# Union Product Database (UPD) release notes

Referring to version 1.7.2643

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# Acronym key and glossary terms

| | | | |
|---|---|---|---|
| **ADO** | Azure DevOps | **NAP** | Nationally Authorised Products |
| **API** | Application Programming Interface | **NCA** | National Competent Authority |
| **APIM** | API Manager | **NP** | National Procedure |
| **AvS** | Availability Status | **OMS** | Organisation Management Service |
| **CA** | Competent Authority | **OPAD** | Other Post Authorisation Data |
| **CAP** | Centrally Authorised Products | **PET** | Veterinary medicinal products intended for animals which are exclusively kept as pets: aquarium or pond animals, ornamental fish, cage birds, homing pigeons, terrarium animals, small rodents, ferrets and rabbits |
| **CMDv** | Coordination group for mutual recognition and decentralised procedures for veterinary medicinal products | **PMS** | Product Management Service |
| **CMS** | Concerned Member State | **PSMF** | Pharmacovigilance System Master File |
| **CSV** | Comma-separated values | **QPPV** | Qualified Person Responsible For Pharmacovigilance |
| **DCP** | Decentralised Procedure | **RMS** | Reference Member State |
| **EAM** | EMA Account Management | **RN** | Release Notes |
| **EC** | European Commission | **SIAMED** | EMA product information and application tracking system |
| **EEA** | European Economic Area | **SIT** | System Integration Testing |
| **EMA** | European Medicines Agency | **SMS** | Substances Management Services |
| **EP** | End Point | **SPOR** | Substances, Products, Organisations and Referentials |
| **EU IG** | European Union Implementation Guide | **SRP** | Subsequent Recognition Procedure |
| **FHIR** | Fast Healthcare Interoperability Resources | **UAT** | User Acceptance Testing |
| **HF** | Hot Fix | **UC** | User Case |
| **HL7** | Health Level Seven | **UI** | User Interface |
| **JSON** | JavaScript Object Notation | **UPD** | Union Product Database |
| **LOC ID** | Location identifier | **URN** | Uniform Resource Names |
| **MAH** | Marketing Authorisation Holder | **UUID** | Universally Unique Identifier |
| **MDM** | Master Data Management | **VNeeS** | Veterinary Non eCTD Electronic Submission |
| **MRP** | Mutual Recognition Procedure | **VNRA** | Variations not requiring assessment |
| **MRPH** | MRP products created after SPC harmonisation procedure | **VoS** | Volume of Sales |
| **MS** | Member State | **XML** | eXtensible Markup Language |

Overview of key changes:

With every new release, the UPD release notes are updated to highlight to the user the changes compared to previous versions by detailing new/updated functionalities and/or issues that have been resolved, are known, and/or are newly reported.

| | |
|---|---|
| Resolved issues since the previous release (UPD version 1.7.2633, released on 4 September 2026) | 33 |
| Known Issues | 18 |
| Next release's expected date | Q1 2027 (to be determined) |

**Overview of new functionality(ies):**

- **VNRA submissions have been enriched by an additional checkbox** allowing MAH user to mark **supergrouping VNRA** and that enables MAH and NCA users to easily identify supergrouping VNRA i.e.:
    - On the VNRA View submission page, MAH and NCA users can now search submitted supergrouping VNRAs by clicking 'supergrouping' checkbox located within the search fields.
    - On the VNRA detailed view page, MAH and NCA users can now see the 'supergrouping' checkbox next to 'Decision maker' in the submission details.
    - Supergrouping identification of the VNRA submissions will now show within the submission PDF.

