Veterinary Medicines Division
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Union Product Database (UPD) – Questions & answers

Network Use

Disclaimer

This document is intended for information only, and it is based on questions asked by competent authorities (CAs) regarding the use of the Union Product Database (UPD). This document does not constitute an explicit commitment on behalf of the Agency or the UPD product team.

As a living document, it will be updated with additional questions and answers as they arise.

For convenience, a glossary of technical terms is provided in the table of abbreviations at the beginning of this document.

For general queries about the UPD, including guidance, scheduled deployments, and volume of sales submission, please contact the Agency via AskEMA: Send a question to the European Medicines Agency.

For technical issues, system errors, bug fixes, lack of access, and expired passwords, please submit a ticket via ServiceNow.

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Acronym key and glossary terms

API	Application Programming Interface	OMS	Organisation Management Service
ASU	Antimicrobial Sales and Use Platform	PSMF	Pharmacovigilance System Master File
ATC Vet Code	Anatomical Therapeutic Chemical veterinary code	QPPV	Qualified Person Responsible for Pharmacovigilance
CA	Competent authority	QRD	Quality Review of Documents
CMDv	Coordination group for mutual recognition and decentralised procedures for veterinary medicinal products	RMS	Referentials Management Service
CMS	Concerned Member State	rms	Reference member state
CSV	Comma-separated values	SPC	Summary of product characteristics
CVMP	Committee for Veterinary Medicinal Products	SPOR	Substances, Products, Organisations and Referentials
DCP	Decentralised procedure	SRP	Subsequent Recognition Procedure
EAM	EMA Account Management	UAT	User Acceptance Test
EDQM	European Directorate for the Quality of Medicines & HealthCare	UI	User Interface
EMA	European Medicines Agency	UPD	Union Product Database
EPAR	European Public Assessment Report	VNeeS	Veterinary Non eCTD Electronic Submission
FHIR	Fast Healthcare Interoperability Resources	VNRA	Variation not requiring assessment
MAH	Marketing authorisation holder	VoS	Volume of sales
MRP	Mutual recognition procedure	VRA	Variation requiring assessment

1. Access & user management

1.1. What is the difference between the UPD restricted portal and the Veterinary Medicines information website?

The UPD restricted portal area is only accessible to staff of the European Commission, national competent authorities and marketing authorisation holders.

The Veterinary Medicines information website is the public interface of the UPD, contains non-confidential product data and is available in 26 different languages.

1.2. Why should CAs use the UPD?

Article 55(1) of the Veterinary Medicines Regulation (Regulation (EU) 2019/6) requires the European Medicines Agency ('the Agency') to establish and, in cooperation with the Member States, maintain a Union database on veterinary medicinal products (UPD).

For further regulatory provisions and practical arrangements for the establishment and maintenance of the UPD, please refer to Commission Implementing Regulation (EU) 2021/16, the 'Guidance for national competent authorities' section of the EMA's UPD webpage.

1.3. How can CA users register for a UPD account?

To register for a UPD account, please consult the registration and access to UPD restricted area section of the UPD webpage.

1.4. Which functionalities are available for competent authorities (CAs) in the UPD?

The following functionalities are available for CAs:

- Introduce new product data;
- Search and view product data;
- Amend marketing authorisation status, in case of revocation/suspension;
- Approve/reject variations not requiring assessment (VNRAs);
- Search for notifications;
- Obtain Volume of Sales data.

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

Similar to other EMA systems (SPOR, IRIS, etc.), one user from a competent authority (CA) is appointed as the Super User. Only the first request for an '*UPD CA Super User*' role is evaluated and granted by EMA.

Once the role of '*UPD CA Super User*' is approved, the user can manage other users from the same organisation. This means the approval, rejection and revocation of UPD access rights for all users within their organisation.

The Agency recommends having a minimum of two '*UPD CA Super User*' roles, to ensure that requests for other user roles (i.e. '*UPD - CA Edit/Search/View*' and '*UPD - CA Search/View*') are not delayed in the event of absences or staff mobility.

1.6. What is the difference between competent authority (CA) user roles?

- *UPD CA Super User* - this role gives full access (Edit/Search/View) to UPD and to EMA Account Management (EAM) portal to administrate (approve/reject/revoke) access rights for new and existing users within the same organisation.
- *UPD CA Edit/Search/View* - this role gives write, read and export access rights to UPD for management (create/update) of data on veterinary medicinal products and to approve/reject variations not requiring assessment (VNRAs).
- *UPD CA Search/View* - this role gives read-only access and export rights to UPD for data on veterinary medicinal products.

