



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Union Product Database (UPD) release notes

Referring to version 1.7.2443

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Acronym key and glossary terms

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

The structure of these release notes has been refined and simplified for enhanced accessibility to all users. The document contains now 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.

Resolved issues since the previous release (UPD version 1.7.2434-12, released on 24 October 2024)	27
Known Issues	24
Next release's expected date	<i>to be determined</i>

Overview of new functionality(ies):

- To prevent accidental nullification, the 'nullify' button is disabled for **MRP products created after SPC harmonisation procedure.**
- **The replacement of non-current substances with SMS-proposed current substances is now an automatic process, eliminating the need for CA updates.**
- **MAHs are able to see always all products under their portfolio based on location-id even when a technical merge of a location has occurred in OMS due to the identification of duplicate addresses.**
- **UPD UI menus have been updated for alignment and compliance.**
- **Ability to provide the QPPV email via UI has been removed for MAHs.**
- **QPPV email is now mandatory to be provided during product creation and optional for update operations.**

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](#): <https://support.ema.europa.eu/>;
 - If you have rows having in the last column the value 'N/A', please resubmit those rows to UPD;
 - If you have rows having in the last column values of the type 'Database updated - Submission 0000 - Product 00000', please do not resubmit as those updates have been processed successfully.

	B	C	D	E	G	H	J	N	O	P
Product	Permanent	Authorisation	Package	Pack	size	Unit	Availability	Availability		
1 Name	Identifier	Procedure Number	Identifier	size_Nu	of	Count	Status	Status Da		
2 Example	600000000001	EMEA/V/C/000000	C81CC9A8-2B9A-6B62	1	Vial	Denmark	100000072075	1/1/2020	ER.36: Package could not be updated - Reason: %s Plea	
3 Example	600000000002	EMEA/V/C/000000	C81CC9A8-2B9A-6B62	1	Vial	Czechia	100000072075	1/1/2020	N/A	
4 Example	600000000003	EMEA/V/C/000000	C81CC9A8-2B9A-6B62	1	Vial	Cyprus	100000072075	1/1/2020	Database updated - Submission 0000 - Product 00000	

- Once the errors of type ER.36 have been addressed, incorporate the AvS of those products into the next submission, and if you again receive any error repeat all the above steps.

Over time, as ER.36 issues are cleaned up, the size of the carry forward from month to month should diminish in size and eventually disappear.

For information:

- From early December 2024 onwards the new QPPV email field will be a mandatory attribute to be provided by Competent Authorities during the creation of a product and optional for update operations.
- For some of the products approved under DCP/MRP, it could be the case that only one RMS and no CMS(s) are involved in the process. The recording and updating these products must be as follows:
 - **Scenario 1:** In case the **marketing authorisations** for DC/MR/SR product have been **withdrawn** from all CMSs and that same product is still authorised only in the RMS, then the Authorisation status for the CMSs products must be set to SURRENDERED and the RMS product updates (via UI and API) will continue as normal.
 - **Scenario 2:** The **application** for DCP/MRP has been **withdrawn** from all CMSs before the end of the authorisation procedure:
 - **Step 1)** the RMS creates the DCP adding Sweden as a CMS and informs the CMS via the UPD contact point.
 - **Step 2)** the RMS must then update the national data of this CMS product and informs the CMS via the UPD contact point:
 - to prevent the product from being available to the general public, the RMS must keep the CMS product in PROVISIONAL status.
 - to prevent the CMS product from being available to the MAH, the RMS will add as MAH the location ID of their own National Competent Authority.
 - to ensure that the product is not considered valid by other consuming systems such as Union Pharmacovigilance Database or Antimicrobial Sales and Use platform, the national data must be filled in with the following values:
 - National veterinary medicinal product name: '-NOT VALID-Dummy product-';
 - Responsible Authority: 'EMA' must be replaced by the National Competent Authority of the CMS;
 - Authorisation/registration/entitlement number: '-NOT VALID-Dummy product-';
 - Legal status for the supply: Same as in RMS;
 - Marketing authorisation date: '01/01/1900', type the date manually;

- Date of authorisation status change: '01/01/1900', type the date manually.
- to prevent the product from being subject to fees, the Authorisation status must be set to SURRENDERED.

Thereafter no further changes are required for the 'dummy' CMS product.

➤ **Scenario 3: Update of legacy 'dummy' CMS products:**

- **Step 1)** the RMS must update then the national data of the CMS product and informs the CMS via the UPD contact point:
 - to prevent the CMS product from being available to the general public, the RMS must keep the product in PROVISIONAL status.
 - to prevent the CMS product from being available to the MAH, the RMS will add as MAH the location ID of their own National Competent Authority.
 - to ensure that the product is not considered valid by other consuming systems such as Union Pharmacovigilance Database or Antimicrobial Sales and Use platform, the national data must be filled in with the following values:
 - National veterinary medicinal product name: '-NOT VALID-Dummy product-';
 - Responsible Authority: 'EMA' must be replaced by the National Competent Authority of the CMS;
 - Authorisation/registration/entitlement number: '-NOT VALID-Dummy product-';
 - Legal status for the supply: Same as in RMS;
 - Marketing authorisation date: '01/01/1900', type the date manually;
 - Date of authorisation status change: '01/01/1900', type the date manually.
 - to prevent the product from being subject to fees, the Authorisation status must be set to SURRENDERED.

