. As of now, MAHs are able to access the UPD and view notifications related to changes in their products (though some not showing the exact details of the change); the date of the action performed and the version of the product.

3.7. In addition to the marketing authorisation date, is it possible to see the date for the latest update of a product?

After performing a search, the UPD Web UI displays the latest version of a product. Users are able to view the different product versions identified by a version number and with the date of the update.

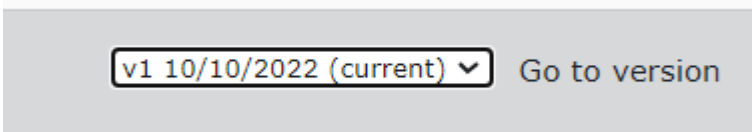


Figure 2 - Latest update of a product

3.8. Is it possible to export and download the information/search results from the UPD?

Yes, search results are downloadable. The UPD allows users to export in a .csv format the following fields of a product: Procedure number, Product name, Active substance and strength, Target species, MAH Product owner, Marketing authorisation number, Pharmaceutical form and Authorisation country. Moreover, an improved version of the .csv document containing more product information is currently being prioritised for implementation.

3.9. Can MAHs request a SPOR RMS update to the EMA when a term is missing?

Please refer to the guidance provided on the [SPOR portal](#).

Please note that some RMS lists are owned by the European Directorate for the Quality of Medicines & HealthCare (EDQM), therefore the rules from the EDQM Standard terms are applicable and the EDQM will be the final decision-maker regarding the requests. For target species, the Committee for Veterinary Medicinal Products (CVMP) in consultation with QRD Working Party and CMDv evaluates and decides on the requests received.

3.10. Will the UPD API be available for use of customised software products, independently from the UI?

At present, MAHs do not have API access. Please note that the API read functionality to product data and write functionality for Volume of Sales will be provided in the near future.

3.11. Are there file size limits for uploads?

The maximum size allowed for PuAR, SPC, PL, labelling is 10MB. For VNeS files, the maximum size allowed is 6GB.

4. General information on availability and authorisation status

4.1. What is the timeline for providing information on availability status for MAHs?

MAHs are obliged to submit this information in UPD and keep it always up-to-date.

4.2. What do MAHs have to enter in terms of authorisation status?

MAHs can update the authorisation status of their respective products from valid or suspended providing the new authorisation status (suspended or revoked) and the date when the authorisation status change. In case of revocation or suspension, the MAH can update the MA status in the UPD, within the Other Post-Authorisation Data (OPAD) section.

Note that Competent Authorities are also able to manage in the system the marketing authorisation status of the veterinary medicinal products under their responsibility and they are the only ones who can set the status of a veterinary medicinal product to 'Valid'.

5. General information about Volume of Sales (VoS)

5.1. Why does the Volume of Sales need to be submitted? What is going to be done with this data?

The Volume of Sales data together with the species spread and dose factors submitted will be used to calculate an estimated number of treated animals, which will subsequently be used, in combination with the number of adverse event reports received for the product, to calculate incidence (to be published from 2024). The sales volumes for antimicrobials will also be used by NCAs as a starting point for the antimicrobial sales data to be submitted by NCAs into the future antimicrobial sales and use data collection system.

5.2. Where can MAHs find information on the procedure to report sales data?

For guidance, data specifications and examples please refer to [Chapter 7 of the EU Implementation Guide \(Vet EU IG\)](#), the [webinar on Volume of Sales](#) held in April 2023, and the [video tutorial "how to submit Volume of Sales"](#).

5.3. Would it be possible to establish some restrictions to some data to, for example, avoid distributors can have access to Volume of Sales for the full portfolio?

Volume of Sales is only accessible to NCAs and to Industry users depending on their affiliation to organisation(s) with MAH role. Please note that wholesale distributors have no reporting obligations in the UPD under Regulation 2019/6 and therefore do not have access to the restricted areas of the UPD. Volume of Sales is not published on the UPD public portal. Therefore, wholesale distributors cannot access Volume of Sales information, unless the relevant MAH Super User gives access to the distributor.

