Veterinary Medicines Division
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Union Product Database (UPD) – Questions & Answers
Industry Use

Disclaimer

This document is for information only and it is based on questions asked 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	**OMS**	Organisation Management Service
AvS	Availability Status	**OPAD**	Other Post-Authorisation Data
CA	Competent Authority	**PuAR**	Public Assessment Report
CAP	Centrally Authorised Products	**PSMF**	Pharmacovigilance System Master File
CMDv	Coordination group for mutual recognition and decentralised procedures for veterinary medicinal products	**PSUR**	Periodic Safety Update Report
CMS	Concerned Member State	**Q&A**	Questions & Answers
CP	Centralised Procedure	**QRD**	Quality Review of Documents
CSV	Comma-separated values	**QPPV**	Qualified Person Responsible For Pharmacovigilance
CVMP	Committee for Veterinary Medicinal Products	**RMS**	Referentials Management Service
DCP	Decentralised Procedure	**SPC**	Summary of Product Characteristics
EDQM	European Directorate for the Quality of Medicines & HealthCare	**SPOR**	Substances, Products, Organisations and Referentials
EEA	European Economic Area	**SRP**	Subsequent Recognition Procedure
EMA	European Medicines Agency	**UAT**	User Acceptance Test
ENTA	Estimated number of treated animals	**UI**	User Interface
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption	**UK**	United Kingdom
EU	European Union	**UK(NI)**	Northern Ireland
EVVet3	EudraVigilance Veterinary	**UPD**	Union Product Database
HMA	Heads of Medicines Agencies	**VMP**	Veterinary Medicinal Product
IG	Implementation Guide	**VNeeS**	Veterinary Non eCTD Electronic Submission
MAH	Marketing Authorisation Holder	**VNRA**	Variations not requiring assessment
MRP	Mutual Recognition Procedure	**VoS**	Volume of Sales
NAP	Nationally Authorised Product	**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 users register for a UPD account?

For information on how to register, please refer to the "Registration and access to UPD restricted area" section of the UPD webpage.

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. If multiple MAHs are involved in a procedure, can all of them edit product data, or only the product owner?

It depends on what the involved MAHs agree on. Super Users can assign roles to users within or outside their organisation. Users can only edit products if they have the correct role for the owning

organisation. External users with access can act across the organisation's product portfolio based on their role. Clear agreements and careful planning are strongly advised.

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. How is it handled if a company operates under slightly different names across countries or within the same country compared to the MAH name? Will NCAs consider this a discrepancy?

No, each legal entity is considered a separate organisation, as in OMS. MAHs should ensure their data is accurate in OMS and request UPD access roles separately for each entity. Where multiple affiliated MAHs are involved in the same MRP/DCP product, users must hold the appropriate role for each MAH to manage the product group effectively.

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.

1.10. Where can I find information about the newest releases, fixed bugs, known issues and workarounds etc?

Please refer to the Release Notes, found here: Union Product Database: release notes | European Medicines Agency (EMA).

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 data is mandatory for new VMPs 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. Should MAHs 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 see Chapter 7 of the EU Implementation Guide (Vet EU IG) and consult the "Product grouping and 3rd country product names Webinar for UPD Industry users".

3.2. Who should 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. For CAPs please submit a ticket via ServiceNow.

3.3. 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.

3.4. How do I configure email address for receiving notifications?

Super users must use the "Email Configuration" form to set the email address(es) for receiving UPD system notifications. For more information please see the Guidance for MAH and CA Super users how to configure email addresses for UPD notifications.

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

Indeed, 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. For further information, please consult the available Quick guide.

3.6. What is the difference between the UI notifications and notifications received by email?

UI notifications are created as soon as an action is performed in UPD whereas Email notifications are created in a batch process at the end of the day.
UI notifications are created per product for every action performed, while Email notifications are sent per action performed, and may contain information about more than one product.

Email notifications are created in a batch process at the end of the day. For all non-centrally authorised products, user receives an email notification for product update the next day (within 24 hours). For all non-centrally authorised products, user receives an email notification for product update the day after (between 24 and 48 hours). For more information please see the Quick Guide, in the Guidance Sections.

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.

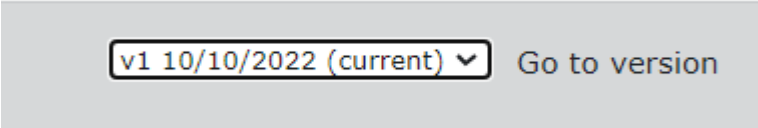

Figure 1 - Latest update of a product

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. For the full list of downloadable fields please see UPD 1.7.2427 Release Notes.

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 have read-only API access. For further details, consult Chapter 5 of the EU IG.

