



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Union Product Database (UPD) release notes

Referring to version 1.7.2417

Release date: 24 April 2024

---

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)

**Send us a question** Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact) **Telephone** +31 (0)88 781 6000

An agency of the European Union



## Acronym key and glossary terms

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

**Pertaining to the structure of these release notes: they have been refined and simplified for enhanced accessibility to all users, and now comprise of 3 sections and 4 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 1.7.2413d , released on 15 March 2024)</b>	<b>45</b>
<b>Known Issues</b>	<b>52</b>
<b>Next Release expected date</b>	<b>6 June 2024</b> <i>(for further details please refer to Annex 3)</i>

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

- **Improved Functionality for UPD VNRA Submissions (MAHs & CAs):**
  - Enhanced VNRA List View: Easily visualise VNRA codes and all associated CMS countries within a single view.
- **Enriched Search Capabilities for UPD Users (MAHs & CAs - UI & API):**
  - Streamlined UI Search fields: Search fields are now reordered for a more intuitive experience.
  - Improved UI organisation: Frequently used search fields are placed at the top level for faster access (applicable functionalities only).
  - Searches with New Fields: The UI and API now include new search fields like "Substances", "Route of administration", "Availability status", "Manufacturer", "Manufacturing activity", "Product cross-reference type", "ATC vet code", "QPPV name", "QPPV location", "PSMF code", "PSMF location", "Procedure type", "Date from To", and "Submission comment" enabling more precise and targeted product searches.
- **New VNRA codes (C.10.d and C.10.e)** have been added to the RMS list of Variation Classification and are now available for UPD users to be selected in the VNRA drop-down lists in UPD.

**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 you may receive two type of error files:
    - In the first case, **no updates have been processed successfully.** This can be evidenced by the fact that last column in the error report only contains ER.36 and values of type 'N/A'. In this case, capture the ER.36 errors in an Excel or CSV file and submit it as a ticket to [EMA Service Now: https://support.ema.europa.eu/](https://support.ema.europa.eu/), and then **resubmit the part of the file containing values 'N/A'.**
    - In the second case, **some updates have been processed successfully.** This can be evidenced by the fact that last column in the error report

contains ER.36 values and values of the type 'Database updated - Submission 0000 - Product 00000'. In this case, just capture the ER.36 errors in an Excel or CSV file and submit it as a ticket to [EMA Service Now: https://support.ema.europa.eu/](https://support.ema.europa.eu/). No need to resubmit the part of the file containing values type '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:**

- EMA has changed the tool used for recording issues for UPD – from JIRA to Azure DevOps (ADO). ADO issue references are a number only without any prefix. The lists of issues within this document (Resolved, New & Outstanding) will continue to include the old JIRA Issue reference until such time as it is no longer deemed necessary.
- As a result of the change in the naming convention of the sprints from 2024, **after release of version 1.6.42, the naming of the releases will change!** For example the new format will be: 1.7.**2413**. **24** stands for the year; **1** stands for the quarter; **3** stands for the sprint when the release reached the SIT environment.
- Please note that **the Technical grouping functionality** for VNRAs involves a certain complexity. Therefore, all users are strongly advised to read the revised [CMDv Best Practice Guide for Variations Not Requiring Assessment](#) (EMA/CMDv/308754/2020 - Rev.5 or above), before they start using the VNRA Supergrouping and have seen the dedicated bite-size video available under 'video tutorials' at [EMA's UPD webpage](#).
- In relation to the updates of legacy data, for some of the products approved under DCP/MRP, it could be the case that only one RMS, and no CMS(s), is involved in the process. Given that the current implementation of the UPD does not support this scenario, the workaround for recording and updating these products will be as follows: I/the RMS will create the DCP adding as CMS a country belonging to EEA (this country should preferably have very few CMSs and no RMS products); II/ to prevent this product from being available to the general public and to the MAH, the CMS will not update the national part of the product, and finally III/ the CMS product will be nullified by the CMS once UPD allows having these products with only one RMS.

## Table of Contents

<b>1. Summary of issues .....</b>	<b>6</b>
1.1. Resolved issues.....	6
1.2. New issues since last release .....	10
<b>2. User support.....</b>	<b>12</b>
2.1. Available training materials and guidance.....	12
<b>3. References .....</b>	<b>12</b>
<b>Annex 1: Overview of functionality and business value.....</b>	<b>13</b>
<b>Annex 2: Known issues.....</b>	<b>17</b>
<b>Annex 3: Release Schedule.....</b>	<b>23</b>
<b>Annex 4: Guidance for API users .....</b>	<b>24</b>
4.1 UPD API to Maintain Products and Product Documents .....	24
4.1.1. Scope of this release for API .....	24
4.1.2. UPD API supported Product Service endpoints .....	25
4.1.3. API Manager product subscription .....	27
4.1.4. Apply Chapter 4 Legacy or Chapter 2 Validation rules.....	28
4.1.5. API EP309 Create, EP311 Update & Nullify product endpoints .....	28
4.1.6. API EP309 Create product example request bundles.....	35
4.1.7. API Manage document.....	45
4.2. UPD API for VNRA .....	50
4.2.1. Scope of this release for VNRA API .....	50
4.2.2. UPD API supported VNRA endpoints .....	50
4.3. UPD API for Volume of Sales Data .....	59
4.3.1. Scope of this release for Volume of Sales API.....	59
4.3.2. Endpoint, Authorisation header, Query Parameters, Pagination.....	59
4.3.3. User registration for Volume of Sales Data API .....	64

# 1. Summary of issues

## 1.1. Resolved issues

Use Case	Affects API and/or UI	Issue reference (ADO)	Resolved issues
<b>All UC</b>	NCA UI & MAH UI	83277	CAP products - some products with status of Withdrawn or Surrendered have been loaded into UPD from EMA's source system (SIAMED) with status of Valid. This ticket has been closed because the issue is considered obsolete.
<b>UC01 Create product</b>	API	144310	Validation endpoint for Create DCP was incorrectly giving a validation error related to missing Marketing authorisation number. When Create DCP payload was posted to the Create endpoint there was no validation error and products were created as expected.
<b>UC01 Create product</b>	NCA UI	166397	When retrieving a product that has documents on the creation of MRP or DCP, these were not visible on the create form.
<b>UC01 Create product</b>	API	83150	Create NAP via API: if payload contains attributes with CMS information this is accepted and the information stored. These attributes should either give validation error or be ignored as not applicable for this procedure type.
<b>UC01 Create product</b>	API & NCA UI	158033	When creating a product from an existing one, the user can select a product that is not under their responsibility, and that should not be allowed by the system. Now a user can select only products under their responsibility.
<b>UC01 Create product</b>	API & NCA UI	157738	Create NAP from existing product - import product does not clear cache. When creating a product from an existing one, if the user repeats the process selecting different products, the second time the system was displaying the information retrieved from the first product.

<b>UC01 Create product</b>	API & NCA UI	162071	When cancelling the creation of a product, confirmation modal was not being presented to the user. User was directed into the Home page.
<b>UC01 Create product</b>	NCA UI	82325	Each ingredient must be selected at least once in one of the manufactured items. This rule was not currently validated.
<b>UC01 Create product UC08 Update product</b>	API	160889	It was possible to add duplicate product name for same Country/Language during Create and update of NAP product.
<b>UC01 Create product</b>	API & NCA UI	82830	If there has been successful rollback in MDM of a transaction when creating a product, there was still a product created (with orphaned entries).
<b>UC03 Search product</b>	NCA UI & MAH UI	144929	New products were not always included in search results immediately and sometimes had to wait up to 15 minutes after receiving Notification.
<b>UC03 Search product</b>	API & NCA UI & MAH UI	82482	Not able to search using marketing authorisation number if has been specified at package level. Affected UI and API users.
<b>UC05 View product</b>	NCA UI & MAH UI	165520	Navigating from older versions of the product to most recent, QPPV information was incorrectly displayed.
<b>UC06 Submit VNRA</b>	MAH UI	155448	When submitting a VNRA with different values defined at product level, the input value at VNRA level is not updated. The same value is presented regardless of changes done on the product card. This was not specified, this behaviour was accepted and remains as is.
<b>UC06 Submit VNRA</b>	MAH UI	104507	An intermittent issue affecting some users when attempting to Submit VNRA. Error message advises of VNRA Creation error and that VNeedS file could not be uploaded.
<b>UC07 Submit Volume of Sales</b>	MAH UI	155860	Users experienced frequent timeouts when trying to download list of packages.
<b>UC08 Update product</b>	API & NCA UI	92687	Able to submit update but does not complete successfully where product has Data Quality issue. OperationOutcome result displays ERR-1003. This is due to incomplete and orphan records for product names in the underpinning PMS MDM database. Affects about 56 products. This ticket has been closed because the issue is considered obsolete.
<b>UC08 Update product</b>	API & NCA UI	83276	Update of product was leaving product in Pending state and this blocked subsequent updates.
<b>UC08 Update product</b>	API & NCA UI	100337	Update of product has not completed successfully and Operation Outcome state remains In-Progress. The error seen in logs is

			OSB-382510. Issue closed following MDM decoupling from FHIR that mitigated this problem.
<b>UC08 Update product</b>	NCA UI	82627	Add button in Package medicinal product section needs to have more meaningful caption. This ticket has been closed because the issue is considered obsolete.
<b>UC08 Update product</b>	NCA UI	83206	The edit screen freezes and does not successfully load if the selected product has an invalid LOC-ID for the Product owner. This situation was possible in a previous release due to a bug. This ticket has been closed because the issue is considered obsolete.
<b>UC08 Update product</b>	API & NCA UI	83205	Update product - error regarding buffer space for connections occurs on server but flag is not set to error preventing further updates and advising user that existing transaction needs to be completed before they submit another. This ticket has been closed because the issue is considered obsolete.
<b>UC08 Update product</b>	API	82865	Update Common Data DCP/MRP/SRP by API only - not all expected Validation errors were displayed if Mandatory attributes were not populated in POST for Update Common.
<b>UC08 Update product</b>	API	82436	Change to Responsible authority or Product Owner was not saved if existing inline attribute id was not included in the request body.
<b>UC08 Update product</b>	NCA UI	167180	RMS National data update raised an error if a package has been deleted on a previous Common Update.
<b>UC08 Update product</b>	API & NCA UI	161214	Update button was not disabled when mandatory field Authorized Pharmaceutical Form is removed.
<b>UC08 Update product</b>	NCA UI	166257	When the RMS deletes and adds a new national document, the common documents were removed from the CMS.
<b>UC09 Approve/Reject VNRA</b>	NCA UI	151292	Automated C1/C5/C6: Where MAH has populated new values at product level only, left fields at VNRA level empty and then the VNRA was submitted: the fields on the VNRA level were populated with the values of the first product card.
<b>UC09 Approve/Reject VNRA</b>	NCA UI	169536	In the VNRA form for approval/rejection of VNRA A.4, the label 'To/Proposed values' displayed as well incorrectly the RMS code of the VNRA that has to be treated.