      For further details, both MAH and NCA users are advised to consult the bite-sized videos that will **shortly be available** in the "**Video tutorials**" sections for MAH and NCAs of the UPD webpage
- **NCA API users can now delete documents by using NCA API's DELETE endpoint**
  Production environment:
  **DELETE** https://spor.azure-api.net/pms/api/v3/DocumentReference/<reference **id>**
  UAT environment:
  **DELETE** https://api-uat.pms.ema.europa.eu/pms/api/v3/DocumentReference/<reference **id>**

  Headers: Authorisation

  For further technical information and examples please see Chapter 5 of the UPD EU Implementation Guide and the portal with NCA API endpoints.
- **All UI users are now offered new buttons with quick access links to 'Guidance, FAQ and training', 'UPD Public portal', 'ServiceDesk' and 'Release Notes'**. The former 'Help' and 'Site Map' links at bottom of the page are removed.
- For **MAH UI users, the operation outcome is now included to the message after a VNRA submission**.
- **For registered homeopathic products, at least package leaflet or package leaflet and labelling or combined file of all documents is mandatory**. Other documents are optional for these products.

**For information:**

- **While creating MRP/DCP/SRP products for the competent authority data field in UPD, the default NCA LOC-ID per country for each CMS as well as for the RMS will be used**. If there is more than one NCA per country the default competent authority is assigned i.e. for Germany the Federal Office of Consumer Protection and Food Safety also known as BVL LOC-100082087 is assigned. Assigning EMA/EC as responsible authority during create and update of the MRP/DCP/SRP products is now prevented.
- **While creating MRP/DCP/SRP products in UPD, the default product owner will be the same MAH as in RMS product during create**. Assigning EMA/EC as product owner during create and update of the MRP/DCP/SRP products is now prevented.
- 'MRP after SPC harmonisation' has been renamed to '**MRP after harmonisation'.**
- **In the UPD UI any link opens a new tab and "Back to Search Results" button has been removed** from everywhere.
- **In Volume of Sales tab the search fields 'Availability Status' and 'Procedure Type' are now functional** for retrieving sales data.
- During an update of common data**, the validation for existing QPPV/PSMF national data within each CMS/RMS product has been removed**. Hence, missing QPPV/PSMF data in any CMS product is not preventing the updates of common data anymore. For national data updates, this data is still mandatory and needs to be provided.
- **Some MAH users may experience incorrect product groupings when products are subject to change of ownership and were previously grouped by the former MAH**. This inconvenience is expected to be resolved in 2027. Meanwhile, for wrong or failed product grouping submissions, MAH users are encouraged to open EMA Service Desk incidents requesting datafixes on their affected products.
- **Chapter 2 of the UPD EU Implementation Guide has been updated** to reflect relevant of the aforementioned changes.

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# 1. Summary of issues

## *1.1. Resolved issues*

| Use Case | Affects API and/or UI | Issue reference (ADO) | Resolved issues |
|---|---|---|---|
| **UC01 Create product** | NCA UI | 342173 | Cross reference validation error not displayed for hybrid application legal basis after create button is clicked. |
| **UC01 Create product** | NCA UI | 351133 | NCA user is unable to create Parallel trade products. |
| **UC03 Search product** | MAH UI | 356881 | UPD UI PROD Export with Product Owner filter fails for industry users ("Failed to export search results"). |
| **UC05 View product** | NCA/MAH UI and Public portal user | 331487 | Marketing Authorisation date changes to adapt to user timezone. |
| **UC07 Volume of sales** | NCA UI & MAH UI | 345263 | Datafix for new MAH user unable to retrieve Volume of sales for a transferred product |
| **UC08 Update product** | NCA UI | 311419 | Manufactured item definition is removed from payload when a CAP product is surrendered. |
| **UC08 Update product** | NCA UI/API | 340915 | If the CMS product does not hold QPPV/PSMF data when the RMS is doing a common update, after generating operation outcome the update will fail anyway. |
| **UC08 Update product** | NCA UI/API | 340662 | If the RMS product does not hold QPPV/PSMF data when the RMS is doing a common update, that update will erase the QPPV/PSMF data from the CMSs product. |
| **UC08 Update product** | NCA UI | 355148 | Create SRP fails if one of the CMS belonging to the product identifier is missing QPPV/PSMF data |
| **UC08 Update product** | NCA UI | 344631 | Cross reference does not get cleared if legal basis value is changed to one without cross reference. |
| **UC08 Update product** | NCA UI | 348195 | Datafix to include the surrendered products back in the list of CMSs in the list on the View product page for RMS. |
| **UC08 Update product** | NCA UI | 348775 | AvS is populated automatically for Parallel trade products and PET products though as per Article 5(6), AvS is not applicable for PTP and PET products |
| **UC08 Update product** | EMA UI | 354520 | Surrendered CAP packages are missing date range in marketing status. |
| **UC08 Update product** | NCA UI | 356511 | CMS country is listed twice in the View product page CMS list when added an SRP for a country with a nullified CMS in the same product identifier |
| **UC08 Update product** | NCA UI & MAH UI | 358768 | Search Responsible Authority filter does not work correctly for Organisation + country parameter combination. |

