EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Version 1.2 – February 2022

## Frequently Asked Questions

# Union Product Database – Q&As for industry users

**This document consolidates questions and answers asked by marketing authorisation holders (MAHs) on the usage of the Union Product Database (UPD)**

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This document consolidates questions and answers asked by marketing authorisation holders (MAHs) on the usage of the Union Product Database (UPD). This is a living document which is intended to be updated with additional questions and answers as and when they become available.

Please submit any questions related to the usage of the UPD to vetchange.programme@ema.europa.eu

# Access

## 1. Is it mandatory to be registered as MAH in SPOR to use the UPD?

Users will have to request access to the UPD on behalf of a given company, as defined in OMS. To have access to the data for a specific group of products in the UPD, that company will have to be MAH for those products.

As a result, companies that are MAH for veterinary medicinal products will need to be registered in SPOR. For legacy products (i.e., the already registered products), NCAs are mapping organisation data to ensure MAHs are correctly recorded in OMS SPOR. From January 2022, MAHs are encouraged to check their organisation and location data in OMS and submit a change request, if necessary. Going forward, MAHs will need to ensure their organisation and location data in OMS are kept up-to-date and will need to register users, as necessary.

In addition, users will have to request UPD roles on behalf of MAH organisations to use the UPD for data submission and view confidential information relating to their products. Users do not necessarily need to be employed by that organisation but need to be affiliated to it.

As there is no concept of 'parent company' within the UPD roles, as needed, individuals may need to be affiliated to all the different MAHs within a group of companies.

Besides, it is not necessary that the same users register both in SPOR OMS and in the UPD, unless they have to perform both types of activities.

For SPOR OMS, user registration guidance is available here. For the UPD, see question 2.

## 2. Are the SPOR roles that have already been established (Industry Super User, Industry User, Guest User), going to be also valid for the UPD, or will MAHs have to create new ones again?

If you have an existing account for other EMA-hosted systems (such as Eudralink, IRIS, SPOR, …) you will use the same credentials, but you will have to request access to the UPD role (s) for that account on the EMA Account Management Portal first. The detailed instructions on how to request these will be shared in due course.
To check whether you already have an EMA account and get more info about EMA SSO (Single Sign-on), please visit https://register.ema.europa.eu.

## 3. How will user management work for Users and Super Users?

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

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

UPD industry Super Users will be able to grant/revoke UPD rights to users in addition to viewing and submitting data.

### 4. Will consultants be able to submit on behalf of MAHs on the UPD?

Consultants must request rights (a role on behalf of an organisation, e.g., submit variations on behalf of organisation XY) in 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 the approved role (view and/or submit) will grant rights to the whole product portfolio of the given MAH, including confidential data.

In the future, additional roles will be implemented to enable granting rights only to certain information or activities.

### 5. Will distributors of a VMP/procedure be able to view/enter/change data (i.e., sales from their territories)?

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

In the future, additional roles will be implemented to enable granting rights only to certain information or activities.

### 6. 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 will be available per MAH (as this is a machine-to-machine interaction). The same applies for NCAs.

## Data available

### 7. What can MAHs see in the UPD? And other users?

The UPD restricted portal has been set up for the users that have been granted a role/permission by CAs and MAHs in line with the access policy. A public portal will be available to any interested users of the public.

- In the restricted UPD: MAHs will be able to see and edit information on their own products (such products that are owned by an organisation they have been granted access permissions for);
- In public portal: any interested users will be able to see limited information for all products, ie. without commercially confidential or personal data.

### 8. Will sales data be available to the public?

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

## 9. One company may have slightly different names in several countries and even within one country. Will NCAs have a remark on this if this is different compared to the MAH? Or will this be handled as equivalent names for one organisation?

The same logic as for OMS should apply. Each legal entity = 1 organisation in OMS. MAHs can already check if all their organisational data are correctly recorded in OMS. Please note that the roles for access to perform activities in the UPD must be requested for each organisation (i.e., if several affiliated organisations are set as MAHs in different countries for the same MRP/DCP product, then someone performing actions for the whole group of products needs the relevant role for each of those MAHs).

## 10. Is it possible to limit the access to a certain user; for example, view only for certain MAH, but full access for another one?

Yes, the Super User of each organisation shall be able to approve user roles request from specific users for their organisation only. A user having different 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.

## 11. If you have multiple MAHs in one procedure. Will all MAHs be able to enter/change data? Or will only the IP owner have access to these products? It is not preferred by the IP owner that every MAH can make changes.

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.

*Note: product-based access allocation has been recorded as part of the post-MVP requirements to be prioritised for future improvements of the UPD.*

## 12. Are parallel traded products in scope of UPD?

Parallel traded products are within the UPD scope and will be provided into the UPD 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.