<b>UC18 Manage document</b>	API	83213	Add or Update document via API: if payload is invalid and does not conform to the JSON/XML format (for example there is an extra comma or other formatting control after an attribute) this returns a Response of 500 Internal Server error. Instead it should return Response of 400 Bad Request with details of the error. This ticket has been closed because the issue is considered obsolete.
<b>UC19 Nullify product</b>	NCA UI	82796	When a product is nullified, the confirmation message did not include the Permanent Identifier.
<b>UC19 Nullify product</b>	API	83064	Any procedure type: After product has been nullified subsequent update to the product was accepted and processed, instead of giving a Validation error
<b>UC21 Manage Notifications</b>	NCA UI	159088	VNRA Notifications & VNRA View – An NCA User without permission to see VNRA had available the link to access the submission and was advised to try again later on error raised. Now a more informative error message is displayed.
<b>UC21 Manage Notifications</b>	NCA UI & MAH UI	161905	Back to search results button cleared applied filter options.
<b>UC21 Manage Notifications</b>	NCA UI & MAH UI	131608	Responsible Authority was displaying the Organisation full name in Notification search results. Now correctly displays only the Acronym.
<b>UC21 Manage Notifications</b>	NCA UI & MAH UI	83114	For CAP products, no Notification was generated on successful creation or update of products from SIAMED.
<b>UC21 Manage Notifications</b>	NCA UI & MAH UI	167823	Notification Action field was wrongly populated with " <i>UPDATE, Upload Document</i> " for Nullify, Marketing status update, Transfer of ownership and Availability status actions
<b>UC21 Manage Notifications</b>	NCA UI & MAH UI	167943	Notification was wrongly displaying as " <i>UPDATE, Upload Document</i> " for Update Product.
<b>UC25 Update Availability status</b>	MAH UI	82625	Not able to select all products to download in the one csv file if product search results were over two or more pages.
<b>UC27 View Volume of Sales</b>	NCA UI & MAH UI	157903	Reset button was not working as expected, not all search fields were cleared, and result table defaults to "No results found"
<b>UC28 View VNRA</b>	NCA UI	154201	Approve/Reject VNRA: When CMS enters decision for their product and before they submit, the summary table was incorrectly updating the user name and decision date for some other CMS product as well as the CMS product; or was only populating the Decision maker field on the CMS product.

<b>UC28 View VNRA</b>	API & NCA UI	162898	NCA - DCP/SRP - The Decision Maker, RMS and CMS checkboxes view was working only when CMS option was selected (should be OR instead of AND logic)
<b>UC28 View VNRA</b>	NCA UI & MAH UI	162882	All queries on VNRA search took the value of Submission Status = PENDING
<b>UC33 Manage Third Country Product Names</b>	MAH UI	129500	3 <sup>rd</sup> Country Data-Industry Search/View User was not able to view and access download 3 <sup>rd</sup> country data file and view submission of 3 <sup>rd</sup> country data Menu
<b>UC34 Bulk Upload for Documents</b>	NCA UI	140303	Bulk upload was failing for veterinary homeopathic medicinal products or VMPs that are intended for animals exclusively kept as pets. However, this functionality cannot be used on those products. Ticket closed with no changes in the system.

## 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>UC01 Create product</b>	NCA UI	171860	When creating a product with multiple ingredients, the unit of presentation dropdown does not present any options for the subsequent ingredients	User can switch between units of measurement and units of presentation to enable the dropdown again
<b>UC03 Search product</b>	NCA UI & MAH UI	173475	Marketing Authorization Number is not displayed in the search results view, if defined at package level. Note: even though this issue has been in UPD since the first implementation, it has just now been well documented in a ticket that is expected to be resolved in the next version of UPD.	
<b>UC03 Search product</b>	NCA UI & MAH UI	162057	The value for the attribute strength will appear as 'N/A' in the search results table for the cases where the strength of an ingredient was provided in terms of concentration.	

<b>UC03 Search product</b>	MAH UI	107914	After organization merge, MAH cannot find their products in General search, VNRA submission screen or VoS csv (UPD, VNRA or OPAD databases). Note: even though this issue has been in UPD and known for a while, but it has not been well documented in a ticket. The issue is expected to be resolved in the near future.
<b>UC05 View product</b>	NCA UI & MAH UI	173232	In Package section - (5.6.2.) Manufactured item quantity is missing the Units of measurement in the view
<b>UC08 Update product</b>	NCA API	172176	It is possible for a user to remove common data in a national update via API
<b>UC21 Manage Notifications</b>	NCA UI & MAH UI	171293	Search by product owner is returning wrong results
<b>UC21 Manage Notifications</b>	NCA UI & MAH UI	175866	Notifications for failed VNRA submissions are not generated
<b>UC25 Update Availability status</b>	MAH UI	153934	When Availability Status is submitted by MAHs, if an ER.36 is thrown by the system (see Vet EUIG-Chapter 7), the description of the error provided in the csv file does not comply with the format expected, even though is correct
<b>UC25 Update Availability status</b>	MAH UI	177951	Submissions of Availability Status fails for some CAP products with Error 36
<b>UC25 Update Availability status</b>	MAH UI	161155	A submission of Availability Status for a DCP/MRP/SRP product where a CMS was removed and then re-added will fail as invalid
<b>UC28 View VNRA</b>	NCA UI & MAH UI	175982	VNRA PDF information missing for the new codes: C.10.d) and C.10.e)

## 2. User support

API and UI users may seek support by contacting the User Support via [EMA Service Now: https://support.ema.europa.eu/](https://support.ema.europa.eu/).

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. [Registration Process for UPD \(See under section 'How to register'\)](#) (PDF document)
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

## Annex 1: Overview of functionality and business value


### Functionalities provided in this release


<b>API</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/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 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

**NCA UI**



- RMS can create DCP products (data and documents)
- RMS can create MRP products (data and documents)
- RMS can create SRP 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 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

<b>MAH UI</b> 	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 <sup>rd</sup> country product names

<b>MAH Validation UI</b> 	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:

- None

MAH UI:

- None



## 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>All UC</b>	API & NCA UI & MAH UI	143996	CAP: there are now two products for Exzolt and expected there just to be one.	
<b>All UC</b>	API & NCA UI	92757	OMS to UPD updates: New or Updated Organisations and Locations from OMS are not available in UPD.	
<b>API Manager</b>	API	82994	API Manager has duplicate Products listed for "UPD API" (v1 and v3 versions of EP); and exposes many EP not intended to be used by API NCA Users. There should only be the one product at this time with v1 Endpoints.	
<b>Data fix</b>	NCA UI & MAH UI	83291	Data Fix Parallel Trade products: where Source Member State product had two or more Ingredients, the first Ingredient from that product was duplicated in the new Parallel trade product. This was due to bug UPD-13162. EMA to query existing Parallel Trade products to identify products that were affected by this issue and then assess how to correct.	
<b>UC01 Create product</b>	API	168950	Create Homeopathic Product via API: if payload contains attributes with CMS information this is accepted and the information stored. These attributes should either give validation error or be ignored as not applicable for this procedure type.	
<b>UC01 Create product</b>	API	83042	Create parallel trade product via API: the GET OperationOutcome response is populating in the DCP	

			format and it was expected would use same pattern as NAP.
<b>UC01 Create product</b>	NCA UI	92816	Free text strength values are not displayed when selecting Ingredients to link in Pharmaceutical product and Manufactured item sections.
<b>UC01 Create product</b>	API	82249	Validation in all resources of URN UUID for full URL attribute: letters allowed are only a to f to form the hexadecimal set from 0 to f pattern of 8-4-4-4-12 The post may not be rejected or may not give an error message that clearly identifies this as being the issue.
<b>UC01 Create product UC08 Update product</b>	NCA UI & API	154083	(Marketing authorisation application) Legal basis: Vet EU IG Chapter 2 section 1.7.1 : some terms from the RMS list are missing.
<b>UC01 Create product UC08 Update product</b>	API & NCA UI	147296	CA should only be able to add Availability status entry for the same country as the Authorisation country of their product.
<b>UC01 Create product UC08 Update product</b>	NCA UI	83327	If product contains two or more Pharmaceutical products, the labels are not properly formatted on the View product screen. The case where two or more Pharmaceutical products should link to the same Ingredient to be considered and review documentation. An Ingredient may only be linked to one Pharmaceutical product in this release.
<b>UC01 Create product UC08 Update product</b>	API & NCA UI	82761	The Manufactured Item Quantity will be truncated to 2 decimal places. It should be possible to enter greater precision if required of up to 8 decimal places.
<b>UC01 Create product UC08 Update product</b>	API & NCA UI	82570	UC01 Create & UC08 Update Product - POST should be valid where Reference Strength is populated but there is no Substance Strength; or if specify Substance Strength a Reference Substance and no Reference Substance Strength. Instead, there is a validation error and Substance Strength must always be specified.

