Union Product Database (UPD) release notes

Referring to version 1.7.2434

Release date: 8 October 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
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Acronym key and glossary terms

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

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 1.7.2427-2, released on 28 August 2024) and subsequent hot fix released on 11 September 2024	**15**
Known Issues	**30**
Next release's expected date	*w/c 18 November 2024 (to be confirmed)*

Overview of new functionality(ies):

- The process of grouping existing National Authorised products in UPD following an **MRP after CMDv SPC harmonisation** is now available with this release. For further details, users are advised to consult the following bite-sized video and also read the following **important notes:**
    - In case of ongoing VNRA(s) for these NAPs it is not possible to proceed with the creation process**.**
    - It is not possible to proceed with the creation process if two or more NAPs from the same country are added, either as RMS or CMSs.
    - Extra caution is required when selecting the CMS products, because after the creation process is finalised, there is no option to remove nor to add other existing products.
    - The RMS product and each CMS product(s) will share the same common data.
    - The Product identifier of the RMS product is maintained and assigned to all CMSs' products.
    - The Permanent identifiers are maintained.
    - For existing packages: the same package identifier from the RMS product will be kept even though some updates are done during the creation process.
    - For new packages: a package identifier is generated and assigned to each package that has been created.
    - A new product version is assigned by the system to all products sharing the same product identifier.
    - All national data for the RMS/CMS products are maintained.
    - After the creation process, all actions in UPD impacting these products will follow the same rules defined for MRP products, except 'product nullification'.
    - After 18 November 2024, the *nullify*" button will be disabled/inactive for use during common and national update processes. In the meantime, users are requested to be careful to not accidently 'nullify' product during common and national update processes.

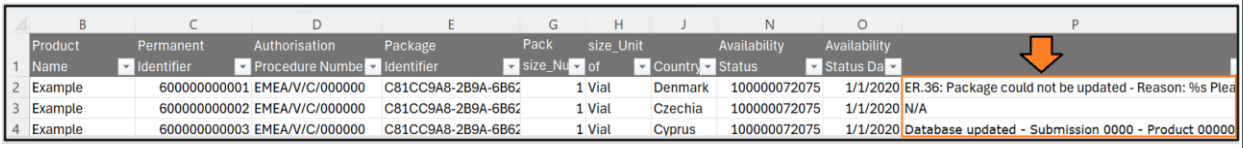
- **New UPD API capabilities:**
    - **MAHs can now connect their systems to UPD via API** and read all their product data**.**
    - **Members of the general public and organisations can now connect to UPD via API** and read all non-confidential product data. Note: the current API configuration does not provide access to product information (SPC, PL, Labelling) documents and public assessment reports. To retrieve these documents please use the public portal.

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

    - **firstly** request access by following the steps described in the UPD Registration guide for UI and API users (a revised version will be published by 11 October 2024 (do not use the version dated 27 September 2023),
    - **secondly** obtain the API specifications and end points (due to be published on the EMA UPD webpage by 16 October 2024).

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
1	Product Name	Permanent Identifier	Authorisation Procedure Numbe	Package Identifier	Pack size_Nu	size_Unit of	Country	Availability Status	Availability Status Da	
2	Example	600000000001	EMEA/V/C/000000	C81CC9A8-2B9A-6B62	1	Vial	Denmark	100000072075	1/1/2020	ER.36: Package could not be updated - Reason: %s Plea
3	Example	600000000002	EMEA/V/C/000000	C81CC9A8-2B9A-6B62	1	Vial	Czechia	100000072075	1/1/2020	N/A
4	Example	600000000003	EMEA/V/C/000000	C81CC9A8-2B9A-6B62	1	Vial	Cyprus	100000072075	1/1/2020	Database updated - Submission 0000 - Product 00000

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

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

For information:

- Combining many products within a single VNRA submission (irrespective of whether it is a technical grouping or supergrouping) via the UPD UI can lead to challenges both for the industry users when submitting, and NCA UI users when approving/rejecting the VNRA. The 'recommended' maximum limit is 2000 changes (1000 products x 2 VNRA codes = 2000

changes). For further information please see CMDv Best Practice Guide for Variations Not Requiring Assessment

- **Since 30 July and until 31 October 2024, marketing authorisation holders are required to manually add in UPD the relevant email addresses of the QPPV for their products, without submitting a VNRA.** Currently, UPD only contains the name and location of the QPPV. For the purpose of Regulation (EU) 2024/568 on fees and charges payable to the European Medicines Agency which will become applicable from 1 January 2025, advice notes, chargeable units line listing(s) and communications will be sent to the QPPV email address available in UPD. Please note that the feature will be available for a limited time and is only for the addition of the QPPV email address. Any other change to QPPV details (name and/or location) must follow the C.1 VNRA process. After this period, any necessary changes to QPPV details including the addition or update of email address, must follow the C.1 VNRA process. **NEW** From 8 October 2024 onwards the QPPV email attribute will be available during VNRA C1 submissions.