Thereafter no further changes are required for the 'dummy' CMS product.

- **For NCA API Users:**

- Annex 4 section 4.1.2 'UPD API supported Product Service endpoints': a new endpoint "EP309 Create Product" regarding the creation of MRP after SPC harmonisation procedure has been added (see below).
- Annex 4 section 4.1.6.1 "EP403 Create document in the example request updated the URL for the UAT environment (see below);
- Annex 4 section 4.1.6.4 "EP404 Update document" in the example request updated the URL for the UAT environment (see below);
- Annex 4 section 4.2 "UPD API for VNRA" the entire section has been updated (see below);
- Annex 4 section 4.3.2 "Endpoint, Authorisation header, Query Parameters, Pagination" in the endpoint and examples the UAT URL has been updated. Replaced pagination payload and sample response payload (see below).

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1. Summary of issues

1.1. Resolved issues

Use Case	Affects API and/or UI	Issue reference (ADO)	Resolved issues
All UC	API & NCA UI & MAH UI	202439	Some CAPs were missing the Procedure number.
All UC	API & NCA UI & MAH UI	207879	There were two CAPs Locatim(s) and Circovac, and only one for each was expected.
UC03 Search	NCA UI & MAH UI	207017	Product Owner name presented duplicated LOC-ID information
UC03 Search product	MAH UI	107914	After organisation merge, MAH cannot find their products in General search, VNRA submission screen or VoS csv (UPD, VNRA or OPAD databases).
UC05 View product	NCA UI & MAH UI	212176	Authorisation Country was not being displayed in Packages for some products in UPD UI
UC06 Submit VNRA	MAH UI	219372	Was not possible to select a Decision Maker when submitting a VNRA
UC06 Submit VNRA	MAH UI	212267	Search location by country did not retrieved results
UC07 Submit Volume of sales	MAH UI	192554	OPAD > Volume of sales submission for County = non-EEA (10000000028) is failing for some DCP/MRP/SRP products (ERR.19)
UC08 Update Product	NCA UI NCA API	205129	When searching for an organisation, the Country filter would fail due to incorrect country 2 letter representation
UC08 Update product	NCA UI	203140	User was unable to add new version for existing document during PTP update
UC08 Update Product	NCA UI	189601	Search Manufacturer modal window fails when using filter 'City'
UC08 Update Product	NCA UI NCA API	199571	Values at package level for Legal status of supply couldn't be removed
UC08 Update Product	NCA UI NCA API	220048	A product update remained in-progress indefinitely if another update is submitted to the same product simultaneously
UC19 Nullify Product	NCA UI	218958	It was not possible to nullify DCP/SRP/MRP CMS products
UC08 Update product	NCA UI	211358	The incorrect procedure name was displayed in the side navigation menu header when updating an MRP after SPC Harmonisation procedure

UC08 Update Product	NCA UI	202277	Edition of the first manufacturer value in a product with multiple manufacturers was throwing an incorrect error
UC19 Nullify Product	NCA UI NCA API	216155	It was not possible to nullify products that do not have a status of 'Current'
UC21 Manage Notifications	NCA UI & MAH UI	202959	Product version number in the Notification quick view and View Product screen did not match
UC25 Update Availability status	MAH UI	177951	Submissions of Availability Status was failing for some CAPs with Error 36
UC28 View VNRA	NCA UI	212021	When viewing VNRA on approve page, submissions with the same code were presented as one
UC28 View VNRA	NCA UI & MAH UI	219359	There was a failure to download VNRA submission PDF
UC28 View VNRA	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 was not able to view the VNRA Submission even after the Responsible Authority has been corrected in the product(s) included in the submission. Problematic product no longer exists and problem was not replicated.
UC28 View VNRA	NCA UI & MAH UI	214397	Implementation Date on the VNRA pdf file downloaded is not the same as the one set in the VNRA form
UC33 Manage Third Country Product Names	MAH UI	196747	Adding or updating a name/country to a previously existing group triggers ERR.25:Group Identifier does not exist in the UPD
UC33 Manage Third country Product names	MAH UI	211662	Download third country product list would fail with time out error if MRP as a result of an SPC Harmonisation procedure product is present in the data
UC34 Bulk Upload	NCA UI	201667	Missing validation allowed for NCA Users who play the role of CMS to submit a National Document to the RMS product
UC34 Bulk Upload	NCA UI	206010	Documents for products grouped under an MRP after SPC Harmonisation procedure cannot be uploaded through the bulk upload functionality

