Union Product Database (UPD) release notes

Referring to version 1.7.2513

Release date: 4 March 2025

Acronym key and glossary terms

ADO	Azure DevOps	**NAP**	Nationally Authorised Products	
API	Application Programming Interface	**OPAD**	Other Post Authorisation Data	
APIM	API Manager	**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	
AvS	Availability Status	**PMS**	Product Management Service	
CA	Competent Authority	**PSMF**	Pharmacovigilance System Master File	
CAP	Centrally Authorised Products	**QPPV**	Qualified Person Responsible For Pharmacovigilance	
CMDv	Coordination group for mutual recognition and decentralised procedures for veterinary medicinal products	**RMS**	Reference Member State	
CMS	Concerned Member State	**RN**	Release Notes	
CSV	Comma-separated values	**SIAMED**	EMA product information and application tracking system	
DCP	Decentralised Procedure	**SIT**	System Integration Testing	
EAM	EMA Account Management	**SMS**	Substances Management Services	
EC	European Commission	**SPOR**	Substances, Products, Organisations and Referentials	
EEA	European Economic Area	**SRP**	Subsequent Recognition Procedure	
EMA	European Medicines Agency	**UAT**	User Acceptance Testing	
EP	End Point	**UC**	User Case	
EU IG	European Union Implementation Guide	**UI**	User Interface	
FHIR	Fast Healthcare Interoperability Resources	**UPD**	Union Product Database	
HF	Hot Fix	**NCA**	National Competent Authority	
HL7	Health Level Seven	**NP**	National Procedure	
JSON	JavaScript Object Notation	**OMS**	Organisation Management Service	
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	

The structure of these release notes has been refined and simplified for enhanced accessibility to all users. The document contains now 3 sections and 3 annexes. It should be noted that specific segments have been excised, owing to their availability within other documents (such as the EU IG).

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 1.7.2443-15, released on 30 January 2025)	**9**
Known Issues	**19**
Next release's expected date	**12 March 2025**

Overview of new functionality(ies):

- This release includes only bug fixes, and no new functionalities are included.

Notes:

- In case of receiving an error file after the Availability Status (AvS) submission, MAHs are advised to follow these steps:

  - If the errors in the file are due to business validations (see section 4.3.2 of Vet EU IG Chapter 7), **fix the errors and resubmit the file**.
  - **If the file contains ER.36** (see section 4.3.1 of Vet EU IG Chapter 7), then pay attention to the last column of the file:
    - The rows that in the last column contain ER.36, please group them in a new Excel or CSV file and submit it in a ticket to EMA Service Now.
    - If you have rows having in the last column the value 'N/A', please resubmit those rows to UPD;
    - If you have rows having in the last column values of the type 'Database updated - Submission 0000 - Product 00000', please do not resubmit as those updates have been processed successfully.

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

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

For information:

- All Competent Authorities that are participating in the SPC harmonisation procedure must ensure that the selected reference 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.

Table of Contents

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	224495	During the creation of an MRP product after SPC harmonisation procedure, if a user adds and then decides to remove a CMS, the reference to the removed product remained on the form
UC03 Search	NCA UI & MAH UI	221404	When a user performed a search by location selecting an organisation with a merged location, search would silently fail
UC21 Manage Notifications	NCA UI & MAH UI	218870	Incorrect information was displayed on Notifications table for Record Status
UC33 3rd Country Submission	MAH UI	228439	Submission made for more than one product group incorrectly failed with ERR.25
UC07 Submit Volume of sales	MAH UI	222086	Submission for non-EEA country on DCP product surrendered or revoked for over 2 years is not allowed if it contains a nullified CMS
UC08 Update product	ETL for CAP products	223864	CAP products without multiplied Target Species after ETL run
UC37 Automatic sending of notifications	NCA & MAH UI	203369	Email notifications are generated for actions performed in UPD
SIAMED to ETL PMS	NCA UI & MAH UI	232043	CAP with all presentations suspended in SIAMED do not appear as "valid" in product card and can be opened in the UI
SIAMED to ETL PMS	NCA UI & MAH UI	232744	CAP products with no multiplied Manufactured Items after ETL run