<b>UC01 Create product UC08 Update product</b>	NCA UI	82452	UC01 UC08 All procedure types - leading and trailing spaces in free-text fields should be removed by the system before validation.	
<b>UC03 Search product</b>	NCA UI & MAH UI	152113	After updating a product and have received Notification, the Search results screen and the Search screen product card may take many minutes before it reflects the updates made to a product. The View product screen does show the updated values.	
<b>UC03 Search product</b>	API	123745	API user not able to search and view products and receives 403 invalid query and 403 Product is NOT in user affiliations response.	
<b>UC03 Search product</b>	API	83332	API user only: A search of products using two parameters of _lastUpdated: the second parameter is ignored and only the first is applied.	
<b>UC03 Search product</b>	NCA UI & MAH UI	83234	Search limitations due to FHIR limitation or MS FHIR limitation.	
<b>UC05 View product</b>	NCA UI & MAH UI	83259	When View product QPPV displays as N/A even although the product does have a LOC-ID populated. This affects only some products and may be due to some Data Quality issue in the affected products.	
<b>UC06 Submit VNRA</b>	MAH UI	83112	If submit an automated variation that will update National Data, for example A.1.a to update MAH, for products under DCP/MRP/SRP where National Data has not been populated: the submission fails with a Validation error that the Marketing Authorisation Number has not been populated. The MAH should be able to submit a variation even if the RMS/CMS has not populated national data. As a workaround for this release the NCA will need to populate national data before the MAH can submit the VNRA.	As a workaround the NCA will need to populate national data before the MAH can submit the VNRA.
<b>UC06 Submit VNRA</b>	MAH UI	83259	When View product QPPV displays as N/A even although the product does have a LOC-ID populated. This affects only some products and may be due to some Data Quality issue in the affected products.	

<b>UC06 Submit VNRA</b>	MAH UI	161519	Foreseen Decision Maker dropdown list is not displaying all countries (options).	User should type in the desired country, matching options to the user input will then be presented, even if not initially visible.
<b>UC07 – Download Packages and Submission of Volume Sales via Form</b>	MAH UI	158743	Surrendered packages are included in the downloaded VoS csv file.	
<b>UC08 Update product</b>	API & NCA UI	79977	All procedure types: if product does not contain any existing value for Responsible Authority or Product Owner, when an update is submitted the new LOC-ID is not saved.	
<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>	API	82437	Change to procedure number not saved if existing inline attribute id is not included in the request body.	
<b>UC08 Update product</b>	NCA UI & MAH UI	83142	For CAP products: there are examples where two products have been created and expected just one. This may occur when a new package has been added or package information has been updated. The cause of the issue will be resolved and affected products corrected.	
<b>UC08 Update product</b>	API & NCA UI	109885	Products that had previously been affected by Bug 89511 (replacing Pharmaceutical product removed the Ingredients) cannot be further updated. EMA to investigate whether it is possible for NCA to update products to correct this issue so that products can be updated.	
<b>UC08 Update product</b>	API	82569	UC08 Update SC2 NAP - should reject update with validation error message if MedicinalProductDefinition.id is not populated.	
<b>UC08 Update product</b>	API & NCA UI	144350	Update Common Data DCP/MRP/SRP to remove the last remaining country from the list of Concerned MS fails	

			with Validation error when submitting via NCA UI. There is no validation error if submitted via API. Acceptance criteria and validation required to be reviewed so that API and NCA UI are aligned.	
<b>UC08 Update product</b>	API & NCA UI	83203	Update of product fails with error in GET OperationOutcome of ERR-1003. An error from previous failed update with an incorrect payload prevents a subsequent update.	
<b>UC09 Approve/Reject VNRA</b>	NCA UI	168118	Decision table is not updated if information is added at VNRA level.	
<b>UC09 Approve/Reject VNRA</b>	NCA UI	84163	CMS NCA is able to select Approve/Reject checkbox when viewing a VNRA, although the Submit button correctly remains disabled.	
<b>UC19 Nullify product</b>	API	82811	API Manager Nullification endpoint: when Try It option is selected the Content-Type request header defaults to application/json and it should be application/fhir+json. Using the default value will give an error.	
<b>UC19 Nullify product</b>	API	132758	Nullify Product via API - OperationOutcome ID now has suffix of "-Patch" which is not expected and is potentially a breaking change for API users. When submitting GET OperationOutcome/ID the response code is 499 Client Closed Request. Therefore it is not possible to nullify a product via the API in this release and NCA UI will need to be used.	In order to nullify a product, please use the Web User Interface.
<b>UC21 Manage Notifications</b>	NCA UI & MAH UI	83254	Date format inconsistent between different actions.	
<b>UC25 - Update availability status and placing on the market via UI</b>	MAH UI	160241	Surrendered packages are included in the downloaded AVS csv file.	
<b>UC28 View VNRA</b>	NCA UI	83344	For a VNRA submitted for a product where the Responsible Authority is not correctly populated (for example may have incorrectly been populated with MAH LOC-ID): an NCA User for that Authorisation country is	

			not able to view the VNRA Submission even after the Responsible Authority has been corrected in the product(s) included in the submission.
<b>UC31 Manage VNRA Submissions via API</b>	API	142804	All of the endpoints for VNRA API <a href="https://spor.azure-api.net/upd/api/vnra/v3/vnra-submission">https://spor.azure-api.net/upd/api/vnra/v3/vnra-submission</a> fail with 404 Resource Not Found.
<b>UC33 Manage Third Country Product Names</b>	MAH UI	159277	Submission of Third country data of the DCP/SRP Product will fail if one of the CMS products is nullified or has a CMS which has marketing status set to suspended.

### Annex 3: Release Schedule

Environment	Closed from	Closed to	Expected to be open	Description
PROD	23 April 2024	23 April 2024	24 April 2024	Upgrade of UPD to <b>1.7.2417</b>
UAT	28 May 2024	28 May 2024	29 May 2024	Upgrade of UPD to <b>1.7.2423</b>
PROD	5 June 2024	5 June 2024	6 June 2024	Upgrade of UPD to <b>1.7.2423</b>

## **Annex 4: Guidance for API users**

### **4.1 UPD API to Maintain Products and Product Documents**

#### **4.1.1. Scope of this release for API**

- Create DCP based on Chapter 4 Legacy or Chapter 2 rules
- Create MRP based on Chapter 4 Legacy or Chapter 2 rules
- Create SRP based on Chapter 4 Legacy or Chapter 2 rules
- RMS can update Common Data for products under DCP/MRP/SRP (data and documents)
- RMS and CMS can complement DCP/MRP/SRP product with national data
- Create NP & Registered Homeopathic based on Chapter 4 Legacy or Chapter 2 rules
- Update NP & Registered Homeopathic product based on Chapter 4 Legacy or Chapter 2 rules
  - Edit existing, add new, or delete an existing non-mandatory attribute
  - Add new resources. For example: add an Ingredient or add another Package
  - Delete an existing non-mandatory resource. For example: remove an Ingredient
- Create & Update Parallel trade based on Chapter 4 Legacy or Chapter 2 rules
- Create & Update Pet products based on Chapter 4 Legacy or Chapter 2 rules
- Search and retrieve products
- Nullify product
- Upload, search, retrieve, and update Documents (for product under any procedure type)



#### 4.1.2. UPD API supported Product Service endpoints

EP302 Search Product Part and EP305 Get Product Part endpoints are no longer available.

SPOR API Specification v2	API Manager
EP301 Search Product	<b>GET</b> MedicinalProductDefinition - Search for a MedicinalProductDefinition resource or resources
EP303 Get Product	<b>GET</b> MedicinalProductDefinition - Get a MedicinalProductDefinition ID
EP304 Get Product Full	<b>GET</b> Everything Current - Get \$everything for a MedicinalProductDefinition ID
EP306 Get Product Version	<b>GET</b> MedicinalProductDefinition Version - Get version of MedicinalProductDefinition ID
EP306a Get Product Version Full	<b>GET</b> Everything Versioned - Get \$everything for a version of MedicinalProductDefinition ID
EP307 Get Product Versions	<b>GET</b> MedicinalProductDefinition - Get history of MedicinalProductDefinition ID

SPOR API Specification v2	API Manager
EP309 Create Product	<p>NAP: <b>POST</b> Bundle - Create/Update resources in the bundle</p> <p>DCP: <b>POST</b> dcp-bundle - Submit a Create DCP payload</p> <p>MRP: <b>POST</b> mrp_bundle – Submit a Create MRP payload</p> <p>SRP: <b>POST</b> srp_bundle – Submit a Create SRP payload</p> <p>Registered homeopathic: <b>POST</b> Bundle - Create/Update resources in the bundle</p> <p>Parallel trade: <b>POST</b> ptp-bundle - Create/Update resources in the bundle</p> <p>Pet: <b>POST</b> pet-bundle - Create/Update resources in the bundle</p> <p>Refer to <a href="#">4.1.5.2. Create and Update endpoints</a></p>
<p>EP309 Create Product EP311 Update Product</p> <p>for use with any Create or Update</p>	<p><b>GET</b> OperationOutcome - Get a resource by ID</p> <p>Note: use this to query the outcome of Create or Update when response to Post is "202 Accepted"</p>
EP311 Update Product	<p>NAP: <b>POST</b> Bundle - Create/Update resources in the bundle</p> <p>Update National Data: <b>POST</b> /upd/api/v1/national-data-bundle/ - Submit an Update National Data payload for DCP/MRP/SRP products</p> <p>Update Common Data: <b>POST</b> /upd/api/v1/common-data-bundle/ - Submit an Update Common Data payload for DCP/MRP/SRP products</p>

