

## Union Product Database (UPD) release notes

Referring to version 1.7.2443-15

Release date: 30 January 2025



## Acronym key and glossary terms

<b>ADO</b>	Azure DevOps	<b>NAP</b>	Nationally Authorised Products
<b>API</b>	Application Programming Interface	<b>OPAD</b>	Other Post Authorisation Data
<b>APIM</b>	API Manager	<b>PET</b>	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
<b>AvS</b>	Availability Status	<b>PMS</b>	Product Management Service
<b>CA</b>	Competent Authority	<b>PSMF</b>	Pharmacovigilance System Master File
<b>CAP</b>	Centrally Authorised Products	<b>QPPV</b>	Qualified Person Responsible For Pharmacovigilance
<b>CMDv</b>	Coordination group for mutual recognition and decentralised procedures for veterinary medicinal products	<b>RMS</b>	Reference Member State
<b>CMS</b>	Concerned Member State	<b>RN</b>	Release Notes
<b>CSV</b>	Comma-separated values	<b>SIAMED</b>	EMA product information and application tracking system
<b>DCP</b>	Decentralised Procedure	<b>SIT</b>	System Integration Testing
<b>EAM</b>	EMA Account Management	<b>SMS</b>	Substances Management Services
<b>EC</b>	European Commission	<b>SPOR</b>	Substances, Products, Organisations and Referentials
<b>EEA</b>	European Economic Area	<b>SRP</b>	Subsequent Recognition Procedure
<b>EMA</b>	European Medicines Agency	<b>UAT</b>	User Acceptance Testing
<b>EP</b>	End Point	<b>UC</b>	User Case
<b>EU IG</b>	European Union Implementation Guide	<b>UI</b>	User Interface
<b>FHIR</b>	Fast Healthcare Interoperability Resources	<b>UPD</b>	Union Product Database
<b>HF</b>	Hot Fix	<b>NCA</b>	National Competent Authority
<b>HL7</b>	Health Level Seven	<b>NP</b>	National Procedure
<b>JSON</b>	JavaScript Object Notation	<b>OMS</b>	Organisation Management Service
<b>LOC ID</b>	Location identifier	<b>URN</b>	Uniform Resource Names
<b>MAH</b>	Marketing Authorisation Holder	<b>UUID</b>	Universally Unique Identifier
<b>MDM</b>	Master Data Management	<b>VNeeS</b>	Veterinary Non eCTD Electronic Submission
<b>MRP</b>	Mutual Recognition Procedure	<b>VNRA</b>	Variations not requiring assessment
<b>MRPH</b>	MRP products created after SPC harmonisation procedure	<b>VoS</b>	Volume of Sales
<b>MS</b>	Member State	<b>XML</b>	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.

<b>Resolved issues since the previous release (UPD version 1.7.2443, released on 5 December 2024)</b>	<b>14</b>
<b>Known Issues</b>	<b>22</b>
<b>Next release's expected date</b>	<b>27 February 2025 (to be confirmed)</b>

#### Overview of new functionality(ies):

- **New UPD API capabilities:**
  - **MAHs can now connect their systems to UPD via API** and read all their product data.
  - **Members of the general public and organisations can now connect to UPD via API** and read all non-confidential product data. Note: 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](#).
  - **NCA API for 'UPD Products/Procedures' is changing and require OAuth 2.0 authentication and authorisation via a valid Bearer Token to use each endpoint (also known as v3 API).** Section 5.1.1. of the [UPD Registration guide for UI and API users](#) provides further information on how a 'Super user' of the organisation can request the NCA API role. A separate communication will to all existing NCA API users will follow with further guidance and timelines.

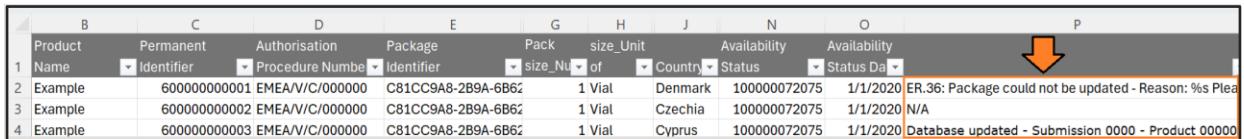
In order **to make use of the UPD API**, users will have to:

- 1) request access by following the steps described in the [UPD Registration guide for UI and API users](#).
- 2) read thoroughly [Vet EU IG Chapter 5](#).