1.7. Do competent authorities have access to a UPD test environment?

Yes. The UPD User Acceptance Testing (UAT) environment is accessible for authorised users from competent authorities (CA) at https://upd-uat.ema.europa.eu/updwebui/home.

To gain access to the UAT environment, UPD CA Super User(s) must request it separately via EMA Test Account Management (EAM) portal. Access to UPD does not automatically grant access to the UAT environment.

UAT is the preferred environment to perform exploratory work (creating or updating veterinary medicine product data) to prevent unwanted changes to the Production data.

1.8. Is there a limit to the number of accounts per competent authority?

There is no limit to the number of user interface (UI) accounts per competent authority (CA). For the application programming interface (API), only one account per Super User is available.

1.9. Where can I find information about available application programming interfaces (APIs)?

For competent authorities, there are three different APIs, and each provides access to a different type of data:

- API for UPD products/procedures;
- API for UPD variations not requiring assessment (VNRA);
- API for volume of sales (VoS).

All three APIs require authentication and authorisation via a valid Client Secret key which is needed to generate a Bearer Token that lasts each time for two hours. With this token, data can be received or sent through the given endpoints provided by each API. Please note that the Client Secret key expires after two years and needs to be renewed by the Super User. The Super User should request the API role if your CA intends to use the UPD API services. For further details, please consult the UPD registration guide for UI and API users and Chapter 5 of the UPD Implementation Guide.

1.10. Why is the UPD restricted portal not available?

The UPD restricted portal may be temporarily unavailable due to scheduled or urgent system deployments. Any downtime required to release new or improved versions is communicated to users

through a banner on the User Interface (UI).

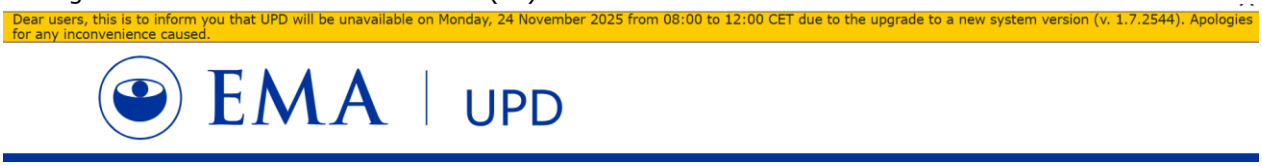

Figure 1 - UI banner

Approximately one week ahead for planned releases, and as early as possible for urgent issues (hot fixes). During this period, all UI and API users are to refrain from using the UPD environment. Once the system is available again, a message is posted via the UPD UI banner.

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

Please refer to the system release notes, found in the Union Product Database: release notes section.

2. Product creation, updates and corrections

Product data creation & terminology

2.1. What can I do if there is an error in the master data of a product?

As *a UPD CA Super User* or *UPD CA edit/search view user,* you can change product data and amend any errors/typos in the product information that are brought to your attention.

2.2. How do I name the product information PDF documents to be uploaded to the UPD?

When using the 'Upload document', 'bulk upload' functionality, CAs must follow the naming conventions and characteristics, as explained in Annex 2 of Chapter 2 of the UPD Implementation Guide. If the CA does not intend to use the 'bulk upload' functionality, then the naming convention provided in Annex 2 is not mandatory.

2.3. Which value should be entered in the UPD if the strength is expressed as a range?

In most cases, you should enter the upper value of the range. However, for immunological products, you should enter the lower value. For more information, please see Chapter 2 of the UPD Implementation Guide.

2.4. Which term can I use in UPD for vaccines instead of 'units' if I already used that term to refer to something else regarding the product?

In UPD, the dropdown lists in UPD use terms from the Referentials Management Services, including both current and non-current terms for creation and update operations. Users can freely select and use non-current RMS terms (e.g. 'dose') when uploading product data via UI or API.

2.5. Can a competent authority request a SPOR RMS update to the EMA when a term is missing?

Please refer to the guidance provided in document A6 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 the QRD Working Party and the CMDv.

2.6. Is it possible to see the date for the latest product update?

Yes, UPD UI displays the latest version of a product, followed by the date. Users can also view previous product versions by clicking the arrow on the right (see figure 1).

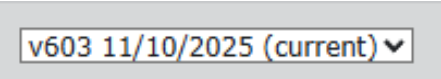

Figure 2 - Latest update of a product

Please note that this relates only to the product data. Product documents will not change when viewing each version, as they are always displayed with the last updated version.