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
UC01 Create Product	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	
UC01 Create Product	NCA UI	225300	No error message displayed while entering QPPV email address in incorrect format	
UC03 Search	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.	
UC03 Search	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	
UC06 Submit VNRA	MAH UI	211470	When a user saves a draft with 2 identical variation codes, one of them will not be present when the draft is retrieved	
UC06 Submit VNRA	MAH UI	216345	Submitting VNRA super grouping may fail with generic error	
UC06 Submit VNRA	MAH UI	211736	Retrieve VNRA does not retrieve all the fields filled while saving draft	
UC07 Submit Volume of sales	MAH UI	217701	Product with invalid data in deleted packages is missing in VoS Download packages file	
UC07 Submit Volume of sales	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	
UC08 Update product	ETL for CAP products	223864	CAP products ended up with multiplied Target Species after ETL run	
UC08 Update product	ETL for CAP products	215513	CAP contains packages with Marketing Authorization status = Withdrawn which is not a valid term for the field	

UC21 Manage Notifications	NCA UI & MAH UI	218870	Incorrect information displayed on Notifications table for Record Status
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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. [UPD registration guide for UI and API users](#)
2. [SPOR API Specification V2_R5 \(europa.eu\) API specifications for SMS and PMS, based on FHIR](#)
3. [HL7 FHIR Release 5 Preview 2: the authoritative source for the FHIR specifications used by EMA to implement SMS and PMS API](#)
4. [Referentials Management System](#)
5. [Additional information](#) on the Referentials Management System
6. [Organisations Management System](#)
7. [Additional information](#) on the Organisations Management System
8. [Substances Management System](#)

Annex 1: Overview of functionality and business value

Functionalities provided in this release


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


NCA UI



- RMS can create DCP products (data and documents)
- RMS can create MRP products (data and documents)
- RMS can create SRP products (data and documents)
- RMS and CMS can complement DCP/MRP/SRP products with national DCP/MRP data (including documents)
- RMS can update Common data for DCP/MRP/SRP products (data and documents)
- NCA can create and update NAP products (data and documents)
- NCA can create & update Registered Homeopathic products (data and documents)
- NCA can create & update Parallel Trade products (data and documents)
- NCA can create & update Pet products (data and documents)
- NCA can group National Authorised products under an MRP following CMDv SPC harmonisation procedure (data and documents)
- NCA can save and retrieve drafts for product submissions
- NCA can Nullify product
- NCA can Bulk Upload Documents
- NCA can Transfer Marketing Authorisation
- Search/view/export products (data and documents)
- Notifications for Create and Update of products and Other Post-Authorisation Data actions
- View Volume of Sales information
- Search, View and Approve/Reject VNRA submissions
- NCA can Approve/Reject VNRA submissions on behalf of other NCAs when a Supergrouping VNRA submission applies

EMA and EC staff can update CAP products

MAH UI 	Search/view/export products (data and documents)
	Notifications for Create and Update of products and Other Post-Authorisation Data actions
	Download, Submit, and View Volume of Sales information
	Submit VNRA and View VNRA submissions
	Submit Supergrouping VNRAs with the selection of the Foreseen Decision Maker that will approve/reject the whole submission on behalf of the others NCAs involved
	Submit updates for Marketing authorisation status
	Download and Submit updates for Availability status
	Submit Products Grouping
	Submit 3 rd country product names

MAH Validation UI
 Validate Volume of Sales submission file

**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

MAH API:

- the whole functionality has been postponed

General public API:

- the whole functionality has been postponed

Annex 2: Known issues

Issue reference is an internal number used by the UPD Project team when managing issues. It has been included as User Support may refer to this reference number when responding to your queries. In addition, you can include this reference number when contacting user support on this topic and seeking clarification.

Filter the columns to find those tickets relevant to your role and for NCAs whether you are an API or NCA User or both.

This table is ordered by Use Case number.