  The new QPPV email field will be visible for all Products under the Pharmacovigilance section and until the end of October 2024 will be an optional attribute to be provided by the Competent Authorities during both the creation and the update of a Product.

  From early November 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.

  Please note that during the update of a Product via API and in case the QPPV Email attribute is not provided in the submitted payload, the existing QPPV Email if already provided, will be deleted. Detailed information has been communicated via email to all industry users registered in the UPD. A separate information has been sent to all NCA users too.

- **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) are 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:
  - **Step 1)** the RMS creates the DCP adding as CMS a country belonging to EEA (this country should preferably have very few CMSs and no RMS products).
  - **Step 2)** to prevent the product from being available to the general public and the MAH, the CMS will not update the national part of the product and will keep the product in PROVISIONAL status
  - **Step 3)** finally, the CMS product will be nullified by the CMS once UPD allows having these products with only one RMS.

- **For NCA UAT Users:** Since 19 September 2024 a **new UAT environment** is accessible via a new URL https://upd-uat.ema.europa.eu/. A separate information with steps to follow has been sent to all NCA users by email on 16 September 2024.

Table of Contents

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	143996	CAP: there were two products for Exzolt. Only one exists now in UPD.
All UC	NCA UI & MAH UI	202411	New or Updated LOC-ID in OMS was not available in UPD.
UC01 Create product UC08 Update product	NCA UI & API	154083	(Marketing authorisation application) Legal basis: Vet EU IG Chapter 2 section 1.7.1 : missing RMS terms are now available
UC01 Create product	NCA API	196768	Create parallel trade product via API - MA Holder added in payload was accepted due to missing validation.
UC01 Create product	NCA UI & API	195811	It was possible to create a DCP with National documents, and the document were added to all RMS and CMSs.
UC04 Export Product Data	NCA UI & MAH UI	202485	Exported file had truncated data in Product owner column.
UC05 View product	NCA UI & MAH UI	83259	When View product QPPV displayed as N/A even although the product does have a LOC-ID populated.
UC06 Submit VNRA	MAH UI	192787	Some VNeeS files from VNRAs did not reach the Common Repository.
UC06 Submit VNRA	MAH UI	199888	When submitting a VNRA with VNRA codes C6 and C1 an error was displayed related to invalid references
UC08 Update Product	NCA API	180967	When updating a product via API, if MedicinalProductDefinition was not the first resource entry in the payload the version date displayed {{date}} in the UI view.
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
UC28 View VNRA	NCA UI & MAH UI	190002	Decision date on the pdf file downloaded was not the same as the one set in the decision form
UC31 Manage VNRA via API	NCA API & MAH API	194891	Download VNeeS endpoint is now available and working as expected
UC37 Automatic sending of notifications	NCA UI & MAH UI	194759	Email notification for updates missed the changes to documents.

UC37 Automatic sending of notifications	NCA UI & MAH UI	192235	An update to PSMF fields was presented as an update to 'Documents'.

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
All UC	API & NCA UI & MAH UI	202439	Some CAP products are missing the Procedure number.	
All UC	API & NCA UI & MAH UI	207879	CAP: there are two products each for Locatim(s) and Circovac, and only one for each is expected.	
UC03 Search	NCA UI & MAH UI	207017	Product Owner name presents duplicated LOC-ID information	
UC05 View product	API & NCA UI & MAH UI	211624	PSMF information has been lost in CAP products	
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	MAH UI	211736	Retrieve VNRA does not retrieve all the fields filled while saving draft	
UC06 Submit VNRA	MAH UI	212267	Search location by country does not retrieve results	User can select the desired location via the other available filters
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	NCA UI	211358	The incorrect procedure name is displayed in the side navigation menu header when updating an MRP_after SPC Harmonization product	
UC08 Update product	NCA UI	203140	User is unable to add new version for existing document during PTP update	
UC21 Manage Notifications	NCA UI & MAH UI	202959	Product version number in the Notification quick view and View Product screen do not match	
UC21 Manage Notifications	NCA UI & MAH UI	184984	Duplicated notifications are created for some VNRA actions	
UC34 Bulk Upload	NCA UI	206010	Documents for products grouped under an MRP as a result of an SPC Harmonisation procedure cannot be uploaded through the bulk upload functionality.	Documents can be uploaded using the Update product functionality.
UC34 Bulk Upload	NCA UI	201667	Missing validation allows for NCA Users who play the role of CMS to submit a National Document to the RMS product	
UC37 Automatic sending of notifications	NCA & MAH UI	203369	Email notifications are not generated for some of the actions performed in UPD	
UC33 Manage third country Product names	MAH UI	211662	Download third country product list fails with time out error if MRP as a result of an SPC Harmonisation procedure product is present in the data	