5.4. When shall MAHs start reporting sales data? How often will Volume of Sales need to be provided?

MAHs have flexibility to submit any number of products per submission, and any number of submissions per year, with granularity fixed at monthly level. The frequency of this submission is to be decided by the MAH (monthly, quarterly, yearly). It is expected that the submission timelines will be aligned to the calendar year. For new products, first-year reporting would cover the period from the date of placing on the market until 31 December.

Marketing authorisation holders for veterinary medicines must submit their data on annual Volume of Sales in 2023 by 29 February 2024 (the annual deadline is end of February from now on). 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. Those who have yet to submit data for 2022 should do so as well. Guidance is available on the [EMA's UPD webpage](#).

5.5. Do MAHs need to report estimated sales in off-label species?

No, MAHs should only report estimated sales in registered species in any EEA or non-EEA country (this means that non-EEA sales may report use in a species not registered in the EEA).

5.6. Do MAHs have to submit sales data also to other EMA databases (i.e., ASU or EVVet3?)

No, only into the UPD.

5.7. Are sales to non-EU countries to be reported?

As a result of pharmacovigilance requirements, a MAH will need to also submit the annual volume of sales in non-EEA countries for each of their veterinary medicinal products. In this case, considering that the volume of sales is submitted at package level, one single value will be submitted for all non-EEA countries against an equivalent package in the UPD (either same pack size or adjusted to an equivalent pack size). For further information see [Chapter 7 of the EU Implementation Guide \(Vet EU IG\)](#).

5.8. Do MAHs need to report non-EEA sales even for products for which there were no EEA sales?

Yes, even if there are no sales in EU for a particular product, the MAH should report the non-EEA sales. Note that reporting of non-EEA volume of sales must be matched to one or more EEA package identifier(s).

5.9. What information shall be submitted as part of the sales data file?

Volume of Sales is submitted in one line per package, country and species. MAHs must provide the mandatory data below:

- Package Identifier
- Country identifier
- Year-Month
- Volume of Sales
- Species Identifier
- Species %
- Dose Factor

Please refer to [Chapter 7 of the EU Implementation Guide \(Vet EU IG\)](#).

5.10. How do MAHs retrieve the relevant information on packages?

MAH users can retrieve the list of packages from the Web UI. The list will contain only information on products of the organisation(s) linked to the current users' assigned access rights (organisation affiliation).

5.11. What to do if packages are missing in the downloaded list?

MAHs should notify the relevant NCA.

5.12. For VMPs approved for several target species, how to know the sales distribution per species?

The species spread (100% if only one species, or the estimated spread across species in case of more than one) must be provided. The spread is estimated in the same way estimation is now done for PSURs. From Chapter 7: For EEA sales the total of the species % figures for a specific package should be 100. For non-EEA sales the total of the Species % figures for a specific package should be between 95 and 105. For packages with only one authorised species, the Species % should be 100. This information shall be provided as a positive number with or without decimal point, between 0 and 100.

5.13. In case of multispecies products, do MAHs need to have as many lines as species for each product and country?

Yes, for multispecies products one line per target species for which estimated sales will be reported, product and country is needed. Users shall indicate from the total Volume of Sales of a package which percentage is estimated to be used in each of the target species.

5.14. Case: how to report volume of sales on a product indicated for use in cattle only in one country, in cattle and sheep 50% and 50% in a second country, and in cattle, sheep and pigs 33% sheep 33% cattle 33% in a third country?

Considering that they are going to be submitted by country, a MAH will need to report:

- For the first case, the total volume of sales of the product will be recorded in one row with the target species 'cattle';
- For the second case, the total volume of sales will be recorded in two rows (i.e. same value recorded twice), one for each target species 'cattle' (row 1) and 'sheep' (row 2) and the species spread will indicate 50% in each row → 2 rows in the submission file'
- For the third case, the total volume of sales will be recorded in three rows, one for each target species 'pigs', 'sheep' and 'cattle' and the species spread recorded in each row → 3 rows in the submission file.