SPOR API Specification v2	API Manager
EP318 Validate Product	<p><b>POST</b> Validate Bundle – To validate a bundle and the resources in the bundle</p> <p>Used for all procedure types; for both chapter 2 or legacy validation rules; and for both Create &amp; Update</p>
EP UC19 Nullify Product	<p><b>POST</b> /upd/api/v1/vmp-nullification/</p>
EP401 Search document	<p><b>GET</b> DocumentReference - Search for DocumentReference</p> <p>No</p>
EP402 Get/Retrieve document by Id	<p><b>GET</b> DocumentReference - Get a DocumentReference by Id</p> <p>Note</p>
EP403 Create document	<p><b>POST</b> DocumentReference - Create a DocumentReference</p>
EP404 Update document by Id	<p><b>PUT</b> DocumentReference - Update a DocumentReference</p> <p>Please note: API Manager method shows as PUT however please use <b>POST</b> with request header is_update=true.</p>

### 4.1.3. API Manager product subscription

Any new API users should register a user and subscribe to the product [Authorised - UPD API - Milestone 3 \(UPD 1.03\)](#) in API Manager.

The credentials for this new product can be used for all supported endpoints as listed in section 4.1.2. UPD API supported Product Service endpoints Refer to the document [UPD 01.03 Registration Process for UPD API in Production/UAT](#) listed in the [References](#) section.

#### 4.1.4. Apply Chapter 4 Legacy or Chapter 2 Validation rules

When submitting a POST for EP309 Create Product or EP311 Update Product, there is a Request header that is used to specify which validation rules are to be applied.

Please note that each type of update may use a different value for the Key.

Value	Validation rules applied
<i>Request header not included</i>	Vet EUIG Chapter 2
false	Vet EUIG Chapter 2
true	Vet EUIG Chapter 4 Legacy

#### 4.1.5. API EP309 Create, EP311 Update & Nullify product endpoints

##### 4.1.5.1. Request headers applicable for all Create, Update & Nullify POST

When submitting a POST for EP309 Create Product or EP311 Update or Nullify Product, the same Request headers are used for all endpoints that specify the format for the request and response.

Request Header: Key	Values	Purpose
Content-type	application/fhir+xml application/fhir+json	Specifies the format of the request body that is being submitted

Request Header: Key	Values	Purpose
Accept	application/fhir+xml application/fhir+json	Specifies the format for the response body of the POST if there are any validation or other errors

#### 4.1.5.2. Create and Update endpoints

- As specified in SPOR API v2 Specification section 6.4.12
- Refer to API Manager developer portal
- The Request body is a Bundle (type=transaction) of MedicinalProductDefinition and other resources
- For all the Update endpoints, the Bundle should be based on all data in the existing product. This includes Update Common Data DCP/MRP/SRP where all existing National data should also be included in the bundle even although it is only Common data that will be updated
- Create MRP is an update to an existing NP product. The Bundle should be based on all national data in that product, with the additional Common data added, and the procedure type updated to MRP
- Create SRP is an update to an existing DCP/MRP/SRP product. The Bundle should be based on all national data in that product, with the additional Common data added
- Please refer to the example bundles and recommended approach sections

Type and Procedure	POST Endpoint	Request header Key for validation rules	Additional Request header
Create NP	/pms/api/v2	chapter4	
Update NP	/pms/api/v2	chapter4	is update = true
Create DCP	/upd/api/v1/dcp-bundle/	chapter4	

Type and Procedure	POST Endpoint	Request header Key for validation rules	Additional Request header
Update Common Data DCP/MRP/SRP	/upd/api/v1/common-data-bundle/	chapter4	is update = true
Update National Data DCP/MRP/SRP	/upd/api/v1/national-data-bundle/	chapter4	is update = true
Create MRP	/upd/api/v1/mrp-bundle/	chapter4	
Create SRP	/upd/api/v1/srp-bundle/	chapter4	
Create Registered Homeopathic	/pms/api/v2	homeopathicschapter2 = true OR homeopathicschapter4 = true	
Update Registered Homeopathic	/pms/api/v2	homeopathicschapter2 = true OR homeopathicschapter4 = true	is update = true
Create Parallel Trade	/upd/api/v1/ptp-bundle/	parallelchapter2 = true OR	

Type and Procedure	POST Endpoint	Request header Key for validation rules	Additional Request header
		parallelchapter4 - true	
Update Parallel Trade	/upd/api/v1/ptp-bundle/	parallelchapter2 = true OR parallelchapter4 - true	is update = true
Create Pet	/upd/api/v1/pet-bundle/	chapter4	
Update Pet	/upd/api/v1/pet-bundle/	chapter4	is update = true
To Validate any Create or Update bundle	/pms/api/v2/\$Validate	Use appropriate request header to apply validation rules based on the procedure type	Use is update = true when validating the following bundles: <ul style="list-style-type: none"> <li>• Update NP</li> <li>• Update Registered Homeopathic</li> <li>• Update Parallel Trade</li> <li>• Update Pet</li> <li>• Update Common Data DCP/MRP/SRP</li> <li>• Update National Data DCP/MRP/SRP</li> <li>• Create MRP</li> <li>• Create SRP</li> </ul>

### 4.1.5.3. Nullify endpoint

Type and Procedure	POST Endpoint	Request header Key for validation rules	Additional Request header
Nullify product	/upd/api/v1/vmp-nullification/	not required	

Content-Type	Request body
JSON	<pre>{   "permanentId": "Permanent Identifier" }</pre>
	<p>For example:</p> <pre>{   "permanentId": "600011984989" }</pre>
XML	<pre>&lt;root&gt;&lt;permanentId&gt; Permanent Identifier &lt;/permanentId&gt;&lt;/root&gt;</pre>
	<p>For example:</p> <pre>&lt;root&gt;&lt;permanentId&gt;600011353107&lt;/permanentId&gt;&lt;/root&gt;</pre>



Response to POST:

- Response code 202 Accepted indicates the nullification has been successfully submitted
- Response code 400 Bad request indicates there is a validation error and the Response body will contain error message. For example: "Resource type 'Bundle' with id '600011984989' couldn't be found."

#### **4.1.5.4. Response to POST for Create, Update or Nullify and use of Get OperationOutcome**

When POST for Create, Update or Nullify is successful and it cannot be honoured timely it is automatically queued. The Response header **Content-Location** contains an id that can be used to obtain the status of the operation.

Content-Location has two parts: **post-operation/operation-outcome-id**

The status of the operation can be consulted, it is one of:

- QUEUED
- IN\_PROGRESS
- MSG\_CREATED
- ERROR

Upon successful creation, update or nullification of the medicinal product, the operation outcome will show a status of MSG\_CREATED along with the unique Permanent identifier(s) of the product(s).

The endpoint GET OperationOutcome/**operation-outcome-id** is used to query the status of the operation and this should be repeated until it is successful with MSG\_CREATED or has ERROR.

The format of the Content-Location is showing in the following table, and the response value can be used for Get OperationOutcome.

<b>POST</b>	<b>Content Location example showing format of the operation-outcome-id</b>
Create NP	OperationOutcome/baab996e-8e58-4825-89d1-90a8f30458db
Update NP	OperationOutcome/c2e2275c-141c-4631-a42e-045726d95adb

POST	Content Location example showing format of the operation-outcome-id
Create DCP	Release 1.6.16 and prior: dcp-operation-outcome/ddb9f96b-10f5-4428-9503-170feb5c58db-DCP Release 1.6.20 is now: OperationOutcome/ddb9f96b-10f5-4428-9503-170feb5c58db-DCP
Update Common Data DCP/MRP/SRP	Release 1.6.16 and prior: common-data-operation-outcome/f4d76850-358a-48f1-a9bb-3fb4b1615bdb-CD Release 1.6.20 is now: OperationOutcome/ f4d76850-358a-48f1-a9bb-3fb4b1615bdb-CD
Update National Data DCP/MRP/SRP	Release 1.6.16 and prior: national-data-operation-outcome/b371f2db-dd29-4c60-b6ab-63b0abf95bdb-ND Release 1.6.20 is now: OperationOutcome/ b371f2db-dd29-4c60-b6ab-63b0abf95bdb-ND
Create MRP	Release 1.6.16 and prior: mrp-operation-outcome/2f89089c-3ad7-4427-9311-7ea491395ddb-MRP Release 1.6.20 is now: OperationOutcome/2f89089c-3ad7-4427-9311-7ea491395ddb-MRP
Create SRP	Release 1.6.16 and prior: srp-operation-outcome/cf7af9a9-b34d-4db9-a551-89d40c077306-SRP Release 1.6.20 is now: OperationOutcome/cf7af9a9-b34d-4db9-a551-89d40c077306-SRP
Create & Update Registered Homeopathic	OperationOutcome/a588416b-7a0b-40b1-8d03-a88ea4668f8f
Create & Update Parallel Trade	OperationOutcome/04b5bc00-16f4-4ea0-b33e-1a95029d8f8f-PTP
Create & Update Pet	OperationOutcome/2664fdf2-6aef-4540-8254-b6df6451b8af-PET

#### **4.1.5.5. Creating products for DCP or Update Common Data if national data is provided**

When the RMS submits a request bundle to create DCP products, they should only provide Common Data. Refer to Annex 1 of Vet EU IG Chapter 2.

