



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Union Product Database (UPD) release notes

Referring to version 1.7.2523

Release date: 16 June 2025

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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	VNeS	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 1.7.2514-3, released on 21 March 2025)	18
Known Issues	23
Next release's expected date	to be determined

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.

Product	Permanent	Authorisation	Package	Pack	size_Unit	Availability	Availability
1 Name	Identifier	Procedure Numbe	Identifier	size_Nu	of	Country	Status
2 Example	600000000001	EMEA/V/C/000000	C81CC9A8-2B9A-6B62	1 Vial		Denmark	10000072075 1/1/2020
3 Example	600000000002	EMEA/V/C/000000	C81CC9A8-2B9A-6B62	1 Vial		Czechia	10000072075 1/1/2020 N/A
4 Example	600000000003	EMEA/V/C/000000	C81CC9A8-2B9A-6B62	1 Vial		Cyprus	10000072075 1/1/2020 Database updated - Submission 0000 - Product 00000

- 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:

- Since 13 June 2024 MAHs can save an incomplete VNRA submission via a user interface and resume it within 30 days. For further details, watch the "How to save and resume draft VNRA submissions" video tutorial available on [UPD video tutorials for MAHs](#). On 8 October

2024 it has been announced (see [UPD release notes for version 1.7.2434](#)) that combining many products within a single VNRA submission (irrespective of whether it is a technical grouping or supergrouping) via the UPD UI can lead to challenges both for the industry users when submitting, and NCA UI users when approving/rejecting the VNRA. The 'recommended' maximum limit is 2000 changes (1000 products x 2 VNRA codes = 2000 changes). For further information please see [CMDv Best Practice Guide for Variations Not Requiring Assessment](#). **Important note:** MAH users should be aware that if they intend to save an incomplete VNRA submission and later resume it within 30 days, that saved file has a limitation of maximum 1000 products that can be saved within the draft VNRA submission. This means that any number of products above 1000 will not be saved nor later retrievable from the draft file. Until a solution is deployed, we recommend all MAH users to submit VNRA submission that exceed 1000 products directly and not saving the draft VNRA submission.

- 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.
- The system is experiencing inconsistencies in the Export csv file related to the QPPV email information for CAPs i.e. the QPPV email field might be displaying N/A instead of the email address. A bug 215611 was raised in October 2024 to find the root cause of the problem. The investigation concluded that there's a timing issue that prevents exporting in real time accurately data from the UPD. Three potential solutions were considered, and the preferred one is a complex task which might be addressed later this year. Unfortunately, this means that **the Export csv file may on rare occasions display N/A (when the QPPV email information has already been submitted)**. Until a solution is deployed, in case of any value missing in the Export csv file for CAPs, we recommend checking the product in the UPD UI to confirm the existing information. If the data displayed in the UPD UI is incorrect (and the MAH has previously submitted the correct QPPV email), then a ticket should be raised via [EMA Service Now](#).

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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 (MRPh)	NCA UI	224552	It was possible to add two or more products with same Authorisation country while creating an MRP after SPC harmonisation. That is corrected and now one Authorisation country can have only one entry either of CMS or RMS
UC02 Landing page	NCA UI & MAH UI	209311	Logout button was not visible when logged in. This is fixed and now. Logout is visible after logging in.
UC03 Search	NCA UI & MAH UI	226774	Substance which has current status in SMS are available in Search via UPD UI
UC03 Search	NCA UI& MAH UI	241467	Unable to search by Product Owner
UC03 Search	NCA UI & MAH UI	245556	If users have multiple affiliation, they were unable to find products from a merged location when searching for Product Owner.
UC05 View product	NCA UI & MAH UI	244254	PSMF Data - Inconsistencies viewing Address and Loc ID through versions
UC05 View product	API & NCA UI & MAH UI	211624	PSMF information has been lost for some CAPs
UC06 Submit VNRA	MAH UI	211736	Retrieve VNRA does not retrieve all the fields filled while saving draft - few fields were missing
UC06 Submit VNRA	MAH UI	247915	DataFix for Procedure Type / Procedure Number for VNRA
UC07 Submission of Volume of Sales	MAH UI	178070	ERR.03: Country identifier does not exist in RMS list while submitting the volume of sales via a form. The error is resolved.
UC07 Submission of Volume of Sales	MAH UI	248122	A new validation to prevent wrong format date in VoS

UC07 Submission of Volume of Sales	MAH UI	237929	MAH user gets blank red error message while retrieving Volume of sales data
UC08 Update product	API & NCA UI	152242	CAP product only - after updating product in UPD there was a duplicated Pack size attribute. The duplicate pack sizes are removed and the products data is corrected
UC08 Update product	API	240066	Marketing authorisation status set to 'surrendered' not changing availability status to 'not marketed' via API
UC08 Update product	NCA UI	242282	Substance after removing reference strength in UI doesn't prevents product to be updated
UC08 Update product	NCA UI	240812	QPPV email field in UI follow same rules as API. The validation is applied for email as generic email format.
UC37 Automatic sending of notifications	NCA & MAH UI	235374	E-mail notifications for VNRA Approval were not being created when multiple decision makers are listed. Added the correction to read the decision makers beyond comma separator.
UC37 Automatic sending of notifications	NCA UI, MAH UI & API	245518	Some email notifications were delayed by a day or not send due to defined email processing window.

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
UC05 – View Product	NCA UI	251172	Opening Product details from search results via UI fails with error 'Sorry no product found'	
UC07 Volume of Sales	MAH UI	243078	ERR16 - Percentile error while summing VoS	Rearrange the rows in the csv file to change the order of the sum of species percentage split
UC08 Update product	NCA UI	248496	Some products have duplicated files that cannot be deleted	
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	NCA UI	250860	Duplicate name for VMP, both as common and national data
UC21 Notifications	NCA UI	248533	Bulgarian alphabet not correctly displayed for Product Name or in Submission Comment
UC21 Notifications	MAH UI	249951	Notifications not available. Error : System error: try again in a few minutes.
UC28 View VNRA	MAH UI	249011	Issue with downloading VNRA zip file
UC28 View VNRA	NCA UI	250851	NCA to view/approve/reject VNRA after fix of ORG-ID
UC33 Manage Third Country Product name	MAH UI	249044	Non Roman characters turning into question mark (?) after upload of 3rd country product names
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

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 Supergrouping 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 Supergrouping 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 Supergrouping 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 3 rd country product names	

MAH Validation UI 	Validate Volume of Sales submission file
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**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.	
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.	
UC07 Volume of Sales	MAH UI	237929	User gets blank error message when attempting to retrieve Volume of Sales information	
UC08 Update Product	NCA UI & NCA API	234682	Is not possible to remove existing "Name Part" field.	
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	
SIAMED to ETL PMS	NCA UI & MAH UI	233428	Pre-authorisation product names are shown in UPD for some CAP products	

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