5.15. How are multilingual/multi-country packages handled?

A package of a product that has been approved under the same decentralised, mutual recognition or subsequent recognition procedure will share the same package identifier among the countries involved in the procedure. When submitting Volume of Sales, a MAH will have to complete a line for each package, country and target species, and when submitting availability status, a line for each package and country.

5.16. Regarding the Volume of Sales, how is parallel trade/distribution handled (mainly related to the calculation of incidence in pharmacovigilance)?

Parallel traded products must be provided into UPD by the NCAs as stand-alone products with reference to the source product and destination country. Sales of the products that have been parallel traded or moved across borders in parallel distribution (i.e., how many packs were moved from one country to the other) will not be reported– i.e., the sales will be reported by the MAHS as sales in the source country only.

For pharmacovigilance purposes, these cross-border movements are expected to have no significant impact on incidence, and it was therefore recommended that this could be disregarded for the UPD implementation of sales volumes reporting, also considering that there is no legal base to ask wholesale distributors to report sales volumes into the UPD.

5.17. What is the 'dose factor'?

The 'dose factor' is part of the information that a MAH will have to provide as part of the Volume of Sales submission. The dose factor refers to the number of animals of a particular species that can be treated on average with 1 of the relevant packs. In combination with the number of packs sold, it will be used to calculate the estimated number of treated animals (ENTA), information needed to support pharmacovigilance activities, including publication of incidence from 2024 onwards. Additional guidance is available on [EMA's UPD webpage](#).

5.18. What is the file format that should be submitted?

All VoS information should be submitted in .csv file format. See [Chapter 7 of the EU Implementation Guide \(Vet EU IG\)](#) for more information.

5.19. The UPD only contains products for UK(NI) authorised under CP, MRP/DCP/SRP, but the sales data typically come from the entire UK. Is it acceptable to submit full UK data to UK(NI) entries in UPD?

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.

5.20. 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.

5.21. 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.)?

Additional guidance on standard bodyweights is available at [Guideline on the calculation of dose factor to be submitted to the Union Product Database \(UPD\)](#).

5.22. 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, complete 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 package/ country/ species/ 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 / species/ year-month.

5.23. 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.

5.24. 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.

5.25. For the species that are not mentioned in Appendix 1 of the [Guideline on the calculation of dose factor to be submitted to the Union Product Database \(UPD\)](#) - List of standard average weights for target species - 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.

5.26. 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.

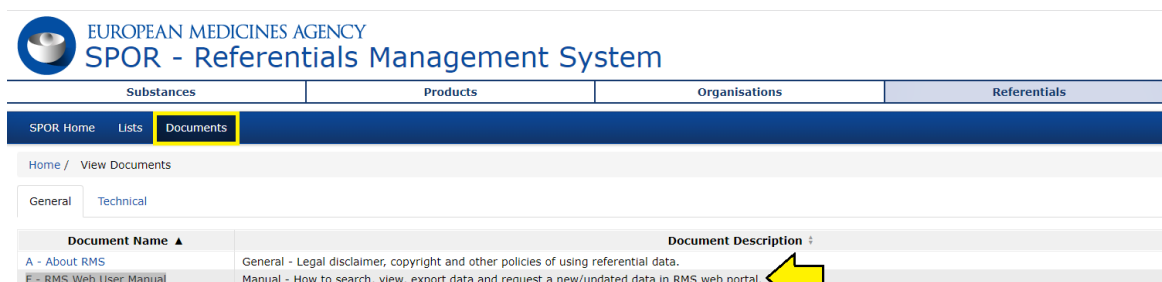


Figure 3 – Documents description

5.27. Do MAHs need to report Volume of Sales even for products that were surrendered?

Yes, even if the product has been surrendered, but packages are still sold during the reporting period, the MAH should report sales for each product presentation.

5.28. 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?

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.