If any National data attributes are populated in the create request bundle this does not result in a validation error. The products for the RMS and each CMS will be created, and any national data entered will be silently ignored.

The same applies for Update Common Data. The RMS should populate the complete Update bundle for their RMS product containing all existing Common and National Data. Only Common Data will be updated to the RMS product and the CMS products under the Product identifier.

#### 4.1.5.6. Key changes in valid request bundle for create and update

Attribute	Change
None	

#### 4.1.6. API EP309 Create product example request bundles

Examples for EP309 Create Product for NP and DCP. Please note that the purpose of these examples is as illustration of the FHIR attributes to be populated. The value for MedicinalProductDefinition as a cross referenced product is a valid permanent identifier from UAT.

**Please note: example files still to be updated and re-released taking into account that pack size is now mandatory.**

Procedure type	Validation rules	Example file
DCP	Chapter 2	UPD_1.6.5-6_DCP_Chpt2_C2_Mandatory_VetIG.JSON
		UPD_1.6.5-6_DCP_Chpt2_C2_Mandatory_VetIG.XML
		UPD_1.6.5-6_DCP_Chpt2_C110_VetEUIG_AllData.JSON
		UPD_1.6.5-6_DCP_Chpt2_C110_VetEUIG_AllData.XML
DCP	Chapter 4 Legacy	UPD_1.6.5-6_DCP_Legacy_C2_Mandatory_VetIG.JSON
		UPD_1.6.5-6_DCP_Legacy_C2_Mandatory_VetIG.XML

Procedure type	Validation rules	Example file
		UPD_1.6.5-6_DCP_Legacy_C110_VetEUIG_AllData.JSON UPD_1.6.5-6_DCP_Legacy_C110_VetEUIG_AllData.XML
NAP	Chapter 2	2.2 Authorisation/registration/entitlement number is specified at Product level UPD_1.6.1-4_NAP_Chpt2_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel.JSON UPD_1.6.1-4_NAP_Chpt2_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel.XML UPD_1.5.1-0_NAP_Chpt2_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel.JSON UPD_1.5.1-0_NAP_Chpt2_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel.XML <hr/> 5.5 Marketing authorisation (package level) UPD_1.5.1-0_NAP_Chpt2_C111_VetEUIG_AllData_MANumber_AtPackageLevel.JSON This example contains 2 packages. There are 3 RegulatedAuthorization resources: <ul style="list-style-type: none"> <li>• One with subject reference = MedicinalProductDefinition resource; populated with attributes from Section 2 (Vet EUIG Chapter 2), excluding the marketing authorisation number</li> <li>• One with subject reference = 1<sup>st</sup> PackagedProductDefinition resource; populated with the Marketing authorisation number for Package 1</li> <li>• One with subject reference = 2nd PackagedProductDefinition resource; populate with the Marketing authorisation number for Package 2</li> </ul>
NAP	Chapter 4 Legacy	UPD_1.6.1-4_NAP_Legacy_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel.JSON UPD_1.6.1-4_NAP_Legacy_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel.XML

Procedure type	Validation rules	Example file
		UPD_1.5.1-0_NAP_Legacy_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel.JSON UPD_1.5.1-0_NAP_Legacy_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel.XML
NAP	Chapter 4 Legacy	UPD_1.5.1-0_NAP_Legacy_Cx_ManyAttributesAndResources_MANumberAtMedicinalProductLevel.XML  This example contains: <ul style="list-style-type: none"> <li>• 2 or more values for those attributes that are repeatable. For example, Product name, ATC Vet Code, Manufacturing Business Operation</li> <li>• 2 Packages (PackagedProductDefinition)</li> <li>• 2 Manufactured Items (ManufacturedItemDefinition)</li> <li>• 3 Ingredients (Ingredient)</li> </ul>
NAP	Chapter 2	UPD_1.5.1-0_NAP_Chpt2_ExampleForStrengthAsPresentationOrConcentration.XML  This example contains Ingredient resources that illustrate how to specify Substance and Reference Strength as either Presentation or Concentration.
NAP	Chapter 2	NAP_Chpt2_Create_BR-178_StrengthFreeTextExample_1.6.22-6.XML  F178: This example contains Ingredient resources that illustrate how to specify free-text substance or reference substance strength
Registered Homeopathic	Chapter 2	UPD_1.6.1-4_HOM_Chpt2_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel.JSON UPD_1.6.1-4_HOM_Chpt2_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel.JSON
Parallel Trade	Chapter 2	UPD_1.6.8-4_PAT_Chpt2_C2_Mandatory_VetIGI.JSON UPD_1.6.8-4_PAT_Chpt2_C110_VetEUIG_AllData.JSON

Procedure type	Validation rules	Example file
Pet	Chapter 2	PET_Chpt2_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel_1.6.34-5.json PET_Chpt2_C110_AllData_VetIG_MANumber_AtMedicinalProductLevel_1.6.34-5.json

#### 4.1.6.1. Recommended approach to prepare update request bundle

The recommended approach for preparing a request bundle to update a product (any procedure type) is:

- Use the response from EP304 GET MedicinalProductDefinition/{permanent identifier}/\$everything as a starting point
- Add Bundle.entry.request for each resource and update Bundle.type

Attribute	Change
Bundle.type	Must be "transaction"
For every Bundle.entry	<p>Bundle.entry.request must also be populated.</p> <p>Bundle.entry.request.method should be:</p> <ul style="list-style-type: none"> <li>• PUT to update an existing resource</li> <li>• POST to add a new resource</li> </ul> <p>Bundle.entry.request.url should be:</p> <ul style="list-style-type: none"> <li>• Same value as Bundle.entry.fullUrl</li> </ul>

For example:

```
<?xml version="1.0" encoding="utf-8"?>
<Bundle xmlns="http://hl7.org/fhir">
  <id value="600000022531" />
  <meta>
    <versionId value="1" />
    <lastUpdated value="2021-07-07T08:52:51.607+00:00" />
  </meta>
  <type value="transaction" />
  <entry>
    <fullUrl value="MedicinalProductDefinition/600000022531" />
    <resource>
      <MedicinalProductDefinition>


---


      </resource>
      <request>
        <method value="PUT" />
        <url value="MedicinalProductDefinition/600000022531" />
      </request>
    </entry>
    <entry>
      <fullUrl value="PackagedProductDefinition/170427" />
      <resource>
        <PackagedProductDefinition>


---


        </resource>
        <request>
          <method value="PUT" />
          <url value="PackagedProductDefinition/170427" />
        </request>
      </entry>
    </entry>
  </entry>
</entry>
```

- DO NOT edit or remove the IDs for each resource and in-line within each resource in the EP304 Get \$everything response

#### 4.1.6.2. How to use Update NP product endpoint and example bundle

Create product via API	POST Bundle	Sample XML bundle used:  UPD_1.5.1-0_NAP_Legacy_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel.XML
------------------------	-------------	---

Check operation outcome	MSG_CREATED message expected containing Permanent identifier	
EP304 Get Product Full	<p>Prepare update bundle based on the response by updating Bundle.type to transaction and adding Bundle.entry.request.method for each resource.  Edit the payload  e.g.</p> <ul style="list-style-type: none"> <li>- modify product name</li> <li>- add another ATC Vet code</li> <li>- add another ManufacturedItemDefinition including this into the existing PackagedProductDefinition</li> </ul>	<p>Sample XML of Get Everything response used as a starting point:  UPD_1.5.1-0_EP311_UpdateProduct_GetEverything_version1.XML</p> <p>Update bundle prepared:  UPD_1.5.1-0_EP311_UpdateProduct_RequestBundle.XML</p>
Update product via API	<p>POST Bundle with request headers to /pms/api/v2</p> <ul style="list-style-type: none"> <li>• "is_update=true"</li> <li>• "chapter4" = true or false for the validation rules to apply</li> </ul>	
Check operation outcome	MSG_CREATED message expected containing Permanent identifier	
EP304 Get Product Full	Check the response for modifications	<p>Sample XML of GET everything after update:  UPD_1.5.1-0_EP311_UpdateProduct_GetEverything_version2.XML</p>



### 4.1.6.3. How to use Update National Data DCP/MRP/SRP product endpoint and example bundle

<p>EP304 Get Product Full</p>	<p>Prepare update bundle based on the response by updating Bundle.type to transaction and adding Bundle.entry.request.method for each resource.</p> <p>Edit the payload and add national data e.g.</p> <ul style="list-style-type: none"> <li>- Product name</li> <li>- Legal status of supply (product level)</li> <li>- Package description</li> <li>- Marketing authorisation number (product level)</li> <li>- Marketing authorisation status &amp; dates</li> <li>- Responsible authority</li> </ul>	<p>Create DCP using this example file: UPD_1.6.16-5_CreateDCPForUpdateNationalData.XML</p> <p>Product Identifier: d0f4414c-cd65-478b-921e-f107c66f7a85</p> <p>CMS for Italy <b>Permanent identifier:</b> 600000251886</p> <p>Sample XML of Get Everything response used as a starting point: UPD_1.6.16_DCP_UpdateNationalData_600000251886_GetEverything_v1.XML</p> <p>Update bundle prepared: UPD_1.6.16_DCP_UpdateNationalData_600000251886_BasedOn_v1.XML</p>
<p>Update product via API</p>	<p>POST Bundle with request headers to /upd/api/v1/national-data-bundle/</p> <ul style="list-style-type: none"> <li>• "is_update=true"</li> <li>• "chapter4" = true or false for the validation rules to apply</li> </ul>	
<p>Check operation outcome</p>	<p>MSG_CREATED message expected containing Permanent identifier</p>	
<p>EP304 Get Product Full</p>	<p>Check the response for modifications</p>	<p>Sample XML of GET everything after update: UPD_1.6.16_DCP_UpdateNationalData_600000251886_GetEverything_v2.XML</p>