Use Case	Affects user	Issue reference (ADO)	Known Issue Description	Workaround
UC03 Search product	MAH UI	107914	After organisation 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.	
UC03 Search product	NCA UI & MAH UI	83234	Search limitations due to FHIR limitation or MS FHIR limitation.	
UC05 View product	API & NCA UI & MAH UI	211624	PSMF information has been lost for some CAPs	
UC05 View product	NCA UI & MAH UI	195439	Opening a Product page from the search results fails with error 'Sorry no product found'.	To resolve the issue, log out, clear the browser's cache memory and log in again.
UC05 View product	NCA UI & MAH UI	207731	Product references are not being displayed properly for CAP products in the UPD UI	
UC06 Submit VNRA & UC28 View VNRA	MAH UI	189703	View VNRA submissions page fails to load results using the Submission Status filter = approved	
UC08 Update product	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.
UC08 Update product	NCA UI	205197	The Edit national data button is not available as expected in some DCP/MRP/SRP products.
UC08 Update product	API & NCA UI	204969	An update to remove repeated English (common data) package descriptions from a DCP/MRP/SRP product fails to complete as expected, as the repeated data is not removed.
UC08 Update product	API & NCA UI	152242	CAP product only - after updating product in UPD there is a duplicated Pack size attribute. This duplicate attribute is only seen view Retrieve product via API. Subsequent updates via UPD for affected products are successful.
UC08 Update product	ETL for CAP products	162162	Retrieve from UPD correct information on 2.5. Authorisation status (MA status) and 2.6. Date of authorisation status change for CAP products
UC21 Manage Notifications	NCA UI & MAH UI	184984	Duplicated notifications are created for some VNRA actions
UC37 Automatic sending of notifications	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	4 June 2024	4 June 2024	5 June 2024	Upgrade of UPD to 1.7.2424
PROD	12 June 2024	12 June 2024	13 June 2024	Upgrade of UPD to 1.7.2424
UAT	20 June 2024	20 June 2024	20 June 2024	Upgrade of UPD to 1.7.2424-1
PROD	1 July 2024	1 July 2024	2 July 2024	Upgrade of UPD to 1.7.2424-1
UAT	22 July 2024	22 July 2024	22 July 2024	Upgrade of UPD to 1.7.2427
PROD	29 July 2024	29 July 2024	30 July 2024	Upgrade of UPD to 1.7.2427
PROD	27 August 2024	27 August 2024	28 August 2024	Upgrade of UPD to 1.7.2427-2
UAT	19 September 2024	19 September 2024	19 September 2024	Upgrade of UPD to 1.7.2434
PROD	7 October 2024	7 October 2024	8 October 2024	Upgrade of UPD to 1.7.2434
PROD	24 October 2024	24 October 2024	24 October 2024	Upgrade of UPD to 1.7.2434-12
UAT	11 November 2024	11 November 2024	11 November 2024	Upgrade of UPD to 1.7.2442
UAT	21 November 2024	21 November 2024	21 November 2024	Upgrade of UPD to 1.7.2443
PROD	4 December 2024	4 December 2024	5 December 2024	Upgrade of UPD to 1.7.2443

Annex 4: Guidance for API users

NCAs can integrate UPD with their national systems via API. For NCAs there are three different APIs and each provides access to different type of data:

- 1) UPD API for Products/Procedures;
- 2) UPD API for VNRA;
- 3) UPD API for VoS.

At present and until Q1 2025 **the API for 'UPD Products/Procedures'** (also known as v2 API) is a Subscription Key based API requiring authentication and authorisation via a valid API Key to use each endpoint. In order to have access to that API and get a Subscription Key, the 'Super user' of the organisation should open a ticket to EMA Service Desk <https://support.ema.europa.eu/esc> adding 'Request UPD NCA API v2 access' as a Subject. To safeguard the integrity, security and performance of UPD, this request must be done first to the UAT environment. A test in the UAT API will be required to grant access to the UPD API in Production. This test will be specified during the registration process via EMA Service Desk. For auditing reasons, you should use only one API account to access the UPD API in UAT and Production. We recommend that the email provided for the registration is a general one, within the ORG ID dominion, and with shared credentials for all the API users in the competent authority. *Note: In Q1 2025 the API for 'UPD Products/Procedures' will change and will require OAuth 2.0 authentication and authorisation via a valid Bearer Token to use each endpoint. The below mentioned registration and authorisation process, as for APIs for VNRA and VoS, will apply in the future.*

The **APIs for VNRA and VoS** require OAuth 2.0 authentication and authorisation via a valid Bearer Token to use each endpoint (also known as v3 API). In section 5.1.1. (point 4) of the [UPD Registration guide for UI and API users](#) you can find how a 'Super user' of the organisation can request the NCA API role.

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
- Create MRPH based on Chapter 4 Legacy or Chapter 2 rules

- RMS can update Common Data for products under DCP/MRP/SRP/MRPH (data and documents)
- RMS and CMS can complement DCP/MRP/SRP/MRPH 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	GET MedicinalProductDefinition - Search for a MedicinalProductDefinition resource or resources
EP303 Get Product	GET MedicinalProductDefinition - Get a MedicinalProductDefinition ID

SPOR API Specification v2	API Manager
EP304 Get Product Full	GET Everything Current - Get \$everything for a MedicinalProductDefinition ID
EP306 Get Product Version	GET MedicinalProductDefinition Version - Get version of MedicinalProductDefinition ID
EP306a Get Product Version Full	GET Everything Versioned - Get \$everything for a version of MedicinalProductDefinition ID
EP307 Get Product Versions	GET MedicinalProductDefinition - Get history of MedicinalProductDefinition ID
EP309 Create Product	<p>NAP: POST Bundle - Create/Update resources in the bundle</p> <p>DCP: POST dcp-bundle - Submit a Create DCP payload</p> <p>MRP: POST mrp_bundle – Submit a Create MRP payload</p> <p>SRP: POST srp_bundle – Submit a Create SRP payload</p> <p>MRPH: POST mrp-harmonisation-bundle – Submit a Create MRP Harmonised payload</p> <p>Registered homeopathic: POST Bundle - Create/Update resources in the bundle</p> <p>Parallel trade: POST ptp-bundle - Create/Update resources in the bundle</p> <p>Pet: POST pet-bundle - Create/Update resources in the bundle</p> <p>Refer to 4.1.4.2. Create and Update endpoints</p>