Duplicates, erroneous entries & recovery

2.7. What should I do if there are duplicate products in the UPD, with more than one product identifier for the same product?

If an erroneous duplicate is identified in the database, the competent authority responsible for the product will need to delete one of them.

Before proceeding with the deletion, it is advisable to check the VNRAs and sales submissions that each product identifier has and delete the one with the least history. It is also recommended to inform the marketing authorisation holder (MAH) so that, in case there are submitted variations, they can save the related documents.

2.8. What should to do if I accidentally enter an incorrect package under my product?

If you added extra packages by mistake, rename the incorrect package(s) as "Created in error" and update the product. Then, delete those packages. This ensures that MAHs can recognise and disregard them when submitting the annual volume of sales data.

If the number of packages is correct but one or more contain incorrect information, simply edit the relevant packages and update the product.

2.9. What should I do if I accidentally delete a valid package?

Once a package is deleted, it cannot be recovered.

You will need to create a new package entry, which will automatically receive a new package ID. Please inform all Concerned Member States (for MRP/DCP procedures) and the MAH about this change.

2.10. Is there any guidance on how to update package information?

Yes, please consult the Quick guide on how Competent Authorities should update packages in UPD without changing the Package identifier.

2.11. What should be done if one or more packages of a product have been surrendered?

In such cases, competent authorities should delete the surrendered packages from the UPD. These packages will remain visible to the MAH for two additional years to allow them to submit their volume of sales data during that period.

EPARs, document publications & public visibility

2.12. A new centrally authorised product has been added to the UPD, but some of the associated documents are not available. When will they be uploaded?

The publication timelines of the veterinary European public assessment report (EPAR), which contain authorisation details, product information, and public assessment reports, may vary. For newly centrally authorised products, EPARs will be published 6 weeks after the European Commission (EC) decision. For post-authorisation procedures (VRAs and VNRAs), the publication timeframe is two months after EC decision or within two months following the CVMP opinion/notification, as applicable.

For more information on publications and their location, please visit What we publish and when.

2.13. A VRA for a product has been approved, but I cannot see the new EPAR. Where can I find it?

The EPAR for each medicine is published or updated following a decision by the European Commission, or when the product information changes. If, after a VRA approval, the product information was not changed, no EPAR update is required, and no new document is published.

As a reminder, EPARs for veterinary medicinal products are publicly available on the Veterinary Medicines information website, which serves as the public interface of the UPD. Each product contains a dedicated 'Product details' page, including product information and public assessment reports, available in the 'Documents' section at the bottom of the page.

2.14. Why are some products listed on the UPD not available on the publicly accessible database of Veterinary Medicines?

When products authorised via DCP, MRP or SRP are created in the UPD, their product record status is set to 'provisional' by default. This feature ensures that a product is publicly available on the website only after the competent authority adds the national data. A CA UPD user with editing rights (e.g., *UPD CA Edit/Search/View or UPD Super User)* should select one product, click on 'edit national data', and amend the 'product record status' to 'current'.

Detailed information can be found in section 1.2. 'Product record status' of Chapter 2 of the UPD Implementation Guide. Additionally, we recommend reviewing the recording of the UPD refresher webinar on basic functionalities, available on the EU Network Training Centre.

3. Product notifications and exports

3.1. What is the difference between the User Interface (UI) notifications and notifications received by email?

UI notifications are created per action and per product, and as soon as an action is performed in UPD. On the other hand, email notifications are generated and sent after business hours (at the end of the day), sent per action performed, and may contain information about more than one product.

For all non-centrally authorised products, the user receives an email notification for a product update the next day (within 24 hours). For all centrally authorised products, the user receives an email notification 24 to 48 hours after the product update. For more information please see the Quick guide for UPD notifications via the User interface and via email.

3.2. How can I see UPD notifications via the UPD UI system?

Under the 'Notifications' menu, all users can filter notifications based on the available search fields. The system will not display any results unless a search is performed.

The system shows products matching the searching criteria: each row represents an action concerning a specific product. By clicking anywhere on a notification row, a notification card will open on the right, with more information. The full product information is accessible by clicking on the links available for each product row or in the notification card.

For CA users, the system lists all available notifications for all products, including those for which they are not the reference member state.

Further information and guidance can be found in the Quick guide for UPD notifications via the User interface and via email.

