

Union Product Database (UPD) release notes

Referring to version 1.7.2541

Release date: 7 November 2025



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	омѕ	Organisation Management Service
CA	Competent Authority	OPAD	Other Post Authorisation Data
САР	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	PMS	Product Management Service
CMS	medicinal products 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
EU IG	European Union Implementation Guide	SRP	Referentials 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
МАН	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 1.7.2534, released on 9 September 2025)	23
Known Issues	23
Next release's expected date	5 December 2025 (to be confirmed)

Overview of new functionality(ies):

- Several system validation checks for Transfer of ownership have been removed to allow smooth transition of products to the new product owner when missing mandatory data or having data quality issues. For example:
 - Allowing products with product record status as provisional also along with current product record status to be selected when changing the product owner.
 - o Removed validation check in case of missing National data.
 - Removed validation check in case of missing PSMF code and PSMF location value.
 - Removed validation check in case of data quality issues.
- VNRA view screen have additional search field for Variation requiring assessment (VRA) procedure number and a column is added in the Search table for the same.
 - o MAH or NCA user can search the VNRA submissions using the VRA procedure number.
 - MAH and NCA user can see the details of which submission is a 'Consequential VNRA' in the Search table using the new column added for VRA procedure number.
 - VNRA submission that is not a 'Consequential VNRA' does not show the VRA procedure number field in VNRA view or pdf file.
- **Parallel trade products can be updated** after the Source and/or destination reference products are surrendered.

Addition notes: Not applicable.

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.
- Some MAH users may experience failed product grouping submissions for products that were subject to transfer of ownership and were previously grouped by the former MAH. This inconvenience is expected to be resolved in Q1 2026 at the latest. Meanwhile, for failed product grouping submissions, MAH users are encouraged to open ServiceNow incidents requesting datafixes on their affected products.

Table of Contents

1. Summary of issues	5
1.1. Resolved issues	
1.2. New issues since last release	
2. User support	8
2.1. Available training materials and guidance	
3. References	8
Annex 1: Overview of functionality and business value	9
Annex 2: Known issues	
Annex 3: Release Schedule	15

1. Summary of issues

1.1. Resolved issues

Use Case	Affects API and/or UI	Issue reference (ADO)	Resolved issues
UC03 Search Product	NCA UI & MAH UI	265632	UPD PROD search displaying "wrong results" under "Active substance and strength" field
UC05 View product	NCA UI & MAH UI	257909	Datafix - German package description is displayed multiple times
UC05 View Product	NCA UI & MAH UI	275807	UPD: Category menu overlaps with footer when scrolling down
UC08 Update product	NCA UI	257052	Datafix – Update product is blocked because of different number of packages in RMS and CMS products
UC08 Update product	NCA UI	248496	Datafix - Some products have duplicated documents that cannot be deleted
UC08 Update Product	NCA UI & NCA API	234682	Update DCP/MRP product – Deletion of the added 'Part name' is not possible via API and UI
UC08 Update Product	NCA UI	266995	Datafix – Correcting MRP product after SPC harmonisation procedure
UC08 Update product	NCA UI	270931	Datafix – Unable to Surrender Parallel trade product when the Source or Destination reference product is surrendered
UC08 Update product	NCA UI	272934	Datafix – Update failure due to validation error
UC08 Update product	NCA UI	273283	Datafix – Correcting MRP product after SPC harmonisation procedure
UC08 Update product	NCA UI	275651	Datafix – Rollback MRP created instead of MRP product after SPC harmonisation procedure
UC08 Update Product	NCA UI	277376	Datafix – Correcting an authorisation status for NAP from Valid to Surrounded
UC09 Approve Reject VNRA	NCA UI	264659	Datafix – VNRA submissions cannot be approved because of wrong decision maker
UC21 Notifications	NCAUI & MAH UI	263955	Datafix - Notifications missing Product record status information
UC25 Update Availability Status	MAH UI	265756	Datafix – Unable to update AvS due to error in Package Description
UC25 Update Availability Status	MAH UI	274859	Datafix – Product is erroneously showing in search results for AvS as 'No Data Provided' filter