SPOR API Specification v2	API Manager
EP309 Create Product EP311 Update Product for use with any Create or Update	GET OperationOutcome - Get a resource by ID Note: use this to query the outcome of Create or Update when response to Post is "202 Accepted"
EP311 Update Product	NAP: POST Bundle - Create/Update resources in the bundle Update National Data: POST /upd/api/v1/national-data-bundle/ - Submit an Update National Data payload for DCP/MRP/SRP products Update Common Data: POST /upd/api/v1/common-data-bundle/ - Submit an Update Common Data payload for DCP/MRP/SRP products
EP318 Validate Product	POST Validate Bundle – To validate a bundle and the resources in the bundle Used for all procedure types; for both chapter 2 or legacy validation rules; and for both Create & Update
EP UC19 Nullify Product	POST /upd/api/v1/vmp-nullification/
EP401 Search document	GET DocumentReference - Search for DocumentReference No
EP402 Get/Retrieve document by Id	GET DocumentReference - Get a DocumentReference by Id Note

SPOR API Specification v2	API Manager
EP403 Create document	POST DocumentReference - Create a DocumentReference
EP404 Update document by Id	PUT DocumentReference - Update a DocumentReference Please note: API Manager method shows as PUT however please use POST with request header <code>is_update=true</code> .

4.1.3. 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

4.1.4. API EP309 Create, EP311 Update & Nullify product endpoints

4.1.4.1. 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
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

4.1.4.2. 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	
Update Common Data DCP/MRP/SRP/MRPH	/upd/api/v1/common-data-bundle/	chapter4	is update = true
Update National Data DCP/MRP/SRP/MRPH	/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 MRPH	/upd/api/v1/mrp-harmonisation-bundle/	chapter4	
Create Registered Homeopathic	/pms/api/v2	homeopathicschapter2 = true OR homeopathicschapter4 = true	
Update Registered Homeopathic	/pms/api/v2	homeopathicschapter2 = true	is update = true

Type and Procedure	POST Endpoint	Request header Key for validation rules	Additional Request header
		OR homeopathicschapter4 = true	
Create Parallel Trade	/upd/api/v1/ptp-bundle/	parallelchapter2 = true OR 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"> • Update NP • Update Registered Homeopathic • Update Parallel Trade • Update Pet • Update Common Data DCP/MRP/SRP • Update National Data DCP/MRP/SRP

Type and Procedure	POST Endpoint	Request header Key for validation rules	Additional Request header
			<ul style="list-style-type: none"> • Create MRP • Create SRP

4.1.4.3. 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>

Content-Type	Request body
XML	<code><root><permanentId> Permanent Identifier </permanentId></root></code>
	<p>For example:</p> <pre><root><permanentId>600011353107</permanentId></root></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."

4.1.4.4. 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.

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

POST	Content Location example showing format of the operation-outcome-id
Create & Update Parallel Trade	OperationOutcome/04b5bc00-16f4-4ea0-b33e-1a95029d8f8f-PTP
Create & Update Pet	OperationOutcome/2664fdf2-6aef-4540-8254-b6df6451b8af-PET

4.1.4.5. *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.

4.1.4.6. *Key changes in valid request bundle for create and update*

Attribute	Change
None	

4.1.5. **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 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:

Procedure type	Validation rules	Example file
		<ul style="list-style-type: none"> One with subject reference = MedicinalProductDefinition resource; populated with attributes from Section 2 (Vet EUIG Chapter 2), excluding the marketing authorisation number One with subject reference = 1st PackagedProductDefinition resource; populated with the Marketing authorisation number for Package 1 One with subject reference = 2nd PackagedProductDefinition resource; populate with the Marketing authorisation number for Package 2
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 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"> 2 or more values for those attributes that are repeatable. For example, Product name, ATC Vet Code, Manufacturing Business Operation 2 Packages (PackagedProductDefinition) 2 Manufactured Items (ManufacturedItemDefinition) 3 Ingredients (Ingredient)
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.