| Use Case | Affects API and/or UI | Issue reference (ADO) | Resolved issues |
|---|---|---|---|
| **UC08 Update product** | NCA UI | 310477 | Allow all document type upload while creating/updating Registered Homeopathic products. |
| **UC08 Update product** | NCA UI | 362312 | Datafix to reinstate a product nullified by mistake. |
| **UC09 Approve/Reject VNRA** | NCA API | 351868 | Datafix of the wrong Date of decision in the VNRA submission approved because of change in timezones. |
| **UC09 Approve/Reject VNRA** | NCA UI | 357425 | Datafix to correct the wrong decision taken by NCA on a VNRA submission. |
| **UC09 Approve/Reject VNRA** | NCA UI | 362367 | Datafix to update the Decision maker organisation of Croatian Agency for the submitted VNRAs. |
| **UC25 Update Availability status** | MAH UI | 336944 | AvS submission failed for few CAP with ER.36. |
| **UC25 Update Availability status** | MAH UI | 336947 | AvS submission failed for CAP ER.36. due to Unit or presentation missing. |
| **UC25 Update Availability status** | MAH UI | 336949 | AvS submission failed for CAP ER.36. due to Withdrawal period missing. |
| **UC25 Update Availability status** | MAH UI | 341240 | MAH user gets ER.36. when trying to submit availability status data for homeopathic products. |
| **UC25 Update Availability status** | MAH UI | 354293 | Datafix to remove Marketing status from Parallel trade products and PET products to avoid failure of update product data. |
| **UC28 View VNRA via UI** | NCA UI & MAH UI | 345110 | Paginating through view VNRA submission, without doing a search, will cause it to show submission from all status. |
| **UC28 View VNRA via UI** | NCA UI & MAH UI | 347773 | Datafix for Luxembourg NCA unable to view a few specific VNRAs. |
| **UC28 View VNRA via UI** | NCA UI & MAH UI | 360573 | Decision maker dropdown list contains wrong and extra decision makers in VNRA submission and VNRA view screens. |
| **UC38 Manage Product grouping** | MAH UI | 359087 | Datafix to clear product group for the products transferred to different MAH. |
| **SIAMED to ETL PMS** | EMA UI | 215513 | SIAMED to UPD - CAP contains packages with Marketing Authorisation status = Withdrawn which is not a valid term for the field. |
| **SIAMED to ETL PMS** | EMA UI | 335762 | Duplicate CAPs are created and visible in UPD. |
| **SIAMED to ETL PMS** | NCA, MAH & EMA UI | 306628 | For a CAP (Mirataz) the manufacturer is listed multiple times with the same manufacturing activity. |
| **SIAMED to ETL PMS** | NCA UI | 329006 | When a CAP is surrendered in SIAMED, it loses the Manufactured item definition in the FHIR payload. |