#### 4.1.6.4. How to use Update Common Data DCP/MRP/SRP product endpoint and example bundle

<p>EP304 Get Product Full</p>	<p>Prepare update bundle based on the response by updating Bundle.type to transaction and adding Bundle.entry.request.method for each resource.</p> <p>Edit the payload e.g.</p> <ul style="list-style-type: none"> <li>- modify common product name</li> <li>- add another ATC Vet code</li> </ul> <p>Important: any national data that has been populated should be also included in the update bundle.</p>	<p>Sample XML of Get Everything response used as a starting point:</p> <p>UPD_1.5.3-4_DCP_UpdateCommonData_Product_600000149642_GetEverything_Version1.XML</p> <p>Update bundle prepared:</p> <p>UPD_1.5.3-4_DCP_UpdateCommonData_Product_600000149642_UpdateBundleBasedOnVersion1.XML</p>
<p>Update product via API</p>	<p>POST Bundle with request headers to /upd/api/v1/common-data-bundle/</p> <ul style="list-style-type: none"> <li>• "is_update=true"</li> <li>• "chapter4" = true or false for the validation rules to apply</li> </ul>	
<p>Check operation outcome</p>	<p>MSG_CREATED message expected containing Permanent identifiers</p>	
<p>EP304 Get Product Full</p>	<p>Only the Common data in the RMS and CMS products under that Product Identifier will be updated</p>	<p>Please refer to Known issues section for any outstanding issues where national data submitted when updating common data is not being ignored.</p>

#### 4.1.6.5. How to use Create MRP product endpoint and example bundle

EP304 Get Product Full	Prepare update bundle based on the response by updating Bundle.type to transaction and adding Bundle.entry.request.method for each resource.	Sample XML of Get Everything response used as a starting point:  UPD_1.5.3-4_CreateMRP_NP_600000184179_GetEverything_version1.XML
Prepare Create MRP Bundle	<ul style="list-style-type: none"> <li>• Change procedure type from NP to MRP</li> <li>• Add Common Name with Country = EU and Language = English</li> <li>• Add Reference member state and Concerned member state</li> <li>• Add Common package description in English (if doesn't exist)</li> </ul>	Create MRP bundle prepared:  UPD_1.5.3-4_CreateMRP_BasedOn_NP_version1.XML
Create MRP via API	POST Bundle with request headers to /upd/api/v1/mrp-bundle/ <ul style="list-style-type: none"> <li>• "chapter4" = true or false for the validation rules to apply</li> </ul>	
Check operation outcome	MSG_CREATED message expected containing Permanent identifiers for RMS NP product and products created for each CMS	
EP304 Get Product Full	RMS: <ul style="list-style-type: none"> <li>• Contains the Common data that was added</li> </ul> CMS:	

	<ul style="list-style-type: none"> <li>Each new product is only populated with Common data, with status of Provisional</li> </ul>	
--	---	--

**4.1.6.6. How to use Create SRP product endpoint and example bundle**

EP304 Get Product Full	Prepare update bundle based on the response by updating Bundle.type to transaction and adding Bundle.entry.request.method for each resource.	Sample XML of Get Everything response used as a starting point:  UPD_1.6.1-4_CreateSRP_RMSPProduct_GetEverything_version1.XML
Prepare Create SRP Bundle	<ul style="list-style-type: none"> <li>Add new Concerned member state(s)</li> <li>Update common data as required</li> </ul>	Create SRP bundle prepared:  UPD_1.6.1-4_CreateSRP_BasedOnRMSPProduct_version1.XML
Create SRP via API	POST Bundle with request headers to /upd/api/v1/srp-bundle/ <ul style="list-style-type: none"> <li>"chapter4" = true or false for the validation rules to apply</li> </ul>	
Check operation outcome	MSG_CREATED message expected containing Permanent identifiers for existing RMS & CMS products and products created for each new CMS	
EP304 Get Product Full	RMS & existing CMS: <ul style="list-style-type: none"> <li>Contains the new CMS</li> <li>Procedure type remains unchanged</li> <li>Contains the Common data that was updated</li> </ul>	

	New CMS: <ul style="list-style-type: none"> <li>Each new product is only populated with Common data, with status of Provisional, and procedure type of SRP</li> </ul>	
--	---	--

## 4.1.7. API Manage document

### 4.1.7.1. EP403 Create document

#### Resource Information

<b>Endpoint</b>	POST /pms/api/v2/DocumentReference
<b>Request</b>	
Accept	application/fhir+xml application/fhir+json
Body	<DocumentReference .. </DocumentReference>
Content-type	application/fhir+xml application/fhir+json

<b>Response</b>	
Body	Document with version 1 and document ID returned  Note: ID expected format example: <span style="color: #C00000;">3c46270e-3c3d-4869-a73c-ad4d7c3f2893</span>

#### Query Parameters

None

## Example Request

For UAT environment: POST <https://spor-uat.azure-api.net/pms/api/v2/DocumentReference>

Example file for request body: UPD\_1.6.1-4\_Doc\_EP403\_CreateDocument.XML

PDF document that was converted to base64: EP403\_UploadDocument.PDF

- Document status value is case-sensitive (e.g.: current will work; CURRENT will fail)
- Document language value is case-sensitive (e.g.: en will work; EN will fail)

### 4.1.7.2. EP401 Search document

#### Resource Information

<b>Endpoint</b>	GET /pms/api/v2/DocumentReference?{ param}={value}[&{param}={value}]
<b>Request</b>	
Accept	application/fhir+xml application/fhir+json
Body	n/a
Content-Type	n/a
<b>Response</b>	
Body	Bundle of <DocumentReference>(s)  e.g. Bundle Total value=N [entry {DocumentReference Resource Type} ] *

## Path Parameters

Name	Description
<b>Version</b>	Service version number <b>Example value:</b> 2

## Query Parameters

Name	Description
related	Permanent identifier of the product the document is related to
type	Type of document
_summary	Boolean set to true or false.  If set to true, the contents of the document is not populated in the response in DocumentReference.content.attachement,data.  There is a url provided but it is not intended that you can use this to retrieve the document.

## Example request

GET /pms/api/v2/DocumentReference?related=MedicinalProductDefinition/600000216133

GET /pms/api/v2/DocumentReference?type=100000155538

GET /pms/api/v2/DocumentReference?related=MedicinalProductDefinition/600000216133&\_summary=true

### 4.1.7.3. EP402 Get/retrieve document

## Resource Information

<b>Endpoint</b>	GET /pms/api/v2/DocumentReference/{document-id}
-----------------	---

<b>Request</b>	
Accept	application/fhir+xml application/fhir+json
Body	n/a
Content-Type	n/a
<b>Response</b>	
Body	Resource of type MedicinalProductDefinition

### Path Parameters

Name	Description
<b>Document id</b>	A unique document identifier UUID <b>Example value:</b> 7a88176d-10f9-4db3-8fa0-4e4ae4594df7
<b>version</b>	Service version number <b>Example value:</b> 2

### Query Parameters

None

### Example Request

GET /v2/DocumentReference/3c46270e-3c3d-4869-a73c-ad4d7c3f2893



#### 4.1.7.4. EP404 Update document

### Resource Information

<b>Endpoint</b>	POST /pms/api/v2/DocumentReference
<b>Request</b>	
Accept	application/fhir+xml application/fhir+json
Body	<DocumentReference> <id value="fcd2c31c-0ef9-455c-99a0-75149b888a27"/> .. </DocumentReference>
Content-type	application/fhir+xml application/fhir+json
is_update	true
<b>Response</b>	
Body	Document with version number incremented by 1

### Query Parameters

None

### Example Request

For UAT environment: POST <https://spor-uat.azure-api.net/pms/api/v2/DocumentReference>

Example file for request body:

- GET of document before update: UPD\_1.6.1-4\_Doc\_EP402\_GetDocument\_version1.XML
- Update posted: UPD\_1.6.1-4\_Doc\_EP404\_UpdateDocument\_BasedOnVersion1.XML
- Response to POST: UPD\_1.6.1-4\_Doc\_EP404\_ResponseAfterUpdate.XML
- GET of document after update: UPD\_1.6.1-4\_Doc\_EP402\_GetDocument\_AfterEP404Update\_version2.XML

#### 4.1.7.5. Changes for Create and Update document payload

- There are no changes to payload

## 4.2. UPD API for VNRA

### 4.2.1. Scope of this release for VNRA API

UPD-UC31 Manage VNRA Submissions via API

- Search and Retrieve VNRA
- Approve/Reject VNRA

### 4.2.2. UPD API supported VNRA endpoints

#### 4.2.2.1. Query / Retrieve VNRA Submission

Query / Retrieve VNRA Submission	GET	<b>Returns the complete collection of submissions which the caller is entitled to view</b> <b><a href="#">/vnra-submission?permanentIdentifier={permanentId}</a></b>
APIM entry point	UAT	<b><a href="https://spor-uat.azure-api.net/upd/api/vnra/v3/vnra-submission?permanentIdentifier=600013438271">https://spor-uat.azure-api.net/upd/api/vnra/v3/vnra-submission?permanentIdentifier=600013438271</a></b>
APIM entry point	PROD	<b><a href="https://spor.azure-api.net/upd/api/vnra/v3/vnra-submission?permanentIdentifier=600013438271">https://spor.azure-api.net/upd/api/vnra/v3/vnra-submission?permanentIdentifier=600013438271</a></b>
Query Parameters		<b>Query Parameters (All Are Optional)</b> <b>Note: Calls to base url , (without parameters) <a href="#">/vnra-submission</a> will return the complete collection of submissions which the caller is entitled to view</b> <ol style="list-style-type: none"><li>1. <b>productName</b> : Product name – free text field and case insensitive</li><li>2. <b>productIdentifier</b> : Product identifier – free text field</li><li>3. <b>permanentIdentifier</b> : Permanent identifier – free text field</li></ol>