### 13. Are parallel distribution products of veterinary medicines in scope of UPD?

Parallel distribution products will exist in the UPD already as products authorised in all EU Member States under the centralised procedure. The parallel distribution activities will not be reflected in the database, i.e., it will not be possible to see which products are parallel distributed.

## General aspects and functionalities

### 14. When will the UPD become implemented and mandatory to be used by MAHs?

As of its go-live on 28 January 2022.

### 15. What is the meaning of “MVP” and "post-MVP-release"?

On 28 January 2022, the UPD minimum viable product (MVP) will go live. After that, post-MVP releases will go live approximately every three months with the aim to provide additional or improved functionalities.

### 16. When will NCAs upload legacy data? Can MAHs immediately check and correct data in case they do find any inaccuracies?

NCA are uploading legacy data and can do so until the UPD go-live on 28 January 2022.

According to the 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. In these cases, a submission is not required by the MAH. Of course, in case the change the MAH requests constitutes a variation not requiring assessment or amendment of the marketing authorisation, that would require a submission (e.g., a change of the QPPV). We suggest checking the data after 28 January 2022.

### 17. What data will NCAs load into the UPD for legacy products, and what will MAHs upload after the initial upload?

The NCAs are responsible for creating/uploading product data and documents resulting from an initial marketing authorisation and updating the data as a result of a variation. The MAHs are responsible for updating information on availability status, placing on the market date, marketing authorisation status (in case of revocation/suspension) and volume of sales. MAHs will also submit variations not requiring assessment into the UPD, which may lead to a change product data or documents after acceptance by the responsible NCA.

## 18. What will MAHs be able to do with the UPD when it will be released in the first instance?

The UPD minimum viable product going live on 28 January 2022 will enable the following functionalities for MAHs:

- View product data;
- Edit availability status (marketed or not);
- Edit marketing authorisation status (in case of revocation/suspension);
- Submit volume of sales;
- Submit variations not requiring assessment (VNRAs).

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

After the MVP version of the UPD is released on 28 January 2022, additional functionalities and improvements will be made available at every iterative release, approximately every 3 months. For example, the possibility to connect to the UPD via an application programming interface (API) for MAHs will be provided in a post-MVP release.

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

That is not implemented in the MVP but will be discussed for prioritisation to be delivered in future releases. As of the go live, MAHs will be able to access the UPD and view notifications related to changes in their products (some not showing the exact details of the change); and versions of the product.

## 21. Will it be possible to see the date for the latest update of a product and not only the marketing authorisations date?

After performing a search, the UPD Web UI will display the latest version of a product. A user will be able to view the different product versions identified by a version number, but not the date of the update. Addition of the timestamp could be discussed and prioritised for post-MVP releases.

## 22. Are the information/search results going to be exported and downloadable from the UPD?

Yes, search results will be downloadable.

The UPD will allow the user to export in a .csv format the following fields of a product: Authorisation Procedure number, Product name, Active substance and strength, Target species, MAH/Product owner, Marketing authorisation number, Pharmaceutical form and Authorisation country.

MAHs can export their own data as soon as the NCA has created or uploaded their products in the UPD including relevant UPD IDs – Permanent ID, Product ID, Package ID.

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

There is no change here: in case industry users consider that the current RMS list does not have any existing terms that is required, they can raise a change request to the RMS team. The request should contain a justification for the term required and supporting documentation (e.g., product information) referring to the term required. Please refer to the guidance provided on the SPOR portal (https://spor.ema.europa.eu/rmswi/#/viewDocuments).

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 the final decision-maker regarding the requests. For target species, the Committee for Medicinal Products for Veterinary Use (CVMP) evaluates and decides on the requests received.

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

Yes. A software product used by an MAH or NCA can use the UPD API functionality available for the corresponding NCA or MAH after passing basic quality tests in the UAT environment. Please note that the API functionality for MAHs will only be provided in a post-MVP release.

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

As of 28 January 2022, MAHs need to have a Pharmacovigilance System Master File (PSMF) in place for all authorised VMPs (new and existing products).

The PSMF reference and location shall be included in the UPD. MAHs shall agree with NCAs on how to do so, e.g., by providing the information to the NCA for the NCA to update the product, or via a VNRA. In the latter case, it is recommended to postpone the action to May/June 2022 when the next release of VNRA functionality will go live, which is providing automation in the field updates and thus is expected to reduce administrative burden on NCAs and potential for errors in product updates.

## 26. 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 have to be different and unique within that company.

Additional advice on how to structure the number is being discussed.

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

### 27. Shall the PSMF summary be included in the UPD?

The PSMF summary does not need to be included in the dossier for legacy products. Updates to the PSMF summary after 28 January 2022 shall be handled via VNRA by MAHs; at that point, they will be reflected in the dossier.

