Union Product Database (UPD) release notes

Referring to version 1.7.2544

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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

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 1.7.2541, released on 7 November 2025)	**7**
Known Issues	**20**
Next release's expected date	**Q1 2026 (to be determined)**

Overview of new functionality(ies):

- **MAHs are able select all their non-centrally authorised products and submit VNRAs related to QPPV and/or PSMF data**
    - **MAH users** are enabled **to choose** whether to:
        - i) continue selecting their products individually when submitting VNRA codes C1, C5 and/or C.6 OR
        - ii) select all their non-centrally authorised products (non-CAPs) by checking the new button '*Select all my non-CAPs*' when submitting VNRAs for codes C1, C5 and/or C6.
    - For further details, **both MAH and NCA users** are advised to consult the **bite-sized video** named "*How to submit changes to QPPV and PSMF information for non-centrally authorised products in bulk via VNRAs"* that will shortly be available in the "videos for MAHs" section of the UPD webpage, and read the following **important notes**:
        - During the submission of a VNRA, a new button labelled 'Select all my non-CAPs' is available next to the existing '*Retrieve products*';
        - The button '*Select all my non-CAPs*', is active only if any of the codes C.1, C.5 and/or C.6 is been selected;
        - In case any other VNRA code is selected the button '*Select all my non-CAPs*' is deactivated;
        - When the button '*Select all my non-CAPs*' is selected, the QPPV and/or PSMF values proposed in the submitted C1, C5 and/or C6 VNRA(s) will concern all the non-CAPs under the users' responsibility, except for the CAP products.
        - When the '*Select all my non-CAPs*' option is used, the products will not be displayed in the UI and the MAH user will not be able to save the draft VNRA i.e. the '*Create Draft*' button will be disabled;
        - Should the MAH have CAPs and wish to change QPPV and/or PSMF information for these products, they should continue using the search and '*Retrieve product*' option and submit C1, C5 and/or C6 VNRA(s);
        - Both MAH and NCA users should be aware that after the NCA approval of the respective VNRAs, the update of products will be overnight tasks in order not to

affect the system performance during working hours. That means that when C1, C5 and/or C6 VNRA(s) are approved by the NCA, the concerned products data will be updated and visible on the following day.

- **Improved 'Sorting' of search results across pages for Product search, OPAD functionality and View VNRA submission** within results:
    - Sorting is applied on all the search results across the multiple pages of results based on search criteria.
    - All columns are available for Sorting in **Product search, OPAD functionality and V**iew V**NRA submission pages except** 'Decision makers', 'VNeeS file' and 'Download VNRA data' columns in the View VNRA submissions tab.
    - **When returning/browsing to search results (e.g., clicking "back" after viewing a product, or prior page numbers), the system display the same filtered/sorted information.**
    - When sorting is changed while browsing, system refreshes the sorting to new criteria and reset the user to page 1.
- **A CMS NCA is enabled to approve/reject submitted VNRA code A2 'Change in the (invented) name' for products under DC/MR/SR procedure**:
    - As per Annex 3 of the CMDv best practice guide for VNRAs only the CMS product (Permanent Ids) impacted by the VNRA have to be added in the submission. The RMS product should not be added. If the same VNRA applies for different CMS(s), one VNRA per CMS has to be submitted.

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

1.1. Resolved issues

Use Case	Affects API and/or UI	Issue reference (ADO)	Resolved issues
UC01 Create Product	NCA UI	279388	Substance not showing and reset button not working in Substance search
UC08 Update product	NCA UI	273750	Updates failure due to same id for PackageProductDefinition id and PackageProductDefinition package id
UC08 Update Product	NCA UI	277376	Authorisation status update failed due to previous update failure for a product
UC21 Notifications	NCA UI & MAH UI	276545	Datafix - Notifications missing Product record status information
UC25 Update Availability Status	MAH UI	277904	Updated availability status details for few CAPs are missing
UC28 View VNRA	NCA UI & MAH UI	275133	Divergence in VNRA's Notification Decision Date between UI and Submission
SIAMED to ETL PMS	Public Portal	248376	For several CAPs wrong manufacturing sites for batch release are displayed

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	279147	Suspended CAP(s) cannot be updated in UPD	
UC09 Approve Reject VNRA	NCA UI	281301	Submit button is enabled for VNRA submissions which are not under User's authority to Approve/reject	Cosmetic error only. No action happens if submit button is clicked without any Variations selected
UC28 View VNRA	NCA UI & MAH UI	280085	Permanent Identifier appears in place of Loc-ID for View VNRA Submission Screen	

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 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	
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	274506	Common documents have not been updated via API within the CMS Products	
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.	
UC21 Notifications	NCA UI & MAH UI	276546	In Notifications Tab product status record information might be missing	
UC25 Update Availability Status	MAH UI	276214	Availability status incorrectly stated on the product summary card	

UC 38 Product Grouping	MAH UI	277195	Datafix – Product is not showing its group when group products csv file is downloaded	
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	EMA user	261428	When reference strength is entered in SIAMED, while data is being transferred to UPD / Strength and reference strength changes places	

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	24 November 2025	24 November 2025	24 November 2025	Upgrade of UPD to **1.7.2544**
PROD	5 December 2025	5 December 2025	5 December 2025	Upgrade of UPD to **1.7.2544**