- 
4. **mah** : OMS LOC\_ID of Product owner – LOC-100005358
  5. **responsibleAuthority** : OMS LOC\_ID of Responsible authority (organisation) – LOC-100001603
  6. **maNumber** : Authorisation/registration/entitlement number – free text field
  7. **procedureType** : Procedure type – RMS Code
  8. **procedureNumber** : Procedure number – free text field with “Starts with” and “Contains” and case insensitive
  9. **submissionIdentifier** : Submission identifier – free text field
  10. **submissionStatus** : Submission status – PENDING | APPROVED | PARTIALLY\_APPROVED | REJECTED
  11. **dateFrom** : Date From-To – calendar field to add interval “from”
  12. **dateTo** : Date From-To – calendar field to add interval “to”
  13. **vnraStatus** : VNRA Status – single selection field with list of VNRA status -PENDING | APPROVED | REJECTED
  14. **vnraClassificationIdentifier** : vnraClassificationIdentifierClassification – field with list of VNRA classifications - RMS Code

---

## Headers

### Headers

The following Headers will be provided / injected by APIM -

1. [APIM-Correlation-ID](#) Generated and Included with all POST / PUT / DELETE by default. For future BAM requirements include with GET
2. [APIM-User-ID](#) ==> From User's bearer token.
3. [APIM-Org-ID](#) ==> org affiliations are included.

### Security Headers (Mandatory)

v3 of the API require a mandatory Bearer Token which is passed via the Authorization header

### Oauth Bearer Token

```
curl -X GET \  
-H "Authorization: Bearer $(oauth-access-token)" \  
https://spor.azure-api.net/upd/api/vnra/v3/vnra-submission
```

---

## Pagination

### Pagination

---

---

Pagination is implemented using Spring Boot Pagination which returns the following standard **Pagination Payload**. submission data are returned with in "content": [...],

PageSize is set using the [\\_size](#) parameter.

Iterating through the pages is managed via `_page=x`totalPages: y evaluation,

If totalPages=y and the consumer searches for the last page, then `_number` should be set to y-1.

[https://spor.azure-api.net/upd/api/vnra/v3/vnra-submission?\\_size=5](https://spor.azure-api.net/upd/api/vnra/v3/vnra-submission?_size=5)

[https://spor.azure-api.net/upd/api/vnra/v3/vnra-submission?\\_size=5&\\_page=2](https://spor.azure-api.net/upd/api/vnra/v3/vnra-submission?_size=5&_page=2)

### Pagination Payload

```
{
  "content": [...],
  "pageable": {
    "sort": {
      "empty": false,
      "sorted": true,
      "unsorted": false
    },
    "offset": 0,
    "pageNumber": 0,
    "pageSize": 1,
    "paged": true,
    "unpaged": false
  },
  "totalPages": 485,
  "totalElements": 485,
  "last": false,
  "sort": {
    "empty": false,
    "sorted": true,
    "unsorted": false
  },
  "size": 1,
  "number": 0,
  "first": true,
  "numberOfElements": 1,
  "empty": false
}
```

---

```
}
```

---

**Sample Payload**

```
{  
  "content": [  
    {  
      "submissionId": 1588,  
      "submissionDate": 1694433983143,  
      "submissionComment": "NoComments",  
      "submissionStatus": "PENDING",  
      "products": [  
        {  
          "permanentId": "600001120431",  
          "procedureType": "100000155062",  
          "productRelationships": [  
            {  
              "organisationId": "ORG-100004089",  
              "relationship": "Holder"  
            },  
            {  
              "organisationId": "ORG-100003944",  
              "relationship": "Regulator"  
            }  
          ]  
        },  
        {  
          "permanentId": "600001120431",  
          "procedureType": "100000155062",  
          "productRelationships": [  
            {  
              "organisationId": "ORG-100004089",  
              "relationship": "Holder"  
            },  
            {  
              "organisationId": "ORG-100003944",  
              "relationship": "Regulator"  
            }  
          ]  
        }  
      ]  
    },  
    {  
      "permanentId": "600001120431",  
      "procedureType": "100000155062",  
      "productRelationships": [  
        {  
          "organisationId": "ORG-100004089",  
          "relationship": "Holder"  
        },  
        {  
          "organisationId": "ORG-100003944",  
          "relationship": "Regulator"  
        }  
      ]  
    }  
  ]  
}
```

---

```
    ]
  }
]
},
],
"pageable": {
  "sort": {
    "empty": false,
    "sorted": true,
    "unsorted": false
  },
  "offset": 0,
  "pageNumber": 0,
  "pageSize": 1,
  "paged": true,
  "unpaged": false
},
"totalPages": 485,
"totalElements": 485,
"last": false,
"sort": {
  "empty": false,
  "sorted": true,
  "unsorted": false
},
"size": 1,
"number": 0,
"first": true,
"numberOfElements": 1,
"empty": false
}
```

#### 4.2.2.2. Retrieve a VNRA Submission

<b>Retrieve a VNRA Submission</b>	GET	Retrieve a specific VNRA submission identified by its submissionId <a href="#">/vnra-submission/&lt;submissionId&gt;?summary={true false}</a> <a href="#">upd/api/vnra/v3/vnra-submission/456?summary=true</a>
<b>APIM entry point</b>	UAT	<a href="https://spor-uat.azure-api.net/upd/api/vnra/v3/vnra-submission/456?summary=false">https://spor-uat.azure-api.net/upd/api/vnra/v3/vnra-submission/456?summary=false</a>
<b>APIM entry point</b>	PROD	<a href="https://spor.azure-api.net/upd/api/vnra/v3/vnra-submission/456?summary=false">https://spor.azure-api.net/upd/api/vnra/v3/vnra-submission/456?summary=false</a>
<b>Path</b>		<a href="#">/vnra-submission/&lt;submissionId&gt;</a>
<b>Parameter</b>		<b>&lt;SubmissionId&gt; is the ID of the submission to retrieve</b>
<b>Query Parameters</b>		<b>Query Parameter (All Are Optional)</b> summary (Optional) : _(true false) Returns a summary view of the submission else a full view_
<b>Headers</b>		<b>Headers</b> The following Headers will be provided / injected by APIM - <ol style="list-style-type: none"><li>1. APIM-Correlation-ID Generated and Included with all POST / PUT / DELETE by default. For future BAM requirements include with GET</li><li>2. APIM-User-ID ==&gt; From User's bearer token.</li><li>3. APIM-Org-ID ==&gt; org affiliations are included.</li></ol> <b>Security Headers (Mandatory)</b> v3 of the API require a mandatory Bearer Token which is passed via the Authorization header <b>Oauth Bearer Token</b> curl -X GET \ -H "Authorization: Bearer \$(oauth-access-token)" \ <a href="https://spor.azure-api.net/upd/api/vnra/v3/vnra-submission/456?summary=false">https://spor.azure-api.net/upd/api/vnra/v3/vnra-submission/456?summary=false</a>
<b>Sample Payload</b>		<pre>{   "submissionId": 1596,   "submissionDate": 1694450625907,   "submissionComment": "Submit VNRA For NAP 11/09/2023",   "submissionStatus": "APPROVED",</pre>
<b>Summary=false</b>		

---

```
"variations": [
  {
    "variationId": 16517,
    "vnraGroup": "a458cce6-5553-4efb-b974-7147069d13fc",
    "productName": "Automation Test Create NAP CH2 2023-09-11 GYxEgH",
    "productIdentifier": "926d544f-3fd6-44a3-9150-48bbb277fed6",
    "permanentIdentifier": "600001120724",
    "procedureNumber": "EMEA/V/C/777777",
    "responsibleAuthority": "LOC-100000065",
    "authorisationCountry": "100000000535",
    "marketingAuthorisationNumber": "EMEA/V/C/777777",
    "vnraCode": "200000018624",
    "implementationDate": 1694390400000,
    "decisionDate": 1694390400000,
    "decisionAuthor": "BeyondAutomation",
    "decisionMaker": "ORG-100003944",
    "decisionComment": "Comment BeyondAutomation",
    "status": "APPROVED",
    "marketingAuthorisationHolder": "LOC-100002851",
    "fieldChanges": []
  }
],
"vnessFileName": "Test.zip"
}
```

---

**Sample  
Payload**

**Summary=true**

```
{
  "submissionId": 1596,
  "submissionDate": 1694450625907,
  "submissionComment": "Submit VNRA For NAP 11/09/2023",
  "submissionStatus": "APPROVED",
  "vnessFileName": "Test.zip"
}
```



#### 4.2.2.3. Download a VNees

<b>Download a VNees</b>	Download a VNees linked to a VNRA Submission
GET	<a href="#">/vnra-submission/&lt;submissionId&gt;/vness</a> <a href="#">upd/api/vnra/v3/vnra-submission/456/vness</a>
<b>APIM entry point</b>	UAT <a href="https://spor-uat.azure-api.net/upd/api/vnra/v3/vnra-submission/vness_">https://spor-uat.azure-api.net/upd/api/vnra/v3/vnra-submission/vness_</a>
<b>APIM entry point</b>	PROD <a href="https://spor.azure-api.net/upd/api/vnra/v3/vnra-submission/456/vness">https://spor.azure-api.net/upd/api/vnra/v3/vnra-submission/456/vness</a>
<b>Path</b>	<a href="#">/vnra-submission/&lt;submissionId&gt;</a>
<b>Parameter</b>	<b>&lt;SubmissionId&gt; is the ID of the submission to retrieve</b>
<b>Query Parameters</b>	None

#### Headers

#### Headers

The following Headers will be provided / injected by APIM -

1. APIM-Correlation-ID Generated and Included with all POST / PUT / DELETE by default. For future BAM requirements include with GET
2. APIM-User-ID ==> From User's bearer token.
3. APIM-Org-ID ==> org affiliations are included.