## *1.2. New issues since last release*

This table is ordered by Use Case number. This section lists known issues in this release that have not previously been included in the Release Notes. Some issues had existed in a previous release, and some are new issues in this new release.

| Use Case | Affects API and/or UI | Issue reference (ADO) | New Issue description | Workaround |
|---|---|---|---|---|
| **UC08 Update product** | NCA UI | 357794 | Tooltip blocks other fields from editing. | |
| **UC21 Notifications** | NCA UI & MAH UI | 366371 | Product owner search filter parameter is not providing the expected results | |
| **UC21 Notifications** | NCA UI & MAH UI | 366389 | Create notifications are missing when search for notifications using Product ID or Permanent ID having multiple notification rows. | |
| **UC21 Notifications** | NCA UI & MAH UI | 366427 | Decision maker is missing from VNRA submission notifications created before 18 March 2024. | |
| **UC25 Update Availability status** | MAH UI | 349287 | AvS submission fails due to 'Surrendered' packages in CAP products. | |
| **UC38 Manage Product grouping** | MAH UI | 360221 | Clear product grouping data after the MAH is changed from Update product data via UI or API. | |
| **SIAMED to ETL PMS** | EMA UI & MAH UI | 353972 | For a CAP (Draxxin) manufacturers are not updated following VNRA changes. | |
| **SIAMED to ETL PMS** | EMA UI | 365617 | CAP FHIR bundle missing some attributes after the update from UPD UI | |

# 2. User support

API and UI users may seek support by contacting the User Support via EMA Service Desk.

For the technical team to address your query in a timely manner, please include the following information as appropriate:

- UI: Print screen of the information entered to create a veterinary product (go to your browser settings, select Print (or press Control + P) and "Save as PDF" on your computer
- API: Operational outcome of the unsuccessful task; the request URL and request headers; and for a Create or Update the request body

## *2.1. Available training materials and guidance*

- Webinars
- Video tutorials
- Guidance for National Competent Authorities
- Guidance for Marketing Authorisation Holders
- EU Implementation Guide
- Release notes

# 3. References


1. UPD registration guide for UI and API users
2. SPOR API Specification V2  R5 (europa.eu)  API specifications for SMS and PMS, based on FHIR
3. HL7 FHIR Release 5 Preview 2: the authoritative source for the FHIR specifications used by EMA to implement SMS and PMS API
4. Referentials Management System
5. Additional information on the Referentials Management System
6. Organisations Management System
7. Additional information on the Organisations Management System
8. Substances Management System

# Annex 1: Overview of functionality and business value

## Functionalities provided in this release

| | |
|---|---|
| **API**  | RMS can create DCP products (data and documents) |
| | RMS can create MRP products (data and documents) |
| | RMS can create SRP products (data and documents) |
| | RMS and CMS can complement DCP/MRP/SRP products with national DCP/MRP/SRP data and documents |
| | RMS can update Common data for DCP/MRP/SRP products (data and documents) |
| | NCA can create and update NAP products (data and documents) |
| | NCA can create & update Registered Homeopathic products (data and documents) |
| | NCA can create & update Parallel Trade products (data and documents) |
| | NCA can create & update Pet products (data and documents) |
| | NCA can group National Authorised products under an MRP following CMDv SPC harmonisation procedure (data and documents) |
| | NCA can Nullify product |
| | NCA can Search/view product (data and documents) |
| | NCA can Search, View and Approve/Reject VNRA submissions |
| | NCA can Approve/Reject VNRA submissions on behalf of other NCAs when a Supergrouping VNRA submission applies |
| | NCA can View Volume of Sales data |
| | NCA can delete document(s) |
| | MAH can Search/view product (data and documents) |
| | MAH can View Volume of Sales data |