5.29. Where can I find more practical information about Volume of Sales?

For further information, please consult the [Volume of sales webinar for UPD industry users](#).

6. Variations not requiring assessment – VNRAs

6.1. Variations not requiring assessment need to be recorded in the UPD within 30 days of making the change. What happens if that variation is rejected? Should MAH undo / reverse the already implemented change?

MAHs would have to cease applying the rejected variation unless a corrected VNRA can be submitted within a reasonable time after implementing the change. If the rejection was based on insufficient supporting documentation, the MAH would have to submit a new complete VNRA as soon as possible. In case of incorrect classification of the change as a VNRA, the change should be resubmitted as soon as possible as a VRA.

6.2. Once a VNRA has been approved by the CA, will the UPD allow generating a .pdf as a proof of this approval?

MAHs can generate a proof through their browser by selecting "print to PDF". A built-in functionality to generate a PDF document is now available in the UPD UI: under the VNRA menu, by accessing the View VNRA submissions submenu, users can download the information submitted and approved by clicking on the link provided on the last column of the results table (bear in mind that to reach this point, the 'Status' column must display 'APPROVED').



Submission id ↑	Submission date ↑	Submission comment ↑	Vnees file	Status ↑	Download VNRA data
4324	18/10/2023	adad	Test Vnees 2.5 gb (1).zip	PENDING	VNRA_Submission id_4324.pdf
4321	18/10/2023	VNRA_submissions_B6_code_verify_SRG	Vnees5 file - less 10MB - 019.zip	PENDING	VNRA_Submission id_4321.pdf

Figure 4 - .pdf of VNRA approval

6.3. How to ensure confidentiality of data for submission of VNRAs against a product approved under DCP|MRP|SRP and owned by different MAHs?

In situations involving unrelated Marketing Authorisation Holders (MAHs), each MAH is limited to submitting VNRAs solely for their own products. The system does not present, in a VNRA submission, products at a permanent ID level that are not part of the respective MAH's portfolio. In the event of a

requirement, both MAHs must independently submit two separate VNRAs, each containing products exclusively within their own portfolio.

6.4. Shall MAHs update QPPV name and location?

The UPD fields on QPPV name and location contain placeholder data which MAHs can update only via variation not requiring assessment (or by providing the information to the NCA so that they can update this). As per the current VNRA functionality, the approval of VNRAs C1, C5 and C6 triggers an automatic update of these fields.

6.5. What does 'VNRA automation' mean?

Automation refers to the functionality that will automatically update a field changed by a VNRA in the UPD when the NCA approves it. VNRA codes that are automated in the UPD are A1a, A4, C1, C5 and C6. For the other VNRA codes, these field updates have to be performed manually by the NCA via the "product update" functionality.

6.6. How can MAHs submit a VNRA for a product which is not yet in the UPD?

In case a product is not yet available in the UPD, MAHs should contact the responsible CA as early as possible to agree on a course of action.

6.7. What should a MAH do in case a variation not requiring assessment is missing in the Implementing Act on VNRAs and from the guideline on VRAs?

A VRA submission would be required until the Implementing Act on VNRAs is updated by the EC. The VRA guidance includes placeholder classifications for unclassified changes in each section.

6.8. What is the difference between VNRA status and submission status?

VNRA status is the status of each 'product + VNRA' belonging to a VNRA submission: it can be 'Pending, Approved or Rejected'. Submission status is the status of the complete submission (that can contain several 'products + VNRA' codes). If we have at least one 'product + VNRA' with status pending, the Submission status will be 'Pending'. If all 'products + VNRAs' are approved – the Submission status is 'Approved'. If all 'products + VNRAs' are rejected – the Submission status is 'Rejected'. If there are no 'product + VNRA' with pending status but containing 'Approved' and 'Rejected' - the Submission status is 'Partially approved'.

6.9. Where can I find more guidance about VNRAs?

For further guidance regarding VNRAs, please consult the [EMA's webpage on VNRAs](#) and [CMDv Best Practice Guide on VNRAs](#)