Union Product Database (UPD) release notes

Referring to version 1.7.2514-3

Release date: 21 March 2025

Version 2

Changes made to the release notes:

- updated the number of resolved and known issues on pages 3, 6 and 12.

For ease of reference see below **NEW** and **UPDATED**.

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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	**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.

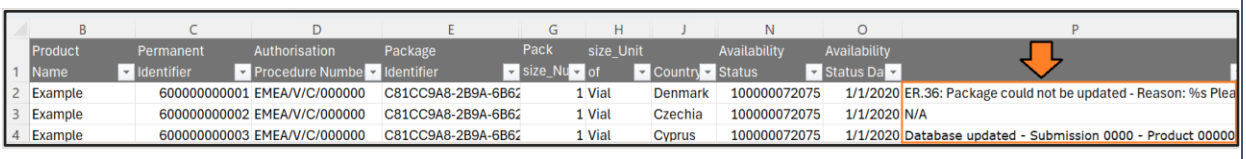
UPDATED Resolved issues since the previous release (UPD version 1.7.2514, released on 12 March 2025)	**1**
UPDATED Known Issues	**15**
Next release's expected date	**Q2 2025**

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.



	B	C	D	E	G	H	J	N	O	P
1	Product Name	Permanent Identifier	Authorisation Procedure Numbe	Package Identifier	Pack size_Nu	size_Unit of	Country	Availability Status	Availability Status Da	
2	Example	600000000001	EMEA/V/C/000000	C81CC9A8-2B9A-6B62	1	Vial	Denmark	100000072075	1/1/2020	ER.36: Package could not be updated - Reason: %s Plea
3	Example	600000000002	EMEA/V/C/000000	C81CC9A8-2B9A-6B62	1	Vial	Czechia	100000072075	1/1/2020	N/A
4	Example	600000000003	EMEA/V/C/000000	C81CC9A8-2B9A-6B62	1	Vial	Cyprus	100000072075	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:

- 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 the 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.

Table of Contents

1. Summary of issues

1.1. Resolved issues

Use Case	Affects API and/or UI	Issue reference (ADO)	Resolved issues
NEW UC08 Transfer of Ownership	MAH UI	234042	Change Ownership for HOM and PET products. Operation was failing with "The user is not responsible for the product" error

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
Not applicable				

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	226774	Substance which has current status in SMS is not available in Search via UPD UI	
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	
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	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
UC37 Automatic sending of notifications	NCA & MAH UI	235374	E-mail notifications for VNRA Approval are not being created when multiple decision makers are listed
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-authorization 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 **1.7.2524-3**