Procedure type	Validation rules	Example file
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
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

4.1.5.1. 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"

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

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>
</Bundle>

```

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

4.1.5.2. 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"> - modify product name - add another ATC Vet code - add another ManufacturedItemDefinition including this into the existing PackagedProductDefinition 	<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"> • "is_update=true" • "chapter4" = true or false for the validation rules to apply 	
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>

4.1.5.3. 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"> - Product name - Legal status of supply (product level) - Package description - Marketing authorisation number (product level) - Marketing authorisation status & dates - Responsible authority 	<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 Permanent identifier: 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"> • "is_update=true" • "chapter4" = true or false for the validation rules to apply 	
<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>

4.1.5.4. 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"> - modify common product name - add another ATC Vet code <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"> • "is_update=true" • "chapter4" = true or false for the validation rules to apply 	
<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>

4.1.5.5. 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"> • Change procedure type from NP to MRP • Add Common Name with Country = EU and Language = English • Add Reference member state and Concerned member state • Add Common package description in English (if doesn't exist) 	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"> • "chapter4" = true or false for the validation rules to apply 	
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"> • Contains the Common data that was added CMS:	

	<ul style="list-style-type: none"> Each new product is only populated with Common data, with status of Provisional 	
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4.1.5.6. 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_RMSProduct_GetEverything_version1.XML
Prepare Create SRP Bundle	<ul style="list-style-type: none"> Add new Concerned member state(s) Update common data as required 	Create SRP bundle prepared: UPD_1.6.1-4_CreateSRP_BasedOnRMSProduct_version1.XML
Create SRP via API	POST Bundle with request headers to /upd/api/v1/srp-bundle/ <ul style="list-style-type: none"> "chapter4" = true or false for the validation rules to apply 	
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"> Contains the new CMS Procedure type remains unchanged Contains the Common data that was updated 	

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

4.1.6. API Manage document

4.1.6.1. EP403 Create document

Resource Information

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

Response	
Body	Document with version 1 and document ID returned Note: ID expected format example: 3c46270e-3c3d-4869-a73c-ad4d7c3f2893

Query Parameters

None

Example Request

For UAT environment: POST <https://api-uat.pms.ema.europa.eu/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)

4.1.6.2. EP401 Search document

Resource Information

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

Path Parameters

Name	Description
Version	Service version number Example value: 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

4.1.6.3. EP402 Get/retrieve document

Resource Information

Endpoint	GET /pms/api/v2/DocumentReference/{document-id}
Request	

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

Path Parameters

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

Query Parameters

None

Example Request

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

4.1.6.4. EP404 Update document

Resource Information

Endpoint	POST /pms/api/v2/DocumentReference
Request	

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
Response	
Body	Document with version number incremented by 1

Query Parameters

None

Example Request

For UAT environment: POST <https://api-uat.pms.ema.europa.eu/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

4.1.6.5. 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	Returns the complete collection of submissions which the caller is entitled to view /vnra/v3?permanentIdentifier={permanentId}
Submission		upd/api/vnra/v3?permanentIdentifier=600013438271
APIM entry point	UAT	https://api-uat.pms.ema.europa.eu/upd/api/vnra/v3?permanentIdentifier=600013438271
APIM entry point	PROD	https://spor.azure-api.net/upd/api/vnra/v3?permanentIdentifier=600013438271
Query Parameters		Query Parameters (All Are Optional) Note: Calls to base url , (without parameters) /vnra/v3 will return the complete collection of submissions which the caller is entitled to view <ol style="list-style-type: none">1. productName : Product name – free text field and case insensitive2. productIdentifier : Product identifier – free text field3. permanentIdentifier : Permanent identifier – free text field4. mah : OMS LOC_ID of Product owner – LOC-1000053585. responsibleAuthority : OMS LOC_ID of Responsible authority (organisation) – LOC-1000016036. maNumber : Authorisation/registration/entitlement number – free text field7. procedureType : Procedure type – RMS Code8. 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

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
```

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?_size=5

https://spor.azure-api.net/upd/api/vnra/v3?_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": 12192,
      "submissionDate": 1731690475360,
      "submissionComment": "VNRA Submission Example",
      "submissionStatus": "PENDING",
      "potentialDecisionMaker": false,
      "decisionMakers": [
        "ORG-100003918"
      ]
    }
  ]
}
```

```
    ],
    "vnessFileName": "File02.zip",
    "decisionMaker": false
  }
],
"pageable": {
  "sort": {
    "empty": false,
    "sorted": true,
    "unsorted": false
  },
  "offset": 0,
  "pageNumber": 0,
  "pageSize": 1,
  "paged": true,
  "unpaged": false
},
"totalPages": 11719,
"last": false,
"totalElements": 11719,
"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

Retrieve a VNRA Submission Retrieve a specific VNRA submission identified by its submissionId

GET [/<submissionId>?summary={true|false}](#)
[upd/api/vnra/v3/456?summary=true](#)

APIM entry point UAT <https://api-uat.pms.ema.europa.eu/upd/api/vnra/v3/456?summary=false>

APIM entry point PROD <https://spor.azure-api.net/upd/api/vnra/v3/456?summary=false>

Path [/<submissionId>](#)