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
UC03 Search	NCA UI & MAH UI	226774	Substance which has current status in SMS is not available in Search via UPD UI	
UC35 Products available via API	NCA API & MAH API	223598	Query parameter "_count" is not functioning in Public API endpoints	
SIAMED to ETL PMS	NCA UI & MAH UI	233428	Pre-authorization product names shown in UPD for some CAP products	
UC08 Update product	NCA UI	234042	Unable to change Ownership for HOM and PET products - Fails with "The user is not responsible for the product"	
UC37 Automatic sending of notifications	NCA & MAH UI	235374	Email notifications for VNRA Approval not being created when comma-separated decision makers are used	
UC07 Submit Volume of sales	MAH UI	236491	Submission to a CAP surrendered package <2 years ago fails with ERR.17: Package Identifier provided was deleted more than 24 months	
UC08 Update product	NCA UI	234682	Deletion of the added 'Part name' is not possible via API and UI for DCP/MRP product	
UC07 Submit Volume of sales	MAH UI	237929	While retrieving VoS, a red box with empty message is displayed on the top corner and no results are displayed	

2. User support

API and UI users may seek support by contacting the User Support via [EMA Service Now](#).

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 Supergouping VNRA submission applies
	NCA can View Volume of Sales data
	MAH can Search/view product (data and documents)
	General public can Search/view product (data)

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

	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

MAH UI	Search/view/export products (data and documents)
	Notifications for Create and Update of products and Other Post-Authorisation Data actions
	Download, Submit, and View Volume of Sales information
	Submit VNRA and View VNRA submissions
	Submit Supergouping VNRAs with the selection of the Foreseen Decision Maker that will approve/reject the whole submission on behalf of the others NCAs involved
	Submit updates for Marketing authorisation status
	Download and Submit updates for Availability status
	Submit Products Grouping
	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
	CA users may search and view all Vet products
	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:

- The current API configuration does not provide access to product information (SPC, PL, Labelling) documents and public assessment reports. To retrieve these documents please use the [public portal](#)

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
UC03 Search product	NCA UI & MAH UI	83234	Search limitations due to FHIR limitation or MS FHIR limitation.	
UC03 Search	NCA UI & MAH UI	225044	When a user searches for an organisation which has a merge location, it shows multiple entries with the survivor location details.	
UC05 View product	API & NCA UI & MAH UI	211624	PSMF information has been lost for some CAPs	
UC05 View product	NCA UI & MAH UI	207731	Product references are not being displayed properly for CAP products in the UPD UI	
UC06 Submit VNRA	MAH UI	211736	Retrieve VNRA does not retrieved all the fields filled while saving draft	
UC06 Submit VNRA & UC28 View VNRA	MAH UI	189703	View VNRA submissions page fails to load results using the Submission Status filter = approved	
UC08 Update product	NCA UI	205197	The Edit national data button is not available as expected in some DCP/MRP/SRP products.	
UC08 Update product	API & NCA UI	152242	CAP product only - after updating product in UPD there is a duplicated Pack size attribute. This duplicate attribute is only seen view Retrieve product via API. Subsequent updates via UPD for affected products are successful.	
UC08 Update product	ETL for CAP products	215513	CAP contains packages with Marketing Authorization status = Withdrawn which is not a valid term for the field	

SIAMED to ETL PMS	NCA UI & MAH UI	232033	Some CAPs are missing Procedure number in UI that is in SIAMED and that prevent updates
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

Annex 3: Release Schedule

Environment	Closed from	Closed to	Expected to be open	Description
UAT	14 January 2025	14 January 2025	14 January 2025	Upgrade of UPD to **1.7.2443-14** A hot fix concerning volume of sales (bug 217701)
PROD	17 January 2025	17 January 2025	17 January 2025	Upgrade of UPD to **1.7.2443-14** A hot fix concerning volume of sales (bug 217701)
UAT	21 January 2025	21 January 2025	21 January 2025	Upgrade of UPD to **1.7.2443-15**
PROD	30 January 2025	30 January 2025	30 January 2025	Upgrade of UPD to **1.7.2443-15**
UAT	19 February 2025	19 February 2025	19 February 2025	Upgrade of UPD to **1.7.2513**
PROD	4 March 2025	4 March 2025	5 March 2025	Upgrade of UPD to **1.7.2513**
UAT	5 March 2025	5 March 2025	5 March 2025	Upgrade of UPD to **1.7.2514**
PROD	12 March 2025	12 March 2025	12 March 2025	Upgrade of UPD to **1.7.2514**