3.3. How do I configure an email address for receiving notifications?

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

3.4. Do notifications for competent authorities contain the exact change in the product data?

Yes. Competent Authorities can view in the notifications the specific actions that have been performed in the UPD system for which they should be aware, either for their information or for any consequent action. For further information, please consult the available Quick guide for UPD notifications via the User interface and via email.

3.5. 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 downloadable fields include: *Product Id, Permanent Id, Procedure Type, Procedure number, Product name, Active substance and strength, Target species, Product owner, Marketing authorisation number, Authorisation Status, Country, Reference Member State, Concerned Member State, Authorisation/Registration/Entitlement Type, Pharmaceutical form, ATC Vet Code, Legal status for the supply, PSMF Code, PSMF Location, QPPV Name, QPPV Location, QPPV Email, Batch Releasing Site*.

3.6. Is there a maximum limit of search results that can be exported from the UPD?

Yes, currently up to 10.000 search results are exportable and downloadable in Excel .csv format. evaluates and decides on the requests received.

3.7. Are there file size limits for uploads?

The maximum size allowed for the volume of sales .csv file, availability status .csv file, public assessment report, summary of product characteristics, package leaflet, and labelling is 10MB. For VNeeS files, the maximum size allowed is 6GB.

4. Authorisation Status, PSMF Data and Regulatory Procedures

4.1. When should I modify the 'date of authorisation status change'?

After creating an authorised product in the UPD, the CA must update the national data for the product under their authority. The authorisation status for a newly created product is 'pending'. The CA is responsible for providing the 'date of authorisation status change' and updating the authorisation status to 'valid'.

Later in the product lifecycle, if the authorisation status of the product is changed to 'suspended', 'surrendered' or 'revoked', the 'date of authorisation status change' must be changed to record the date on which the 'authorisation status' was updated. The 'date of authorisation status change' can also be modified if a variation that results in a change to the product authorisation status is approved.

In all other cases, the 'date of authorisation status change' should not be modified, as it can create discrepancies for the MAH when submitting VoS.

4.2. Who must change the product availability status from not marketed to marketed?

By default, newly created products in UPD have the marketing status set to '*not marketed*'. As soon as the product is marketed, the MAH should change the availability status in UPD to '*marketed*'.

4.3. Which Location-ID should I use for UPD data entry if more than one marketing authorisation holder (MAH) shares the same PSMF location and QPPV?

It is possible for multiple MAH to have the same PSMF and QPPV at the same physical location, and are under the same pharmacovigilance system. In such cases, the PSMF address on Organisation Management Services (OMS) would have several Location-IDs assigned, one for each MAH.

When enterincg data into UPD, the Location-ID used for the PSMF must correspond to the responsible MAH. Location-ID IDs are organisation-specific and should not be used indistinctly.

4.4. What should I do if the marketing authorisation holder (MAH) surrenders the product in one or more concerned member states (CMS)?

If a product has had a valid marketing authorisation in one or more CMS and the MAH later surrenders the product in any CMS, the product's authorisation status for that CMS must be set to 'surrendered'. Please note that the list of CMSs within the common data shall remain as is.

Before updating the marketing authorisation status to 'surrendered', the CMS must ensure that all attributes required by Antimicrobial Sales and Use (ASU) reporting have been properly updated. Otherwise, after the status change, the product will no longer be editable, which can cause issues with ASU reporting.

For further details, please refer to Annex 4 of Chapter 2 of the UPD Implementation Guide.

4.5. What should I do if a concerned member state (CMS) was accidentally added and needs to be nullified?

If a CMS was added accidentally by the reference member state (rms), removing the product from the procedure requires two steps:

1. The CMS must be deleted (nullified), either by the rms or the CMS. In both cases, it is advisable to check whether the product to be deleted has any processed VNRAs. If so, please

inform the marketing authorisation holder so they can save the relevant documents related to the VNRAs before the deletion.

2. After the deletion, the rms must perform an update to the common data by removing the CMS from the list of CMSs.

4.6. Do products that are within the scope of the SPC harmonisation procedure contain all mandatory data?

CAs participating in the SPC harmonisation procedure must ensure that the selected reference veterinary medicinal products contain all mandatory data before the rms creates the procedure in UPD. If any of these products is missing mandatory data, the creation of MRP will fail.

4.7. 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 CAs 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.

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

As stated in Chapter 2 of the UPD Implementation Guide, the PSMF data is mandatory for new veterinary medicinal products for which marketing authorisation is granted under Regulation (EU) 2019/6.

For legacy data, marketing authorisation holders should submit a VNRA to provide the PSMF code and PSMF location as soon.