Union Product Database (UPD) release notes

EMA/343642/2025 Page 5/16

Use Case	Affects API and/or UI	Issue reference (ADO)	Resolved issues
UC27 View Volume of sales	NCA UI & MAH UI	262383	Datafix – View VoS retrieve - Bulgarian alphabet not correctly displayed for Product Name.
UC28 View VNRA	NCA UI & MAH UI	269917	Datafix – VNRA not showing in submission view for EMA
UC 38 Product Grouping	MAH UI	274505	Datafix – Product is not showing its group when group products csv file is downloaded
UC 38 Product Grouping	MAH UI	260167	Datafix – Product is not showing its group when group products csv file is downloaded
Document Service	NCA UI	264725	Unable to upload Documents to SharePoint
Document Service	NCA UI	275173	Public portal and UPD - impossible to download documents
SIAMED to ETL PMS	NCA UI & MAH UI	232033	Datafix – Some CAPs are missing Procedure number and that prevent updates

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 product	NCA API	274528	Different results between Search results for UPD portal (v3 API) and Public portal (v4 API)	
UC03 Search Product	NCA UI & MAH UI	277682	Incomplete list of Target species displayed in Search results and Summary card for products	
UC08 Update product	NCA UI	273750	·	
UC08 Update product	NCA UI	274506	Common documents have not been updated via API within the CMS Products	
UC21 Notifications	NCA UI & MAH UI	276545	Datafix - Notifications missing Product record status information	
UC21 Notifications	NCA UI & MAH UI	276546	In Notifications Tab product status record information might be missing	

EMA/343642/2025

UC25 Update Availability	MAH UI	276214	Availability status incorrectly stated on the
Status			product summary card
UC25 Update Availability	MAH UI	277904	Updated availability status details for few CAPs
Status			are missing
UC28 View VNRA	NCA UI & MAH UI	275133	Divergence in VNRA's Notification Decision Date
			between UI and Submission
UC 38 Product Grouping	MAH UI	277195	Datafix – Product is not showing its group when
			group products csv file is downloaded

Union Product Database (UPD) release notes

EMA/343642/2025 Page 7/16

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. <u>HL7 FHIR Release 5 Preview 2: the authoritative source for the FHIR specifications used by EMA to implement SMS and PMS API</u>
- 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

EMA/343642/2025 Page 8/16

Annex 1: Overview of functionality and business value

Functionalities provided in this release

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)

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

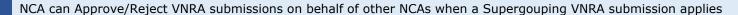
Search/view/export products (data and documents)

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





EMA and EC staff can update CAP products

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

MAH UI



Validate Volume of Sales submission file



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





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 <u>public portal</u>

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.	
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 & UC28 View VNRA	MAH UI	189703	View VNRA submissions page fails to load results using the Submission Status filter = approved	
UC07 Volume of Sales	MAH UI	236491	Submission to a CAP surrendered package fails. User should be able to submit if package was surrendered less than 2 years ago.	
UC08 Update product	API	248758	Update DCP via API, chapter 2, returns error when one CMS doesn't hold PSMF data	
UC08 Update product	NCA UI	251306	PSMF Location for one CAP is lost after QPPV email update	
UC08 Update product	ETL for CAP products	215513	CAP contains packages with Marketing Authorisation status = Withdrawn which is not a valid term for the field.	
UC08 Update product	NCA UI	251306	PSMF Location for CAP is lost after QPPV email update	
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	NCA UI & MAH UI	215651	Purevax FeLV with 2 strengths in SIAMED and 3 products in UPD (instead of 2)	

SIAMED to ETL PMS	Public Portal	248376	For several CAPs wrong manufacturing sites for	
			batch release are displayed	
SIAMED to ETL PMS	EMA user	261428	When reference strength is entered in SIAMED, while	
		data is being transferred to UPD / Strength and		
			reference strength changes places	

Union Product Database (UPD) Release Notes

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
PROD	21 March 2025	21 March 2025	21 March 2025	Upgrade of UPD to 1.7.2514-3
UAT	22 May 2025	22 May 2025	22 May 2025	Upgrade of UPD to 1.7.2523
PROD	16 June 2025	16 June 2025	16 June 2025	Upgrade of UPD to 1.7.2523
UAT	19 August 2025	19 August 2025	19 August 2025	Upgrade of UPD to 1.7.2533
PROD	9 September 2025	9 September 2025	9 September 2025	Upgrade of UPD to 1.7.2534
UAT	27 October 2025	27 October 2025	27 October 2025	Upgrade of UPD to 1.7.2541
PROD	7 November 2025	7 November 2025	7 November 2025	Upgrade of UPD to 1.7.2541

Environment	Closed from	Closed to	Expected to be open	Description
UAT	21 November 2025 (tbc)	21 November 2025 (tbc)	21 November 2025 (tbc)	Upgrade of UPD to 1.7.254x
PROD	5 December 2025 (tbc)	5 December 2025 (tbc)	5 December 2025 (tbc)	Upgrade of UPD to 1.7.254x