Union Product Database (UPD) release notes

Referring to version 1.7.2413d

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

Pertaining to the structure of these release notes: they have been refined and simplified for enhanced accessibility to all users, and now comprise of 3 sections and 4 annexes. It should be noted that specific segments have been excised, owing to their availability within other documents (such as the EU IG).

Overview of key changes:

With every new release, the UPD release notes are updated to highlight to the user the changes compared to previous versions by detailing new/updated functionalities and/or issues that have been resolved, are known, and/or are newly reported.

Resolved issues since the previous release (UPD version 1.6.42, released on 12 February 2024)	**53**
Known Issues	**86**
Next Release expected date	**9 April 2024** *(for further details please refer to Annex 3)*

Overview of new functionality(ies):

- MAH UI user functionality to group nationally authorised veterinary medicinal products from different Member States or MRP/DCP/SRP products with different RMSs within one single VNRA submission (hereafter called 'VNRA Supergrouping') and to define a Responsible Authority as the Foreseen Decision Maker:
    - Please be aware of a pre-submission condition which requires the Foreseen Decision Maker for the VNRA Supergrouping to be requested and agreed in advance of the submission. This process is managed by the NCAs outside of the UPD.
    - After the submission both MAH and NCAs are able to search for specific VNRA Supergrouping submissions by using the Decision Maker defined as a search criterion.
    - The NCA UI/API user from the Responsible Authority defined as Foreseen Decision Maker will be responsible to approve/reject the whole VNRA Supergrouping submission on behalf of the remaining involved NCAs and is the only one having the permission to perform that action.
    - Please note that it is not possible to include centrally authorised products in a VNRA Supergrouping submission.
    - The process for VNRA Supergrouping is different from the VNRA technical grouping and both should not be mixed. Therefore all users are strongly advised to read the revised CMDv Best Practice Guide for Variations Not Requiring Assessment (EMA/CMDv/308754/2020 - Rev.5 or later[1]), before they start using the VNRA Supergrouping and have seen the dedicated bite-size video available under 'video tutorials' at EMA's UPD webpage.
- As a UPD user you may experience improvements in reliability, availability and system performance due to a major architectural update implemented in this release (decoupling MDM-FHIR).

Notes:

- In case of receiving an error file after the Availability Status (AvS) submission, MAHs are advised to follow these steps:
    - If the errors in the file are due to business validations (see section 4.3.2 of Vet EU IG Chapter 7), **fix the errors and resubmit the file**.

- **If the file contains ER.36** (see section 4.3.1 of Vet EU IG Chapter 7), then you may receive two type of error files:
  - In the first case, **no updates have been processed successfully**. This can be evidenced by the fact that last column in the error report only contains ER.36 and values of type 'N/A'. In this case, capture the ER.36 errors in an Excel or CSV file and submit it as a ticket to EMA Service Now: https://support.ema.europa.eu/, and then **resubmit the part of the file containing values 'N/A'**.
  - In the second case, **some updates have been processed successfully**. This can be evidenced by the fact that last column in the error report contains ER.36 values and values of the type 'Database updated - Submission 0000 - Product 00000'. In this case, just capture the ER.36 errors in an Excel or CSV file and submit it as a ticket to EMA Service Now: https://support.ema.europa.eu/. No need to resubmit the part of the file containing values type 'Database updated - Submission 0000 - Product 00000'.
- Once the errors of type ER.36 have been addressed, incorporate the AvS of those products into the next submission, and if you again receive any error repeat all the above steps.

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

For information:

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

[1] The revised CMDv Best Practice Guide for VNRA (EMA/CMDv/308754/2020 - Rev.5) is expected to be published end of March 2024.

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1. Summary of issues

1.1. Resolved issues

Use Case	Affects API and/or UI	Issue reference (ADO)	Resolved issues
UC01 Create product	API	82433	MedicinalProductDefinition.name.type used to be an attribute that was required to be populated. This is no longer required to be populated for the create. When you retrieve the product you will find this attribute has been populated with the term code for full name. This ticket has been closed because the issue is considered obsolete.
UC01 Create product	API	82432	PackagedProductDefinition.package.quantity is not an attribute to be populated for a create. When you retrieve the product you will find this attribute has been populated with a value of zero. The attribute quantity is part of the metadata populated by the system that is not under the control of UPD. This ticket has been closed and the issue is considered obsolete as it only affects read-only information operations and it is not blocking any operations.
UC01 Create product	NCA UI	92814	Create SRP where no Pack size specified for a package: when create submitted the page remained with progress control and product was not created.
UC01 Create product **UC08 Update product**	API & NCA UI	82481	Do not select term of "Full name" when entering a name part. It is not an option that should be included as an available option. If used, the created/updated product will have an additional full name rather than the intended name part. Resolved as the Vet EU IG was updated to provide clear guidance to the UPD users on how the Full name of a product needs to be provided.
UC01 Create product **UC08 Update product**	NCA UI	82628	Error Messages need to be more meaningful. Ticket closed as this will be covered by upcoming feature 117. No changes implemented now.
UC01 Create product	API & NCA UI	151180	CAP: incorrect Availability values had been assigned by the system (according to chapter 2) to a new CAP authorised under Regulation (EU) 2019/6 at the time of creation.