4.9. Is the competent authority (CA) responsible for completing the PSMF, or is it the marketing authorisation holder's (MAH) responsibility?

CA are responsible for populating the correct product information in UPD. Afterwards, if the PSMF information is changing, MAH can submit a VNRA to update this information.

5. Variations Not Requiring Assessment (VNRA)

5.1. Where can I find more guidance on VNRAs?

For further guidance regarding VNRAs, please consult the CMDv Best Practice Guide on VNRAs.

5.2. 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 CA approves it. VNRA codes that are automated in the UPD are A.1.a, A.4, C.1, C.5 and C.6.

For the other VNRA codes, these field updates have to be performed manually by the CA via the "product update" functionality.

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

VNRA status refers to 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 at least one 'product + VNRA' has a pending status, 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'.

5.4. How can a competent authority (CA) identify which VNRAs are assigned as the 'Decision maker'?

In UPD UI, the CA can easily identify VNRAs where they are the assigned 'Decision Maker' by selecting the 'View VNRA Submissions' under the 'VNRA' main menu:

- Submissions containing at least one product for which the CA is the 'Decision Maker' are highlighted in orange.
- Submissions that contain at least one product for which the CA would typically be the 'Decision Maker' but the MAH assigned a different one during the submission are highlighted in blue.

More information and guidance on how to identify and sort the desired VNRAs can be found on Quick guide on VNRA highlighting for CAs or in the Video: Identifying pending VNRA submissions.

5.5. How can I see an overview of all the VNRA submissions in UPD where I have a role?

All VNRA submissions that contain at least one product under the responsibility of the competent authority (CA) logged-in user are displayed in the 'View VNRA submissions' menu. A CA UI user will see the full list of VNRA submissions for which they have a role (as rms, CMS or CA). Statuses can be filtered by using the "Submission status" filter available on the same page.

5.6. Can I approve a VNRA submission for a new product that has been submitted through DCP/MRP/SRP, if the national approval phase is still ongoing?

Yes, the system allows the marketing authorisation holder (MAH) to submit VNRAs even when the national approval phase is still ongoing and data is missing (e.g. MA numbers). The system also allows CAs to approve those VNRA submissions. After approval, the system will automatically update the product(s) concerned.

5.7. What is the maximum number of characters in the 'comment' field for VNRA decisions?

Decision comments can be up to 2000 (two thousand) characters. If the decision comment is longer, the submit button will still be available, but the decision will fail. As a result, the PDF will show empty fields for decision, author, date and comment. When rejecting/approving a VNRA, ensure that the decision comment is concise and does not exceed 2000 characters.

5.8. If I am a CMS for a VNRA approved by the rms, should I update the data nationally in the UPD, or does only the rms have to do it?

If the rms has approved or rejected the VNRA, the CMS does not have to update the national data. However, if the product information at the national level is affected, then it is the responsibility of the CMS to review and upload the documents in UPD.

6. DCP/MRP/SRP Procedures and Multi-Member-State coordination

6.1. How to update MRP/DCP product when only one reference member state (rms) and no concerned member states (CMS) are involved?

Some products approved under DCP/MRP may have only one rms and no CMS involved in the process. The recording and updating of these products must be as follows:

Scenario 1: The marketing authorisations for DC/MR/SR product have been withdrawn from all CMS, except for the rms.

- *Action:* the authorisation status for the CMS products must be set to *surrendered.* The rms product updates (via UI and API) will continue as normal.

Scenario 2: The application for DCP/MRP has been withdrawn from all CMSs before the end of the authorisation procedure.

- *Action:* Step 1) the rms creates the DCP, adding Country A as a CMS and informs the CMS via the UPD contact point.
- Step 2) the rms must then update the national data of this CMS product and inform the CMS via the UPD contact point:
    - to prevent the product from being available to the general public, the rms must keep the CMS product in ***provisional*** status.
    - to prevent the CMS product from being available to the MAH, the rms will add as the MAH the location ID of their own national competent authority.
    - to ensure that the product is not considered valid by other consuming systems, such as Union Pharmacovigilance Database or the Antimicrobial Sales and Use platform, the national data must be filled in with the following values:
        - National veterinary medicinal product name: '-NOT VALID-Dummy product-';
        - Responsible Authority: 'EMA' must be replaced by the National Competent authority of the CMS;
        - Authorisation/registration/entitlement number: '-NOT VALID-Dummy product-';
        - Legal status for the supply: Same as in RMS;
        - Marketing authorisation date: '01/01/1900', type the date manually;
        - Date of authorisation status change: '01/01/1900', type the date manually.
        - To prevent the product from being subject to fees, the Authorisation status must be set to ***surrendered***.