2. User support

API and UI users may seek support by contacting the User Support via EMA Service Now: 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. Regulatory authorities interested in connecting to the UPD via API (Application Programming Interface) should contact the Agency through the EMA Service Desk (ServiceNow).
3. Referentials Management System
4. Additional information on the Referentials Management System
5. Organisations Management System
6. Additional information on the Organisations Management System
7. Substances Management System

Annex 1: Overview of functionality and business value

Functionalities provided in this release

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

	General public can Search/view product (data)

NCA UI 	RMS can create DCP products (data and documents)
	RMS can create MRP products (data and documents)
	RMS can create SRP RMS can create SRP products (data and documents)
	RMS and CMS can complement DCP/MRP/SRP products with national DCP/MRP data (including documents)
	RMS can update Common data for DCP/MRP/SRP products (data and documents)
	NCA can create and update NAP products (data and documents)
	NCA can create & update Registered Homeopathic products (data and documents)
	NCA can create & update Parallel Trade products (data and documents)
	NCA can create & update Pet products (data and documents)
	NCA can group National Authorised products under an MRP following CMDv SPC harmonisation procedure (data and documents)
	NCA can save and retrieve drafts for product submissions
	NCA can Nullify product
	NCA can Bulk Upload Documents
	NCA can Transfer Marketing Authorisation
	Search/view/export products (data and documents)
	Notifications for Create and Update of products and Other Post-Authorisation Data actions

	View Volume of Sales information
	Search, View and Approve/Reject VNRA submissions
	NCA can Approve/Reject VNRA submissions on behalf of other NCAs when a Supergouping VNRA submission applies
	EMA and EC staff can update CAP products

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

MAH Validation UI 	Validate Volume of Sales submission file

Authorisation for NCA & MAH UI 	Integration with EMA Account Management (EAM) system for CA and Industry (MAH) roles
	CA users may search and view all Vet products
	MAH users may search and view only products under the responsibility of the organisations the user represents

Banner for UPD UI 	EMA can maintain messages to appear in banner of UPD UI

Functionality not included in this release

The following functionality is not included in this release.

NCA UI:

- None

MAH UI:

- None

General public API:

- The current API configuration does not provide access to product information (SPC, PL, Labelling) documents and public assessment reports. To retrieve these documents please use the public portal

Annex 2: Known issues

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

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

This table is ordered by Use Case number.

Use Case	Affects user	Issue reference (ADO)	Known Issue Description	Workaround
UC03 Search product	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.	
UC03 Search product	NCA UI & MAH UI	83234	Search limitations due to FHIR limitation or MS FHIR limitation.	
UC06 Submit VNRA & UC28 View VNRA	MAH UI	189703	View VNRA submissions page fails to load results using the Submission Status filter = approved	
UC07 Submit Volume of sales	MAH UI	192554	OPAD > Volume of sales submission for County = non-EEA (100000000028) is failing for some DCP/MRP/SRP products (ERR.19)	
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	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	NCA UI	189601	Search Manufacturer modal window fails when using filter 'City'
UC08 Update Product	NCA UI	202277	Edition of the first manufacturer value in a product with multiple manufacturers throws an incorrect error
UC25 Update Availability status	MAH UI	177951	Submissions of Availability Status fails for some CAP products with Error 36
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 is not able to view the VNRA Submission even after the Responsible Authority has been corrected in the product(s) included in the submission.
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	180823	View Submission of third country product names' returns no results for new and previous submissions

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**
UAT	TBC	TBC	TBC	*w/c 11 November 2024 (to be confirmed)*
PROD	TBC	TBC	TBC	*w/c 18 November 2024 (to be confirmed)*