#### Security Headers (Mandatory)

v3 of the API require a mandatory Bearer Token which is passed via the Authorization header

#### Oauth Bearer Token

```
curl -X GET \
```

```
-H "Authorization: Bearer $(oauth-access-token)" \
```

```
https://spor.azure-api.net/upd/api/vnra/v3/vnra-submission/456?summary=false
```

#### 4.2.2.4. Submit a decision for the VNRA

<b>Submit a decision for the VNRA</b>	PUT	VNRA submit decision - Approve/Reject VNRA <a href="#">/vnra-submission/&lt;submissionId&gt;/decision</a> <b>ⓧ</b> <a href="#">upd/api/vnra/v3/vnra-submission/456/decision</a>
<b>APIM entry point</b>	UAT	<a href="https://spor-uat.azure-api.net/upd/api/vnra/v3/vnra-submission/456/decision">https://spor-uat.azure-api.net/upd/api/vnra/v3/vnra-submission/456/decision</a>
<b>APIM entry point</b>	PROD	<a href="https://spor.azure-api.net/upd/api/vnra/v3/vnra-submission/456/decision">https://spor.azure-api.net/upd/api/vnra/v3/vnra-submission/456/decision</a>
<b>Path</b>		<a href="#">/vnra-submission/&lt;submissionId&gt;</a>
<b>Parameter</b>		<b>&lt;SubmissionId&gt; is the ID of the submission containing the variation to approve</b>
<b>Query Parameters</b>		None

**Headers**

**Headers**

The following Headers will be provided / injected by APIM -

1. **APIM-Correlation-ID** Generated and Included with all POST / PUT / DELETE by default. For future BAM requirements include with GET
2. **APIM-User-ID** ==> From User's bearer token.
3. **APIM-Org-ID** ==> org affiliations are included.

**Security Headers (Mandatory)**

v3 of the API require a mandatory Bearer Token which is passed via the Authorization header

**Oauth Bearer Token**

curl -X GET \

-H "Authorization: Bearer \$(oauth-access-token)" \

<https://spor.azure-api.net/upd/api/vnra/v3/vnra-submission/456/decision>

**Sample Payload**

```
{
  "vnraDecisionItems": [
    {
      "variationId": 3711,
      "vnraDecision": "APPROVED",
      "decisionComment": "Submission-decision-approve-all test case",
      "decisionAuthor": "Beyond Automation",
      "decisionDate": "2022-05-03T12:00:00Z",
    }
  ]
}
```

---

```
        "decisionMaker": "ORG-100003944",
        "utils": {}
    }
]
}
```

#### **4.2.2.5. User registration for VNRA API**

Access to the VNRA API is requested by the Super user of an NCA (i.e. user with the role “UPD - CA Super User”); who will request a new role of “UPD CA API”.

On receipt of the email confirming API role has been approved, the API credentials can be used to obtain the OAuth bearer token required to use with the VNRA API endpoints.

Refer to the document [Registration guide: Union product database for veterinary medicinal products](#) listed in the References section.

### **4.3. UPD API for Volume of Sales Data**

#### **4.3.1. Scope of this release for Volume of Sales API**

- Retrieve Volume of Sales Data

#### **4.3.2. Endpoint, Authorisation header, Query Parameters, Pagination**

##### **Endpoint**

UAT **GET** <https://spor-uat.azure-api.net/upd/api/vos/v3/vos-sales-json?>

PROD **GET** <https://spor.azure-api.net/upd/api/vos/v3/vos-sales-json?>

---

## Request Security Header (Mandatory)

This endpoint requires a mandatory OAuth Bearer Token which is passed via the Authorization header

---

### Query Parameters

*Note: Calls to the base url without any parameters will return the complete collection of sales data for all products.*

/upd/api/vos/v3/vos-sales-json?permanentId={permanentID}&yearFrom={yearFrom}&yearTo={yearTo}&modifiedDate={modifiedDate}

**permanentId** (optional) :- Permanent identifier of Medicinal Product. Will return sales for the provided Permanent identifier e.g.  
`permanentId=600000225806`

**yearFrom** (optional) :- yearFrom={year-month} Start date for range of sales data to be returned

**yearTo** (optional) :- yearTo={year-month} End date for range of sales data to be returned

e.g. `yearFrom=2020-01&yearTo=2021-07`

**modifiedDate** (optional) :- Modified Date of Sales data of Medicinal Product. Will return sales modified since a date  
The following prefixes apply to date comparisons against a stored (modified date) value. If no prefixes are specified, the default is eq.

- eq: equals, the exact stored value is inside the range defined by the precision of the parameter value
- gt: the exact stored value is greater than the exact parameter value

e.g. `modifiedDate=2023-03-01` or with prefix `modifiedDate=gt2023-03-01`

### Examples:

GET `https://spor-uat.azure-api.net/upd/api/vos/v3/vos-sales-json?permanentId=600000225806&yearFrom=2020-01&yearTo=2021-07&modifiedDate=gt2023-01-01`

GET `https://spor-uat.azure-api.net/upd/api/vos/v3/vos-sales-json?yearFrom=2020-01&yearTo=2021-07`

GET `https://spor-uat.azure-api.net/upd/api/vos/v3/vos-sales-json?permanentId=600000225806`

---

---

## Pagination

Pagination is implemented using Spring Boot Pagination which returns the following standard **Pagination Payload**.

- sales data is returned within "content": [...],
- pageSize is set using the `_size` parameter
- iterating through the pages is managed using the `_page=x` parameter
- totalPages: y evaluation: If totalPages=y and the consumer searches for the last page, then page number parameter should be set to y-1.

Examples:

GET [https://spor-uat.azure-api.net/upd/api/vos/v3/vos-sales-json?\\_size=5](https://spor-uat.azure-api.net/upd/api/vos/v3/vos-sales-json?_size=5)

GET [https://spor-uat.azure-api.net/upd/api/vos/v3/vos-sales-json?\\_size=5&\\_page=2](https://spor-uat.azure-api.net/upd/api/vos/v3/vos-sales-json?_size=5&_page=2)

## Pagination Payload

```
{
  "content": [...],
  "pageable": {
    "sort": {
      "empty": false,
      "sorted": true,
      "unsorted": false
    },
    "offset": 0,
    "pageNumber": 1,
    "pageSize": 100,
    "paged": true,
    "unpaged": false
  }
}
```

```
},
"totalPages": 6,
"totalElements": 596,
"last": false,
"sort": {
  "empty": false,
  "sorted": true,
  "unsorted": false
},
"size": 100,
"number": 0,
"numberOfElements": 100,
"first": true,
"empty": false
}
```

---

### Sample Response Payload

```
{
  "content": [
    {
      "productIdentifier": "c74a510c-1689-4f46-bdce-f3a5dd84b1da",
      "productName": "TEST-PRODUCT-NAME2-95363f02-c9b9-442b-8bdf-21a54bf15b2e-VOS",
      "permanentIdentifier": "600013438271",
      "authorisationProcedureNumber": "VOS/TEST/HOLDER-NAME2/TEST/EMEA/H/C/000175",
      "packageIdentifier": "be7bfd42-df3f-45e2-8af9-3d96a870f5f7",
      "packageDescription": "PACKAGE3-TEST-PRODUCT-NAME2-95363f02-c9b9-442b-8bdf-21a54bf15b2e-VOS",
      "packSizeNumericValue": "94",
      "packSizeUnitOfPresentation": "Capsule",
      "packSizeUnitOfPresentationIdentifier": "200000002113",
      "country": "European Union",
      "countryIdentifier": "100000000390",
      "marketingAuthorisationNumber": "VOS/TEST/HOLDER-NAME2-1591819011837",
      "creationDateOfProduct": "2021-11-12",
    }
  ]
}
```

```
"yearMonth": "2021-03",
"volumeOfSales": "111",
"speciesIdentifier": "100000108926",
"speciesPercent": "100.00",
"doseFactor": "1.00",
"comment": "Mandatory",
"modifiedDate": "2023-06-14 09:06:28.047"
}
],
"pageable": {
  "sort": {
    "empty": true,
    "unsorted": true,
    "sorted": false
  },
  "offset": 0,
  "pageNumber": 0,
  "pageSize": 1,
  "paged": true,
  "unpaged": false
},
"totalElements": 5,
"totalPages": 5,
"last": false,
"sort": {
  "empty": true,
  "unsorted": true,
  "sorted": false
},
"size": 1,
"number": 0,
"first": true,
"numberOfElements": 1,
```

```
"empty": false  
}
```

### 4.3.3. User registration for Volume of Sales Data API

Access to the Volume of Sales API is requested by the Super user of an NCA (i.e. user with the role "UPD - CA Super User"); who will request a new role of "UPD CA API".

On receipt of the email confirming API role has been approved, the API credentials can be used to obtain the OAuth bearer token required to use with the VoS API endpoint.