Parameter *<SubmissionId> is the ID of the submission to retrieve*

Query Parameters **Query Parameter (All Are Optional)**

summary (Optional) : `_(true|false)` Returns a summary view of the submission else a full view

Headers

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/v3/456?summary=false
```

Sample Payload

Summary=false

```
{  
  "submissionId": 12193,  
  "submissionDate": 1731690732660,  
  "submissionComment": "Example VNRA Submission",  
  "submissionStatus": "PENDING",  
  "variations": [  
    {  
      "variationId": 39103,
```

```
"vnraGroup": "45c0d03d-a091-43bb-b6cc-ffffb7ac4e5b8",
"vnraCode": "200000018623",
"implementationDate": 1731625200000,
"decisionDate": null,
"decisionAuthor": null,
"decisionMaker": "ORG-100003918",
"decisionComment": null,
"fieldChanges": [
  {
    "variationFieldChangeId": 17006,
    "key": "Ala-MarketingAuthorisationHolder-LocId",
    "currentValue": "600011430510",
    "currentValueAdditional": "\"600011430510\"",
    "proposedValue": "LOC-100002852",
    "proposedValueAdditional": "{\"locationId\":\"LOC-100002852\", \"name\":\"Pfizer
Manufacturing Deutschland GmbH - Heinrich-Mack-Strasse 35, Illertissen, 89257,
Germany\", \"targetField\":\"Ala-MarketingAuthorisationHolder-LocId\", \"location\":{\"locationId\":\"LOC-
100002852\", \"organisationId\":\"ORG-100004089\", \"organisationName\":\"Pfizer Manufacturing Deutschland
GmbH\", \"shortName\":\"Pfizer Manufacturing Deutschland
GmbH\", \"country\":\"DE\", \"locationIdsArray\":[\"LOC-
100002852\"], \"city\":\"Illertissen\", \"address\":\"Heinrich-Mack-Strasse
35\", \"postCode\":\"89257\", \"status\":\"ACTIVE\"}}",
    "changeProposedDate": 1731690742783,
    "changeImplementedDate": null
  }
],
"productName": "Example Product Name",
"productIdentifier": "aef948ee-a9a0-4a28-8b14-2f7896c8c614",
"permanentIdentifier": "600011430510",
"procedureNumber": "1",
"status": "PENDING",
```

```
        "productStatus": "200000005004",
        "marketingAuthorisationHolder": "LOC-100002852",
        "responsibleAuthority": "LOC-100002852",
        "authorisationCountry": "100000000377",
        "marketingAuthorisationNumber": "1",
        "rmsCode": "",
        "cmsCodes": [],
        "procedureType": "100000155062",
        "availabilityStatus": "100000072075",
        "pendingVNRAsForSameProduct": [
            5675,
            12191
        ]
    }
], ,
"foreseenDecisionMaker": "ORG-100003918",
"vneesFileName": "File01.zip"
}
```

Sample Payload**Summary=true**

```
{
    "submissionId": 12193,
    "submissionDate": 1731690732660,
    "submissionComment": "Example VNRA Submission",
    "submissionStatus": "PENDING",
    "variations": [],
    "vneesFileName": "File01.zip"
}
```

4.2.2.3. Download a VNeES

Download a VNeES	GET	Download a VNeES linked to a VNRA Submission /<submissionId>/vnees upd/api/vnra/v3/456/vnees
APIM entry point	UAT	https://api-uat.pms.ema.europa.eu/upd/api/vnra/v3/456/vnees
APIM entry point	PROD	https://spor.azure-api.net/upd/api/vnra/v3/456/vnees
Path		/<submissionId>
Parameter		<SubmissionId> is the ID of the submission to retrieve
Query Parameters		None
Headers		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/v3/456/vnees

4.2.2.4. Submit a decision for the VNRA

Submit a decision for the VNRA	PUT	VNRA submit decision - Approve/Reject VNRA /<submissionId>/decision_ upd/api/vnra/v3/456/decision
APIM entry point	UAT	https://api-uat.pms.ema.europa.eu/upd/api/vnra/v3/456/decision
APIM entry point	PROD	https://spor.azure-api.net/upd/api/vnra/v3/456/decision
Path		/<submissionId>

Parameter	<SubmissionId> is the ID of the submission containing the variation to approve
Values	<p>Decision APPROVED REJECTED</p> <p>Decision Date Date format should be provided as a string following SO 8601 Format. Examples: Date and time in UTC: 2024-11-21T11:34:35Z Date and time with the offset: 2024-11-20T23:34:35+02:00 Date: 2024-11-21</p>
Query Parameters	None
Headers	<p>Security Headers (Mandatory) v3 of the API require a mandatory Bearer Token which is passed via the Authorization header</p> <p>OAuth Bearer Token curl -X GET \ -H "Authorization: Bearer \$(oauth-access-token)" \ https://spor.azure-api.net/upd/api/vnra/v3/456/decision</p>
Sample Payload	<pre>{ "vnraDecisionItems": [{ "variationId": 40378, "vnraDecision": "APPROVED", "decisionComment": "This change is being approved", "decisionAuthor": "John", "decisionDate": "2024-11-21T00:00:00.000Z", "decisionMaker": "ORG-100003944" }] }</pre>

Sample Response