3.11. Are there file size limits for uploads?

The maximum size allowed for volume of sales .csv file, availability status .csv file, Public Assessment Report, summary of product characteristics, package leaflet, labelling is 10MB. For VNeeS 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 should MAHs enter in terms of authorisation status?

The system allows MAHs to 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.

Notes:

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'.

MAH users must not change the status of an MA via UPD unless this is both the correct status and has been explicitly agreed with the relevant competent authority to avoid confusion.

In other cases where a MA status is incorrect, users must contact the competent authority directly to arrange for the necessary corrections.

4.3. What do I do if I receive an error file after the Availability Status (AvS) submission

If the errors in the file are due to business validations (see section 4.3.2 of Chapter 7 of the EU Implementation Guide (Vet EU IG)), **fix the errors and resubmit the file**.

If the file contains ER.36 (see section 4.3.1 of Chapter 7 of the EU Implementation Guide (Vet EU IG)), then pay attention to the last column of the file:

- The rows that in the last column contain ER.36, please group them in a new Excel or .csv file and submit it in a ticket to EMA Service Now.
- If you have rows having in the last column the value 'N/A', please resubmit those rows to UPD;
- If you have rows having in the last column values of the type 'Database updated - Submission 0000 - Product 00000', please do not resubmit as those updates have been processed successfully.

	B	C	D	E	G	H	J	N	O	P
1	Product Name	Permanent Identifier	Authorisation Procedure Numbe	Package Identifier	Pack size_Nu	size_Unit of	Country	Availability Status	Availability Status Da	
2	Example	600000000001	EMEA/V/C/000000	C81CC9A8-2B9A-6B62	1	Vial	Denmark	100000072075	1/1/2020	ER.36: Package could not be updated - Reason: %s Plea
3	Example	600000000002	EMEA/V/C/000000	C81CC9A8-2B9A-6B62	1	Vial	Czechia	100000072075	1/1/2020	N/A
4	Example	600000000003	EMEA/V/C/000000	C81CC9A8-2B9A-6B62	1	Vial	Cyprus	100000072075	1/1/2020	Database updated - Submission 0000 - Product 00000

- Once the errors of type ER.36 have been addressed, incorporate the AvS of those products into the next submission, and if you again receive any error repeat all the above steps.

Over time, as ER.36 issues are cleaned up, the size of the carry forward from month to month should diminish in size and eventually disappear.

5. General information about Volume of Sales (VoS)

For specific 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 December 2024, and the video tutorial "how to submit Volume of Sales".

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 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 antimicrobial sales and use data collection system.

5.2. 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.

5.3. When shall MAHs report 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 complete their submission of data on annual Volume of Sales by the end of February of the following year.

5.4. 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).

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

No, only into the UPD.

5.6. Should sales to non-EU countries 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).

5.7. Should MAHs 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).

5.8. 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

5.9. 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).

5.10. What should MAHs do in case of missing packages in the downloaded list?

MAHs should notify the relevant NCA.

5.11. For VMPs authorised for multiple target species, how can the sales be attributed or distributed across each 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.

5.12. In case of multispecies products, should MAHs provide 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.

5.13. How should the third country volume of sales be reported in case of a product indicated for use in cattle only country A, in cattle and sheep 50% and 50% in a country B, and in cattle, sheep and pigs 33% sheep 33% cattle 33% in country C?

Considering that third country sales are reported as a single sales figure for the 'Non-EEA' country, then a MAH will need to report: (note - the MAH will need to determine a non-EEA species split for each non-EEA target species)

- the total volume of non-EEA sales of the product will be recorded in one row with the MAH non-EEA species split for the target species 'cattle';
- the total volume of non-EEA sales of the product will be recorded in one row with the MAH non-EEA species split for the target species 'sheep;
- the total volume of non-EEA sales of the product will be recorded in one row with the MAH non-EEA species split for the target species 'pigs;

For this product – there will be three rows in the submission file for the non-EEA sales.

5.14. How should the volume of sales be reported in the EEA in the case of a product/package indicated for use in cattle only in one EEA country, in cattle and sheep 50% and 50% in a second EEA country, and in cattle, sheep and pigs 33% sheep 33% cattle 33% in a third EEA country?

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

- For the first case, the total volume of sales of the product/package will be recorded in one row with the target species 'cattle';
- For the second case, the total volume of sales for the product/package 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 for the product package 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 on standard bodyweights is available at Guideline on the calculation of dose factor to be submitted to the Union Product Database (UPD).

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

All Volume of Sales 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 comes 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 UK(NI) CAPs/MRP/DCP/SRP products only. Where the MAH is not able to split out UK(NI) sales from the MAH total UK sales (i.e. Great Britain + Northern Ireland), then it is possible to estimate UK(NI) sales from the total of all UK sales data. 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, MAHs' aim is to get data from each of them. Are MAHs 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 resubmit data for a month already submitted? If incorrect data was previously uploaded, can users replace it by submitting an updated CSV file?