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	GET MedicinalProductDefinition - Search for a MedicinalProductDefinition resource or resources
EP303 Get Product	GET MedicinalProductDefinition - Get a MedicinalProductDefinition ID
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

SPOR API Specification v2	API Manager
EP309 Create Product	NAP: POST Bundle - Create/Update resources in the bundle DCP: POST dcp-bundle - Submit a Create DCP payload MRP: POST mrp_bundle – Submit a Create MRP payload SRP: POST srp_bundle – Submit a Create SRP payload Registered homeopathic: POST Bundle - Create/Update resources in the bundle Parallel trade: POST ptp-bundle - Create/Update resources in the bundle Pet: POST pet-bundle - Create/Update resources in the bundle Refer to 4.1.5.2. Create and Update endpoints
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"

SPOR API Specification v2	API Manager
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
EP403 Create document	POST DocumentReference - Create a DocumentReference

SPOR API Specification v2	API Manager
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 is_update=true.

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

Regulatory authorities interested in connecting to the UPD via API (Application Programming Interface) should contact the Agency through the EMA Service Desk (ServiceNow).

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
Request header not included	Vet EUIG Chapter 2
false	Vet EUIG Chapter 2

Value	Validation rules applied
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
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	
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	

Type and Procedure	POST Endpoint	Request header Key for validation rules	Additional Request header
		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 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: • Update NP • Update Registered Homeopathic • Update Parallel Trade

Type and Procedure	POST Endpoint	Request header Key for validation rules	Additional Request header
			• Update Pet • Update Common Data DCP/MRP/SRP • Update National Data DCP/MRP/SRP • Create MRP • Create SRP

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	{
	"permanentId": "*Permanent Identifier*"
	}

	For example:
	{
	"permanentId": "600011984989"
	}

XML	<root><permanentId> *Permanent Identifier* </permanentId></root>
	For example: <root><permanentId>600011353107</permanentId></root>

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.

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

POST	Content Location example showing format of the operation-outcome-id
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 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

Procedure type	Validation rules	Example file
		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 _____ 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: • 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

Procedure type	Validation rules	Example file
NAP	Chapter 4 Legacy	UPD_1.5.1-0_NAP_Legacy_Cx_ManyAttributesAndResources_MANumberAtMedicinalProductLevel.XML This example contains: • 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.
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_VetIGl.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