#### 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 Identifier	Authorisation Number	Package Identifier	Pack size	Unit	Availability	Status	Status Date	Reason
1 Example	60000000001	EMEA/V/C/000000	C81CC9A8-2B9A-6B62	1	Vial	Denmark	100000072075	1/1/2020	ER.36: Package could not be updated - Reason: %s Please
2 Example	60000000002	EMEA/V/C/000000	C81CC9A8-2B9A-6B62	1	Vial	Czechia	100000072075	1/1/2020	N/A
3 Example	60000000003	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:**

- The entire Annex 4 'Guidance for API users' has been removed from the release notes and transferred to [Yet EU IG Chapter 5](#).

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## 1. Summary of issues

### 1.1. Resolved issues

Use Case	Affects API and/or UI	Issue reference (ADO)	Resolved issues
<b>UC01 Create Product</b>	NCA UI	225300	No error message displayed while entering QPPV email address in incorrect format
<b>UC01 Create Product</b>	NCA UI	227330	New OMS LOC-ID was not present on UPD. Full load of OMS cache was performed.
<b>UC05 View product</b>	NCA UI & MAH UI	195439	Opening a Product page from the search results fails with error 'Sorry no product found'.
<b>UC06 Submit VNRA</b>	MAH UI	216345	Submitting VNRA super grouping may fail with generic error
<b>UC06 Submit VNRA</b>	MAH UI	211470	When a user saves a draft with 2 identical variation codes, one of them would not be present when the draft is retrieved
<b>UC07 Submit Volume of sales</b>	MAH UI	217701	Product with invalid data in deleted packages was missing in VoS Download packages file
<b>UC07 Submit Volume of sales</b>	MAH UI	166228	Submission of Volume of Sales failed with "query did not return a unique result: 2". Data Fix was applied.
<b>UC08 Update product</b>	ETL for CAP products	162162	Retrieve from UPD correct information on 2.5. Authorisation status (MA status) and 2.6. Date of authorisation status change for CAP products
<b>UC08 Update product</b>	API & NCA UI	204969	Data Fix applied to remove repeated English package descriptions on affected products
<b>UC09 Manage VNRA</b>	NCA UI	226213	Some VNRAAs already managed were appearing forever in PENDING status. Data fix was applied to the affected submissions.
<b>UC19 Nullify Product</b>	NCA UI	218958	It was not possible to nullify DCP/SRP/MRP CMS products
<b>UC21 Manage Notifications</b>	NCA UI & MAH UI	184984	Duplicated notifications are created for some VNRA actions
<b>UC27 View Volume of Sales</b>	NCA API	229681	User registered as UPD NCA API got error 403 when accessing Volume of Sales endpoint
<b>UC28 View VNRA</b>	NCA API	230897	User registered as UPD NCA API got error 403 when accessing VNRA endpoint

## 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
<b>UC03 Search</b>	NCA UI & MAH UI	226774	Substance which has current status in SMS is not available in Search via UPD UI	
<b>UC33 3<sup>rd</sup> Country Submission</b>	MAH UI	228439	Submission made for more than one product group incorrectly fails with ERR.25	
<b>UC35 Products available via API</b>	NCA API & MAH API	223598	Query parameter "_count" is not functioning in Public API endpoints	
<b>SIAMED to ETL PMS</b>	NCA UI & MAH UI	232043	CAP with all presentations suspended in SIAMED appears as "valid" in product card and cannot be opened in the UI	
<b>SIAMED to ETL PMS</b>	NCA UI & MAH UI	232033	After ADF run, CAP is missing Procedure number in UI that is in SIAMED	
<b>SIAMED to ETL PMS</b>	NCA UI & MAH UI	232744	CAP products present multiplied Manufactured Items after ETL run	
<b>SIAMED to ETL PMS</b>	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	

## 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	<p>RMS can create DCP products (data and documents)</p> <p>RMS can create MRP products (data and documents)</p> <p>RMS can create SRP products (data and documents)</p> <p>RMS and CMS can complement DCP/MRP/SRP products with national DCP/MRP/SRP data and documents</p> <p>RMS can update Common data for DCP/MRP/SRP products (data and documents)</p> <p>NCA can create and update NAP products (data and documents)</p> <p>NCA can create &amp; update Registered Homeopathic products (data and documents)</p> <p>NCA can create &amp; update Parallel Trade products (data and documents)</p> <p>NCA can create &amp; update Pet products (data and documents)</p> <p>NCA can group National Authorised products under an MRP following CMDv SPC harmonisation procedure (data and documents)</p> <p>NCA can Nullify product</p> <p>NCA can Search/view product (data and documents)</p> <p>NCA can Search, View and Approve/Reject VNRA submissions</p> <p>NCA can Approve/Reject VNRA submissions on behalf of other NCAs when a Supergouping VNRA submission applies</p> <p>NCA can View Volume of Sales data</p> <p>MAH can Search/view product (data and documents)</p> <p>General public can Search/view product (data)</p>
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<b>NCA UI</b> 	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