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, volume of sales 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 from the RMS Target Species list (which includes further subdivision of species with regard to e.g. gender or production type), volume of sales data must be submitted using RMS Species list identifiers. The RMS Species list provides no such additional subdivision. Regarding the example "Indian hen", please take note that this is a bird species and does not in fact refer to a female bird as the term "hen" implies. However, if for example the SPC species term is *Chicken (hen)* then the term *Chicken* from the Species list shall be used for the submission of volume of sales.

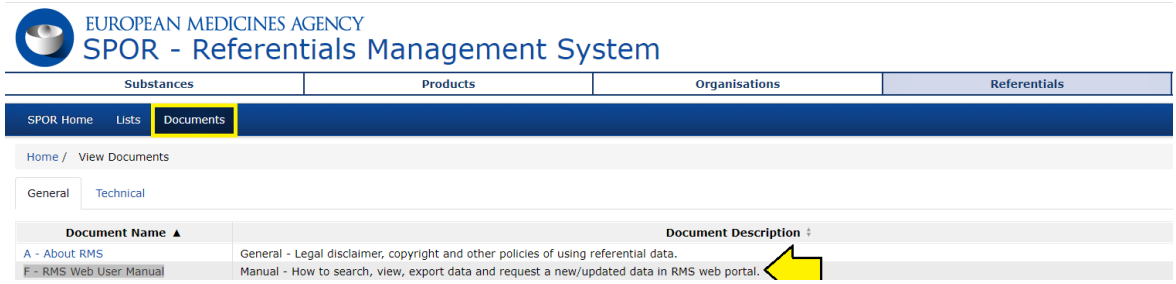

Figure 2 – Documents description

5.27. Should MAHs 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 are no sales for certain months but the corresponding columns have already been included, can users enter a "ZERO" value for those months, or is it possible to remove them entirely 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:

- Chapter 7 of the EU Implementation Guide (Vet EU IG),
- the webinar on Volume of Sales held in December 2024,
- the video tutorial "how to submit Volume of Sales",
- Guideline on the calculation of dose factor to be submitted to the Union Product Database (UPD).

6. Other post-authorisation data (OPAD)

Further information regarding submission of Third Country Product Names (mandatory) and MAH Product Grouping (optional but recommended) can be found by referring to Chapter 7 of the EU Implementation Guide (Vet EU IG).

7. Variations not requiring assessment (VNRAs)

7.1. Variations not requiring assessment must be recorded in the UPD within 30 days of implementation. If such a variation is subsequently rejected, is the MAH required to reverse the change already made?

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.

7.2. Is there a limit to the number of variations in a single VNRA submission?

Combining many products within a single VNRA submission (irrespective of whether it is a technical grouping or supergrouping) via the UPD UI can lead to challenges both for the industry users when submitting, and NCA UI users when approving/rejecting the VNRA. The 'recommended' maximum limit is 2000 changes (1000 products x 2 VNRA codes = 2000 changes).

7.3. Can I save an incomplete VNRA submission as draft and resume it later?

MAHs can save an incomplete VNRA submission via a user interface and resume it within 30 days. For further details, watch the "How to save and resume draft VNRA submissions" video tutorial available on UPD video tutorials for MAHs.

Note: MAH users should be aware that if they intend to save an incomplete VNRA submission and later resume it within 30 days, that saved file has a limitation of maximum 1000 products that can be within the draft VNRA submission. This means that any number of products above 1000 will not be saved nor later retrievable from the draft file. Until a solution is deployed, we recommend all MAH users to submit VNRA submission that exceed 1000 products directly and not saving the draft VNRA submission.

7.4. 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').

Figure 3 - .pdf of VNRA approval

7.5. How is data confidentiality ensured when submitting VNRAs for a product authorised under DCP, MRP, or SRP procedures, particularly when the product is owned by different MAHs?

In situations involving unrelated MAHs, each one 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.

7.6. Should MAHs update the 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.

7.7. 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.

7.8. 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.

7.9. What should a MAH do if a VNRA is not listed in either the Implementing Act on VNRAs or 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.

7.10. What should a MAH do if the VNRA is consequential to a VRA?

MAHs should select the checkbox for consequential VNRA and provide the VRA number associated with it. When providing the "Consequential VNRA as a result of a VRA" value during the submission of a VNRA, the corresponding field and the value are visible to both NCAs and MAHs. Moreover, the VRA number is available in the VNRA PDF downloads when provided during submissions.

7.11. What do I do if product grouping fails after Transfer of Ownership?

Please submit a ticket via ServiceNow requesting datafix(es) on affected product(s).

7.12. 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'.

7.13. 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.