| | |
|---|---|
| | General public can Search/view product (data and documents) |
| | UK(NI) CA can create and update NAP products (data and documents) |
| | UK(NI)CA can create & update Registered Homeopathic products (data and documents) |
| | UK(NI) CA can complement DCP/MRP/SRP products with national DCP/MRP/SRP data and documents as a CMS |
| | UK(NI) CA can create & update Pet products (data and documents) |
| | UK(NI) CA can Nullify product authorised for UK(NI). |
| | UK(NI) CA can Search/view product (data and documents) authorised for UK(NI). |
| | UK(NI) CA can Search, View and Approve/Reject VNRA submissions of products authorised for UK(NI) |
| | UK(NI) CA can delete documents from products authorised for UK(NI) |

| | |
|---|---|
| **NCA UI**  | RMS can create DCP products (data and documents) |
| | RMS can create MRP products (data and documents) |
| | RMS can create SRP products (data and documents) |
| | RMS and CMS can complement DCP/MRP/SRP products with national DCP/MRP data (including documents) |
| | RMS can update Common data for DCP/MRP/SRP products (data and documents) |
| | NCA can create and update NAP products (data and documents) |
| | NCA can create & update Registered Homeopathic products (data and documents) |
| | NCA can create & update Parallel Trade products (data and documents) |
| | NCA can create & update Pet products (data and documents) |
| | NCA can group National Authorised products under an MRP following CMDv SPC harmonisation procedure (data and documents) |
| | NCA can save and retrieve drafts for product submissions |

| | |
|---|---|
| | NCA can Nullify product |
| | NCA can Bulk Upload Documents |
| | NCA can Transfer Marketing Authorisation |
| | Search/view/export products (data and documents) |
| | Notifications for Create and Update of products and Other Post-Authorisation Data actions |
| | View Volume of Sales information and download Volume of Sales data of maximum one year |
| | Search, View and Approve/Reject VNRA submissions |
| | NCA can Approve/Reject VNRA submissions on behalf of other NCAs when a Supergouping VNRA submission applies |
| | EMA and EC staff can update CAP products |
| | UK(NI) CA can create & update NAP products (data and documents) |
| | UK(NI) CA can create & update Registered Homeopathic products (data and documents) |
| | UK(NI) CA can create & update Parallel Trade products (data and documents) |
| | UK(NI) CA can create & update Pet products (data and documents) |
| | UK(NI) CA can complement DCP/MRP/SRP products with national DCP/MRP data (including documents) as a CMS. |
| | UK(NI) CA can save and retrieve drafts for product submissions |
| | UK(NI) CA can Nullify product authorised for UK(NI). |
| | UK(NI) CA can Bulk Upload Documents of products authorised for UK(NI). |
| | UK(NI) CA can Transfer Marketing Authorisation of products authorised for UK(NI). |
| | UK(NI) CA can Search/view/export products (data and documents) authorised for UK(NI). |
| | UK(NI) CA can view notifications for Create, Update and Other Post-Authorisation Data actions of products authorised for UK(NI). |
| | UK(NI) CA user can Search, View and Approve/Reject VNRA submissions of products authorised for UK(NI). |

| | |
|---|---|
| **MAH UI**  | Search/view/export products (data and documents)<br>Notifications for Create and Update of products and Other Post-Authorisation Data actions<br>Submit/View Volume of Sales information and download Volume of Sales data of maximum one year<br>Submit VNRA and View VNRA submissions<br>Submit Supergrouping VNRAs with the selection of the Foreseen Decision Maker that will approve/reject the whole submission on behalf of the others NCAs involved<br>Submit updates for Marketing authorisation status<br>Download and Submit updates for Availability status<br>Submit Products Grouping<br>Submit 3rd country product names |
| **MAH Validation UI**  | Validate Volume of Sales submission file |
| **Authorisation for NCA & MAH UI**  | Integration with EMA Account Management (EAM) system for CA and Industry (MAH) roles<br>NCA users may search and view all Vet products<br>UK(NI) CA users may search and view all Centrally Authorised products and products authorised in the UK(NI)<br>MAH users may search and view only products under the responsibility of the organisations the user represents |

| Banner for UPD UI | EMA can maintain messages to appear in banner of UPD UI |
|---|---|

**Functionality not included in this release**

The following functionality is not included in this release.