### 28. Will MAHs have to provide data on third country product names?

No, that will not be required to MAHs for the time being. This is a requirement to be implemented in the future and additional guidance will be provided by EMA when this is scheduled for implementation.

## Availability status

### 29. Does availability status have to be reported at package level?

Yes.

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

For existing veterinary medicinal products that were placed on the market before 28 January 2022 availability status is recommended to be submitted as soon as possible after 28 January 2022, as the public portal will display this information to the general public (including veterinarians and animal owners), and it constitutes important information for them. Please note that there is however no specific deadline.

For products approved after 28 January 2022 or under the new Regulation, it is also in the interest of the MAH to submit this information as soon as is available, bearing in mind that until it is updated, the value that will appear published in the UPD public portal will be 'not marketed' (at package level).

## Authorisation status

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

The authorisation status should be submitted as part of legacy data within the 'national dataset' by the applicable NCA. Please note only products with 'valid' marketing authorisation fall in the scope of the legacy data submission, hence the value 'Valid' (Term ID 100000072099) from the list Regulatory Entitlement Status (RMS List ID 100000072049) is specified.

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'.

The possible authorisation statuses of a veterinary medicinal product based on the Regulatory Entitlement Status list from RMS are as follows: pending, valid, surrendered, suspended, revoked, and expired.

MAHs can update the authorisation status of their respective products to:

Revoked: products for which the authorisation has been revoked by the competent authority

Suspended for MA status should be used for special circumstances; MA is still valid, but the medicinal product must not for some reason be placed on the market.

# Date of placing on the market

## 32. How does the MAH submit the first date when a product is marketed?

The UPD will consider as "date of placing on the market" the date when any package of a product is first reported as marketed in any EEA country. Therefore, the system shall record this date in the database for a product whenever the MAH sets the availability status value 'marketed' for the first time for any of the packages of that product in any EEA country. For legacy data where the first marketed date (or estimate) is not known, this date can be set as 28 January 2022 (the date Regulation (EU) 2019/6 becomes applicable).

# Volume of sales

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

For guidance, data specifications and examples please refer to EU Implementation Guide (Vet EU IG) on veterinary medicines product data in the Union Product Database (europa.eu).

## 34. Why does the volume of sales need to be submitted? What is going to be done with these 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 might also be used by NCAs as a starting point for the antimicrobials sales data to be submitted by NCAs into the future antimicrobials sales and use data collection system.

## 35. When shall MAHs start reporting sales data? How often will sales volumes need to be provided?

The MAH will 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 will 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 into the market until 31 December.

In early 2023 all the sales data for 2022 will have been submitted by MAHs. For January 2022, MAHs have the option to either submit sales data for the period of 28-31 January 2022 or the full month of January – whichever is most convenient for the MAH.

Additional guidance will be reflected in the relevant Pharmacovigilance guidelines under development. Further guidance is being prepared as to the deadline for submission, ie. by when after a certain date the overall annual submission must be complete.

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

No, only into the UPD.

## 37. What information shall be submitted as part of sales data file?

Volume of sales is submitted in one line per package, country and species

MAHs will have to provide the data below:

i. Package Identifier
ii. Country
iii. Country identifier
iv. Month/Year
v. Volume of sales
vi. Species Identifier
vii. Species %
viii. Dose Factor
ix. Comment (optional field)

The data specifications and explanation on the information above is provided in EU Implementation Guide (Vet EU IG) on veterinary medicines product data in the Union Product Database (europa.eu).

## 38. 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).

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

MAHs should notify the relevant NCA. To ensure that missing package information are provided in the UPD and the reporting timelines are met, MAHs should start preparing their submission earlier, in 2022.

## 40. 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.

## 41. What is the 'dose factor'?

The 'dose factor' is part of the information that an 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.

## 42. What file format be submitted?

For the MVP, all information (on volume of sales) will have to be submitted in .csv file format. See EU Implementation Guide (Vet EU IG) on veterinary medicines product data in the Union Product Database (europa.eu) for more information.

## 43. 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 EU Implementation Guide (Vet EU IG) on veterinary medicines product data in the Union Product Database (europa.eu)

## 44. 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 (ie. 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.

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

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

## 46. How will multilingual/multicounty packages be 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.

## 47. Regarding the reporting of sales data: 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. Species split are to be reported as whole numbers (integers); therefore, some splits will not be exact as they need to sum up to 100 (percent).

## 48. Would it be possible to establish some restrictions to some data to, for example, avoid distributors can have access to volumes of sales for the full portfolio?

Volume of sales will only be 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 will 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.

## 49. Regarding the volume of sales, how will parallel trade/distribution be handled (mainly related to the calculation of incidence in pharmacovigilance)?

Parallel traded products will be provided into UPD by the NCAs as stand-alone products with reference to the source product and a 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 MAH 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.