	<p>Search, View and Approve/Reject VNRA submissions</p> <p>NCA can Approve/Reject VNRA submissions on behalf of other NCAs when a Supergouping VNRA submission applies</p> <p>EMA and EC staff can update CAP products</p>
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<b>MAH UI</b> 	<p>Search/view/export products (data and documents)</p> <p>Notifications for Create and Update of products and Other Post-Authorisation Data actions</p> <p>Download, Submit, and View Volume of Sales information</p> <p>Submit VNRA and View VNRA submissions</p> <p>Submit Supergouping VNRA with the selection of the Foreseen Decision Maker that will approve/reject the whole submission on behalf of the others NCAs involved</p> <p>Submit updates for Marketing authorisation status</p> <p>Download and Submit updates for Availability status</p> <p>Submit Products Grouping</p> <p>Submit 3<sup>rd</sup> country product names</p>
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<b>MAH Validation UI</b> 	<p>Validate Volume of Sales submission file</p>
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<b>Authorisation for NCA &amp; MAH UI</b>  	<p>Integration with EMA Account Management (EAM) system for CA and Industry (MAH) roles</p> <p>CA users may search and view all Vet products</p> <p>MAH users may search and view only products under the responsibility of the organisations the user represents</p>
<b>Banner for UPD UI</b>  	<p>EMA can maintain messages to appear in banner of UPD UI</p>

### **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
<b>UC01 Create Product</b>	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 remains on the form	
<b>UC03 Search product</b>	NCA UI & MAH UI	83234	Search limitations due to FHIR limitation or MS FHIR limitation.	
<b>UC03 Search</b>	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.	
<b>UC03 Search</b>	NCA UI & MAH UI	221404	If a user proceeds to perform a search by location selecting an organisation with a merged location, search will silently fail	
<b>UC05 View product</b>	API & NCA UI & MAH UI	211624	PSMF information has been lost for some CAPs	
<b>UC05 View product</b>	NCA UI & MAH UI	207731	Product references are not being displayed properly for CAP products in the UPD UI	
<b>UC06 Submit VNRA</b>	MAH UI	211736	Retrieve VNRA does not retrieve all the fields filled while saving draft	
<b>UC06 Submit VNRA &amp; UC28 View VNRA</b>	MAH UI	189703	View VNRA submissions page fails to load results using the Submission Status filter = approved	
<b>UC07 Submit Volume of sales</b>	MAH UI	222086	Submission for non-EEA country on DCP product surrendered or revoked for over 2 years is allowed if it contains a nullified CMS	

<b>UC08 Update product</b>	NCA UI	205197	The Edit national data button is not available as expected in some DCP/MRP/SRP products.
<b>UC08 Update product</b>	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.
<b>UC08 Update product</b>	ETL for CAP products	223864	CAP products ended up with multiplied Target Species after ETL run
<b>UC08 Update product</b>	ETL for CAP products	215513	CAP contains packages with Marketing Authorization status = Withdrawn which is not a valid term for the field
<b>UC21 Manage Notifications</b>	NCA UI & MAH UI	218870	Incorrect information displayed on Notifications table for Record Status
<b>UC37 Automatic sending of notifications</b>	NCA & MAH UI	203369	Email notifications are not generated for some of the actions performed in UPD

## 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 <b>1.7.2443-14</b> A hot fix concerning volume of sales (bug 217701)
PROD	17 January 2025	17 January 2025	17 January 2025	Upgrade of UPD to <b>1.7.2443-14</b> A hot fix concerning volume of sales (bug 217701)
UAT	21 January 2025	21 January 2025	21 January 2025	Upgrade of UPD to <b>1.7.2443-15</b>
PROD	30 January 2025	30 January 2025	30 January 2025	Upgrade of UPD to <b>1.7.2443-15</b>
UAT	18 February 2025	18 February 2025	18 February 2025	<i>To be confirmed. Release containing only bug fixes.</i>
PROD	26 February 2025	26 February 2025	27 February 2025	<i>To be confirmed. Release containing only bug fixes.</i>
UAT	4 March 2025	4 March 2025	4 March 2025	<i>To be confirmed. Release containing only bug fixes.</i>
PROD	12 March 2025	12 March 2025	13 March 2025	<i>To be confirmed. Release containing only bug fixes.</i>