```
{
  "submissionId": 12630,
  "submissionDate": 1732116222663,
  "submissionComment": "Example VNRA Submission",
  "submissionStatus": "PENDING",
  "variations": [
    {
      "variationId": 40378,
      "vnraGroup": "5468f0a2-c218-470b-b523-45d4ecef2ff9",
      "productName": "Example NAP Product",
      "productIdentifier": "c0d2abcb-d0a0-4f0f-b32e-045849846a55",
      "permanentIdentifier": "700000047035",
      "procedureNumber": "EMEA/V/C/777777",
      "responsibleAuthority": "LOC-10000064",
      "authorisationCountry": "10000000535",
      "marketingAuthorisationNumber": "EMEA/V/C/777777",
      "vnraCode": "200000018632",
      "implementationDate": 1651446000000,
      "decisionDate": 1732186836,
      "decisionAuthor": "John",
      "decisionMaker": "ORG-100003944",
      "decisionComment": "This change is being approved",
      "status": "APPROVED",
      "marketingAuthorisationHolder": "LOC-100002852",
      "fieldChanges": []
    },
    {...}
  ],
  "potentialDecisionMaker": false,
  "decisionMakers": [
    "ORG-100003944"
  ]
}
```

```
    ],  
    "decisionMaker": true  
  }  
}
```

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://api-uat.pms.ema.europa.eu/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://api-uat.pms.ema.europa.eu/upd/api/vos/v3/vos-sales-json?permanentId=600000225806&yearFrom=2020-01&yearTo=2021-07&modifiedDate=gt2023-01-01>

GET <https://api-uat.pms.ema.europa.eu/upd/api/vos/v3/vos-sales-json?yearFrom=2020-01&yearTo=2021-07>

GET <https://api-uat.pms.ema.europa.eu/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, if the consumer searches for the last page, then page number parameter should be set to y-1.

Examples:

GET https://api-uat.pms.ema.europa.eu/upd/api/vos/v3/vos-sales-json?_size=5
GET https://api-uat.pms.ema.europa.eu/upd/api/vos/v3/vos-sales-json?_size=5&_page=2

Pagination Payload

```
"content": [...],  
"pageable": {  
  "sort": {  
    "empty": true,  
    "sorted": false,  
    "unsorted": true  
  },  
  "offset": 0,  
  "pageNumber": 0,  
  "pageSize": 100,  
  "paged": true,  
  "unpaged": false  
},  
"totalElements": 3823,  
"totalPages": 39,  
"last": false,  
"sort": {  
  "empty": true,  
  "sorted": false,  
  "unsorted": true  
},  
"size": 100,  
"number": 0,  
"first": true,
```

```
"numberOfElements": 100,  
"empty": false  
}
```

Sample Response Payload

```
{  
  "content": [  
    {  
      "productIdentifier": "aa4f3491-ea17-4b38-af07-41eaf4f1b55d",  
      "productName": "Example NAP Product",  
      "permanentIdentifier": "600010556679",  
      "authorisationProcedureNumber": "EMEA/V/C/777777",  
      "packageIdentifier": "68a997f8-2296-4210-9e78-8606b7e8dead",  
      "packageDescription": "Example Package",  
      "packSizeNumericValue": "600",  
      "packSizeUnitOfPresentation": "Actuation",  
      "packSizeUnitOfPresentationIdentifier": "200000002163",  
      "country": "Sweden",  
      "countryIdentifier": "100000000535",  
      "marketingAuthorisationNumber": "EMEA/V/C/777777",  
      "creationDateOfProduct": "2024-01-13",  
      "creationDateOfPackage": "2024-01-13",  
      "deletionDateOfPackage": null,  
      "yearMonth": "2024-09",  
      "volumeOfSales": "170",  
      "speciesIdentifier": "200000000205",  
      "speciesPercent": "100.00",  
      "doseFactor": "1.00",  
      "comment": "",  
      "modifiedDate": "2024-10-11 08:36:30.583"  
    }  
  ]  
}
```

```
    },
    (...),
  ],
  "pageable": {
    "sort": {
      "empty": true,
      "unsorted": true,
      "sorted": false
    },
    "offset": 0,
    "pageNumber": 0,
    "pageSize": 100,
    "paged": true,
    "unpaged": false
  },
  "totalElements": 2,
  "totalPages": 1,
  "last": true,
  "sort": {
    "empty": true,
    "unsorted": true,
    "sorted": false
  },
  "size": 100,
  "number": 0,
  "first": true,
  "numberOfElements": 2,
  "empty": false
}
```