### 50. If you have multiple MAHs in one procedure, will all MAHs be able to view sales data from all territories relating to the procedure? Or will only the IP owner be able to view the sales data relating to the whole procedure?

An MAH user will be able to see volume of sales data for products for which s/he has a role. However, this is not the case with the view of 'submission of volume of sales', where only a user who has the relevant role for all products included in the submission will be able to see the status of the submissions, the sales data, and the report on errors, as applicable.

## Variations not requiring assessment – VNRAs

### 51. 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.

### 52. 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 though their browser ("print to PDF"). A built-in functionality to generate a PDF document is part of the post-MVP requirements to be prioritised by the future governance for the continuous improvement of the UPD.

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

For the UPD MVP, one representative for all involved MAHs will have to make the necessary arrangements to ensure that only one submission is sent to the UPD when several MAHs own the

same product approved under DC|MR|SR procedure (e.g., MAHs could work with a third party and sign the confidentiality agreements needed – the third party would then have access to the whole portfolio from the different unrelated MAHs).

During a post-MVP release of the UPD, specific MAHs roles per functionality will be set up, e.g., a role for submission of VNRAs or for volume of sales.

## 54. 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). If possible, the updates could be performed after May/June 2022 when the first post-MVP release of the VNRA functionality will go live, providing automation of those field updates. This will introduce automation of field updates and would therefore reduce administrative burden on NCAs and potential for errors in product updates. MAHs are encouraged to align with NCAs on the matter.

## 55. What shall MAHs do should they need to submit a VNRA after 28 January 2022 and the product is not yet in the UPD?

MAHs should attempt to submit the VNRA immediately after the change was implemented and in case the product is not in the UPD yet, contact the responsible NCA as early as possible to agree on a course of action.

## 56. How to handle Type IA variations implemented in 2021 but not yet notified due to 12-months reporting timeframe?

Article 151 of the Regulation (EU) 2019/6 states that certain procedures that started under the current regulation shall be completed under the current rules. While this Article is not directly applicable to Type 1A variations as they are not validated, its spirit should nevertheless be considered applicable also to Type 1A variations: any Type IA variation implemented before 28 January 2022 may be submitted in accordance with the current rules, i.e., be notified within 12 months, but will have to be recorded in the UPD nonetheless.

## 57. What does ‘VNRA automation’ mean?

The UPD MVP system will allow:

- submission of multiple VNRAs in one submission for each NAP
- submission of one VNRA to many (level 2) products
- submission of more than one VNRA to one product (level 2).

A product (level 2) in UPD is understood as the combination of name, substance, form, strength and country (NPs), even for for DC|MR|SRP products.

The ‘automation’ functionality to submit multiple changes to one product (level 1) and grouping several changes to several MRP/DCP products in one submission will be made available in a subsequent release.

In addition, automation refers to functionality that will automatically update a field changed by a VNRA in the UPD when the NCA accepts it. In the MVP, these field updates have to be performed manually by the NCA via the "product update" functionality.

## 58. What should a MAH do in case a change not requiring assessment would be missing in the Implementing Act on VNRAs and would also not be a specific entry in the guideline on VRAs?

As an interim solution, a VRA submission would be required until the VNRA IA is updated by the EC. The VRA guidance includes placeholder classifications for unclassified changes in each section.

# List of Acronyms

| | |
|---|---|
| **AM** – Antimicrobials | **MWD** – Manufacturing and Wholesale Distribution Database |
| **API** – Application Programming Interface | **NCA** – National Competent Authority |
| **AR** – Assessment Report | **NVR** – New Veterinary Regulation (EU) 2019/6 |
| **ASU** – Antimicrobials Sales and Use | **OMS** – Organisation Management Services |
| **CA** – Competent Authorities | **OPAD** – Other Post-Authorisation Data |
| **CESP** – Common European Submission Portal | **PL** – Package leaflet |
| **eAF** – Electronic Application Form | **PMS** – Product Management Service |
| **EAM** – EMA Account Management | **RMS** – Referentials Management Services |
| **ENTA** – Estimated number of treated animals | **SMS** – Substance Management Services |
| **EU IG** – EU Implementation Guide | **SPC** – Summary of Product Characteristics |
| **EVV** – Union Pharmacovigilance Database | **SPOR** – Substances, products, organisations and referentials |
| **FHIR** - Fast Healthcare Interoperability Resources | **UAT** – User Acceptance Test |
| **GW** – Gateway | **UI** – User Interface |
| **HMA TF** – Heads of Medicines Agencies Task Force | **UPD** – Union Product Database |
| **MAH** – Marketing Authorisation Holder | **VMP-Reg** – Veterinary Medicinal Products Regulation (EU) 2019/6 |
| **MVP** – Minimum Viable Product | **VNRA** – Variations Not Requiring Assessment |

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