Thereafter, no further changes are required for the 'dummy' CMS product.

Scenario 3: Update of legacy 'dummy' CMS products:

- Action: Step 1) The rms must update then the national data of the CMS product and inform the CMS via the UPD contact point:

- to prevent the CMS product from being available to the general public, the rms must keep the product in ***provisional*** status.
- to prevent the CMS product from being available to the MAH, the rms will add as MAH the location ID of their own national competent authority.
- to ensure that the product is not considered valid by other consuming systems, such as the Union Pharmacovigilance Database or the Antimicrobial Sales and Use platform, the national data must be filled in with the following values:
  - National veterinary medicinal product name: '-NOT VALID-Dummy product-';
  - Responsible Authority: 'EMA' must be replaced by the national competent authority of the CMS;
  - Authorisation/registration/entitlement number: '-NOT VALID-Dummy product-';
  - Legal status for the supply: Same as in RMS;
  - Marketing authorisation date: '01/01/1900', type the date manually;
  - Date of authorisation status change: '01/01/1900', type the date manually.
- to prevent the product from being subject to fees, the Authorisation status must be set to ***surrendered***.

Thereafter, no further changes are required for the 'dummy' CMS product.

6.2. In a DCP or MRP, which CA is responsible for the product cross-reference information?

Product cross-reference information must be entered by the reference member state (rms) and provided as common data. If a concerned member state (CMS) wants to cross-reference a product, they must use the 'Permanent ID' entered by the RMS, not the one entered by another CMS. If the product does not exist in the UPD, a dummy product will be referenced. See also Chapter 2 of the Implementation Guide.

6.3. How should a new rms map the package identifier from the previous rms?

If a competent authority (CA) changes its role from concerned member state (CMS) to reference member state (rms) for a product authorised under the MRP/DCP/SRP, the new rms is responsible for maintaining the common part of the product, including product package information.

There are two types of package identifiers, and both must remain exactly as they are in UPD to avoid accidentally deleting the existing packages:

- The 'packageIdentifier': uniquely identifies a package and is shared across all products within an MR/DC/SR procedure, regardless of whether the product is managed by the rms or a CMS.
- The 'packageMedicinalProduct id': defines the resource in the FHIR payload and acts as a reference to 'Medicinal Product Definition' resource within the payload. This ID is unique to each package, per product (i.e. same package in different products within DCP will have a different ID value).

The new RMS of a product, after having been a CMS, should be aware that both 'packageIdentifier' and 'packageMedicinalProduct id' remain unchanged. The new rms should first synchronise the existing FHIR product along with the package and all other information from UPD to your internal database, and when updating products to UPD, ensure that 'packageIdentifier' and 'packageMedicinalProduct id'

remain unchanged. Otherwise, if an update payload does not contain the existing identifiers, the package(s) will be deleted from the UPD product.

6.4. What happens if the primary marketing authorisation of a product in the rms is under different legal basis in other CMS that were involved later in an SRP?

It is possible that the primary marketing authorisation of a product is based on a different Article/Directive/Regulation than those in other CMSs involved at a later time on the SRP, due to legislative changes. The legal basis for the primary marketing authorisation is recorded in the UPD under common data. However, if the legislation changed, this may create discrepancies between the legal basis in the 'new' CMS and the one recorded in the UPD for the rms.

According to Chapter 2 of the UPD Implementation guide, the legal basis for MRP/DCP/SRP products is a mandatory common data field and must be the same for rms and CMS.

In this instance, the previously agreed approach should remain as it is. The legal basis is a mandatory common data field and must be the same for rms and CMS, and it is not a blocking issue for creating the SRP product in the UPD.

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

In the case of DCP, SRP or MRP, the rms is responsible for entering the product data in the UPD.

6.6. Can the EMA be set as default for the UPD field 'MAH/Product owner' or 'Responsible authority (organisation)'?

No. The EMA must never be set as the 'MAH/Product owner' or 'Responsible authority (organisation)' for a medicinal product. If these fields are left empty when creating the product, the system will automatically complete the field with the EMA LOC id. CAs have to pay special attention and introduce the right LOC id, as listed in OMS, that corresponds to the organisation that holds the MA for the product and to the competent authority that issued the MA.

This is important to ensure that the proper fees are charged to the correct organisations, and to avoid the extra administrative burden upon CAs and EMA.