Procedure type	Validation rules	Example file

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	Bundle.entry.request must also be populated. Bundle.entry.request.method should be: • PUT to update an existing resource • POST to add a new resource Bundle.entry.request.url should be: • 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>
```

- 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	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. - modify product name - add another ATC Vet code - add another ManufacturedItemDefinition including this into the existing PackagedProductDefinition	Sample XML of Get Everything response used as a starting point: UPD_1.5.1-0_EP311_UpdateProduct_GetEverything_version1.XML Update bundle prepared: UPD_1.5.1-0_EP311_UpdateProduct_RequestBundle.XML
Update product via API	POST Bundle with request headers to /pms/api/v2 • "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	Sample XML of GET everything after update: UPD_1.5.1-0_EP311_UpdateProduct_GetEverything_version2.XML

4.1.6.3. How to use Update National Data DCP/MRP/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. Edit the payload and add national data e.g. - Product name - Legal status of supply (product level) - Package description - Marketing authorisation number (product level) - Marketing authorisation status & dates - Responsible authority	Create DCP using this example file: UPD_1.6.16-5_CreateDCPForUpdateNationalData.XML Product Identifier: d0f4414c-cd65-478b-921e-f107c66f7a85 CMS for Italy **Permanent identifier:** 600000251886 Sample XML of Get Everything response used as a starting point: UPD_1.6.16_DCP_UpdateNationalData_600000251886_GetEverything_v1.XML Update bundle prepared: UPD_1.6.16_DCP_UpdateNationalData_600000251886_BasedOn_v1.XML
Update product via API	POST Bundle with request headers to /upd/api/v1/national-data-bundle/ • "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	Sample XML of GET everything after update: UPD_1.6.16_DCP_UpdateNationalData_600000251886_GetEverything_v2.XML

4.1.6.4. How to use Update Common Data DCP/MRP/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. Edit the payload e.g. - modify common product name - add another ATC Vet code Important: any national data that has been populated should be also included in the update bundle.	Sample XML of Get Everything response used as a starting point: UPD_1.5.3-4_DCP_UpdateCommonData_Product_600000149642_GetEverything_Version1.XML Update bundle prepared: UPD_1.5.3-4_DCP_UpdateCommonData_Product_600000149642_UpdateBundleBasedOnVersion1.XML
Update product via API	POST Bundle with request headers to /upd/api/v1/common-data-bundle/ • "is_update=true" • "chapter4" = true or false for the validation rules to apply	
Check operation outcome	MSG_CREATED message expected containing Permanent identifiers	
EP304 Get Product Full	Only the Common data in the RMS and CMS products under that Product Identifier will be updated	Please refer to Known issues section for any outstanding issues where national data submitted when updating common data is not being ignored.

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	• 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/ • "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: • Contains the Common data that was added CMS:	

	• Each new product is only populated with Common data, with status of Provisional	

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_RMSProduct_GetEverything_version1.XML
Prepare Create SRP Bundle	• 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/ • "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: • Contains the new CMS • Procedure type remains unchanged • Contains the Common data that was updated	

	New CMS: • Each new product is only populated with Common data, with status of Provisional, and procedure type of SRP	

4.1.7. API Manage document

4.1.7.1. 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://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

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.atttachement,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

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

4.1.7.4. 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://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	***Returns the complete collection of submissions which the caller is entitled to view*** ***/vnra-submission?permanentIdentifier={permanentId}*** ***upd/api/vnra/v3/vnra-submission?permanentIdentifier =600013438271***
APIM entry point	UAT	***https://spor-uat.azure-api.net/upd/api/vnra/v3/vnra-submission?permanentIdentifier=600013438271***
APIM entry point	PROD	***https://spor.azure-api.net/upd/api/vnra/v3/vnra-submission?permanentIdentifier=600013438271***
Query Parameters		**Query Parameters (All Are Optional)** ***Note: Calls to base url , (without parameters) /vnra-submission will return the complete collection of submissions which the caller is entitled to view*** 1. **productName : Product name – free text field and case insensitive** 2. **productIdentifier : Product identifier – free text field** 3. **permanentIdentifier : Permanent identifier – free text field**

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&_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"
```

```
            }
          ]
        }
      ]
    }
  ],
  "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

Retrieve a VNRA Submission	GET	Retrieve a specific VNRA submission identified by its submissionId ***/vnra-submission/<submissionId>?summary={true|false}*** ***upd/api/vnra/v3/vnra-submission/456?summary=true***
APIM entry point	UAT	***https://spor-uat.azure-api.net/upd/api/vnra/v3/vnra-submission/456?summary=false***
APIM entry point	PROD	***https://spor.azure-api.net/upd/api/vnra/v3/vnra-submission/456?summary=false***
Path Parameter		***/vnra-submission/<submissionId>*** ***<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		**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
Sample Payload **Summary=false**		{ "submissionId": 1596, "submissionDate": 1694450625907, "submissionComment": "Submit VNRA For NAP 11/09/2023", "submissionStatus": "APPROVED",

```
  "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": "Beyond Automation",
      "decisionMaker": "ORG-100003944",
      "decisionComment": "Comment Beyond Automation",
      "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

Download a VNeeS	GET	Download a VNeeS linked to a VNRA Submission ***/vnra-submission/<submissionId>/vness*** ***upd/api/vnra/v3/vnra-submission/456/vness***
APIM entry point	UAT	***https://spor-uat.azure-api.net/upd/api/vnra/v3/vnra-submission/vness***
APIM entry point	PROD	***https://spor.azure-api.net/upd/api/vnra/v3/vnra-submission/456/vness***
Path Parameter		***/vnra-submission/<submissionId>*** ***<SubmissionId> is the ID of the submission to retrieve***
Query Parameters		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

Submit a decision for the VNRA	PUT	VNRA submit decision - Approve/Reject VNRA ***/vnra-submission/<submissionId>/decision*** ***{*** ***upd/api/vnra/v3/vnra-submission/456/decision***
APIM entry point	UAT	***https://spor-uat.azure-api.net/upd/api/vnra/v3/vnra-submission/456/decision***
APIM entry point	PROD	***https://spor.azure-api.net/upd/api/vnra/v3/vnra-submission/456/decision***
Path Parameter		***/vnra-submission/<submissionId>*** ***<SubmissionId> is the ID of the submission containing the variation to approve***
Query Parameters		**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.

Regulatory authorities interested in connecting to the UPD via API (Application Programming Interface) should contact the Agency through the EMA Service Desk (ServiceNow).

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

GET 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.