NCA UI and API:

- None

MAH UI and API:

- None

General public API:

- None

# Annex 2: Known issues

Issue reference is an internal number used by the UPD Project team when managing issues. It has been included as User Support may refer to this reference number when responding to your queries. In addition, you can include this reference number when contacting user support on this topic and seeking clarification. Filter the columns to find those tickets relevant to your role and for NCAs whether you are an API or NCA User or both.

This table is ordered by Use Case number.

| Use Case | Affects user | Issue reference (ADO) | Known Issue Description | Workaround |
|---|---|---|---|---|
| **UC07 Volume of Sales** | MAH UI | 284628 | Deleted package for CAP is not present in file for VoS submission. | |
| **UC08 Update product** | NCA UI | 260784 | Drop down list does not show all the items while scrolling. Only when user starts typing shows matching items, but the scroll is limited to only a few entries. | |
| **UC08 Update product** | NCA UI | 314357 | Location ID for Manufacturer/QPPV location for some CAP products shows as 0. | |
| **UC08 Update product** | NCA UI | 339386 | Reference Identifiers are changing after update in DCP/SRP/MRP. | |
| **UC21 Notifications** | NCA UI & MAH UI | 312695 | UI Notifications are missing for some procedure type for 'VNRA approved' and 'VNRA rejected' actions. | |
| **UC28 View VNRA** | NCA & MAH UI | 332164 | PDF shows only one section when same VNRA code is used multiple times in a submission. | |
| **SIAMED to ETL PMS** | NCA UI & MAH UI | 227315 | CAPs are updated several times on the same day increasing the version numbers and causing unmanageable queues in the public portal. | |
| **SIAMED to ETL PMS** | NCA UI & MAH UI | 233428 | Pre-authorisation product names are shown in UPD for some CAP products. | |
| **SIAMED to ETL PMS** | EMA UI | 261428 | When reference strength is entered in SIAMED, while data is being transferred to UPD / Strength and reference strength changes places. | |
| **SIAMED to ETL PMS** | EMA UI | 224846 | Date of Authorisation status change is not in sync with the actual date updated | |

# Annex 3: Release Schedule

| Environment | Closed from | Closed to | Expected to be open | Description |
|---|---|---|---|---|
| UAT | 27 February 2026 | 2 March 2026 | 2 March 2026 | Upgrade of UPD to **1.7.2615** |
| PROD | 13 March 2026 | 16 March 2026 | 16 March 2026 | Upgrade of UPD to **1.7.2615** |
| UAT | 13 April 2026 | 13 April 2026 | 13 April 2026 | Upgrade of UPD to **1.7.2615-3**<br>A specific version for the UK/NI users deployed. |
| PROD | 5 May 2026 | 5 May 2026 | 5 May 2026 | Upgrade of UPD to **1.7.2615-3**<br>A specific version for the UK/NI users deployed. |
| UAT | 5 June 2026 | 5 June 2026 | 5 June 2026 | Upgrade of UPD to **1.7.2625** |
| PROD | 26 June 2026 | 26 June 2026 | 26 June 2026 | Upgrade of UPD to **1.7.2625** |
| UAT | 21 August 2026 | 21 August 2026 | 21 August 2026 | Upgrade of UPD to **1.7.2633** |
| PROD | 4 September 2026 | 4 September 2026 | 4 September 2026 | Upgrade of UPD to **1.7.2633** |
| UAT | 16 November 2026 | 16 November 2026 | 16 November 2026 | Upgrade of UPD to **1.7.2643** |
| PROD | 27 November 2026 | 27 November 2026 | 27 November 2026 | Upgrade of UPD to **1.7.2643** |