UC01 Create product	API & NCA UI	151748	DCP/MRP/SRP: When creating a DCP/MRP/SRP, the Availability Status value was not displaying “not marketed” as default term.
UC01 Create product	API & NCA UI	152291	NAP: When Creating a NAP, the Availability Status was not displaying "not marketed" as default term. The default values for Availability status were not populated into each Package.
UC01 Create product	NCA UI	92479	The “Add Package” button remained disabled when adding new packages during the creation of an MRP product.
UC01 Create product	API	83093	Using $Validate endpoint for Parallel Trade product: the response code is 400 Bad Request and validation errors that are not relevant for Parallel Trade product are displayed.
UC01 Create product **UC08 Update product**	NCA UI	82617	The date field could have given an erroneous value when you clicked on the date picker widget after entering some partial value manually.
UC01 Create product **UC08 Update product**	NCA UI	151471	When creating or updating products (NAP/DCP/MRP/SRP), the button to Retrieve reference product should be activated only for specific options selected in the Legal basis field. Instead, it was always active.
UC01 Create product **UC08 Update product**	API & NCA UI	154001	NAP: It was possible to add duplicate product name for same Country/Language during Create and Update of NAP product. This should have given a validation error and not allow the submission of the Create or Update.
UC01 Create product **UC08 Update product**	NCA UI	82440	This should not be mandatory for Legacy products. An ingredient must be selected in this release for the create of a NAP product. It is no longer mandatory for a DCP. This ticket has been closed as it only affects legacy data which already has been provided to UPD by Competent Authorities.
UC01 Create product **UC08 Update product**	NCA UI	153736	Organisations were being displayed with full name when acronyms were available, during the create and update of products.
UC01 Create product	NCA UI	151167	DCP: expected validation error was not displayed if submit Create DCP with same country as RMS and CMS. Submission was not possible with same value for both but there was no error message.
UC03 Search product	NCA UI & MAH UI	112859	Sometimes the pagination widget in the bottom of the search page displays the total number of results and current range of products being displayed on the page overlapping the drop down for the number of products to display per page.
UC03 Search product	NCA UI & MAH UI	152101	Searching products using product name filter containing Bulgarian Letter (й) did not list product even if it included that letter in the product name.

UC03 Search product	NCA UI & MAH UI	164941	Not all previous filters were retained after clicking 'Back to search results'.
UC03 Search product **UC05 View product**	NCA UI & MAH UI	146968	After creating an MRP, the RMS product, which was a NAP, did not display the Common product name in the Search results table or in the heading at the top of the View product screen.
UC05 View product	API & NCA UI & MAH UI	83432	View CAP product – the MAH Organization name displayed may not be the same as seen in SPOR Portal for that LOC ID.
UC05 View product	NCA UI & MAH UI	82822	When view product, there has been an example where Marketing authorisation date shows differently for MAH and NCA user. This ticket has been closed because the issue occurs infrequently and examples have differed by 1 day. Anyway a task 83197 was created to further investigate this.
UC05 View product	NCA UI & MAH UI	152389	CAP products only: Surrendered packages were included when View Product in UPD UI and they should have been excluded.
UC06 Submit VNRA	MAH UI	82652	The overall date of submission showed a red outline if it had been populated, then the value removed, and individual values added for each variation for each product.
UC06 Submit VNRA	MAH UI	152295	It was not possible to submit a VNRA if the Date of implementation at Submission information level was not filled in.
UC06 Submit VNRA	MAH UI	143619	When submitting a VNRA for Automated codes C1 QPPV and C5, C6 PSMF, the labels on the screen for the current and proposed values were not as expected and not aligned with the mock-up.
UC07 Submit Volume of Sales	MAH UI	92026	Download Packages - some users receive the following error and download file is not created: "ERROR Resource(s) not found for User Id: Y and Organisation Id: X" (from release 1.5.4).
UC07 Submit Volume of Sales	MAH UI	144183	There appeared to be two duplicate validation errors for the Species %. ER.27 and ERR.15. ER.27 was displayed.
UC08 Update product	API & NCA UI	147083	Update product for any procedure type: The error message when updating product that had a non-current Substance was not the correct error message and was different across the procedure types. Error message was amended for all procedures to the same expected wording.
UC08 Update product	API & NCA UI	147984	When updating National Data for DCP/MRP/SRP, the Availability status was not updated to "Not marketed" when the Authorization status was

			updated to Suspended or Revoked, if the product had no existing record for Availability status from when the product was created.
UC08 Update product	NCA UI	82735	The quantity and units of presentation were not shown in the package table for the Manufactured Item. The values were displayed if the package was edited. This was only an issue with the display of information on the UI, and no data had been lost from the product.
UC08 Update product	NCA UI	156077	If Strength (free text) or Reference Strength (free text) was present, deleting or editing the free text disabled the 'Edit Ingredient' button.
UC18 Manage document	API	148970	In the EP401 Search document endpoint, an error was returned if a value greater than 100 was used for the page size parameter "_count".
UC21 Manage Notifications	NCA UI	82641	For an update National Data for DCP/MRP/SRP UPD-UC08-AC018, the CMS should only see notifications for their own product. At present they also see notifications for RMS & other CMS products. This ticket has been closed because the UPD business analysis team has confirmed that this behaviour is aligned with the specifications.
UC21 Manage Notifications	NCA UI	83359	Notification for VNRA actions Submitted/Approved/Rejected for a NAP product should not be visible for an NCA who is not the Responsible Authority. This ticket has been closed because the UPD business analysis team has confirmed that this behaviour is aligned with the specifications.
UC21 Manage Notifications	NCA UI & MAH UI	146700	Notifications for PET products showed "null" in the field "Procedure Number" instead of "N/A".
UC25 Update Availability status	MAH UI	131136	Submission of Availability status - example where products submitted in the file have not been updated. Further analysis is required before further details can be provided of affected products but appears to be some DCP/MRP/SRP products where availability status entries for countries other than the Authorisation country were incorrectly added into some products.
UC25 Update Availability status	MAH UI	149382	After downloading the Availability status for one or more products and clicking the Reset button, then selecting other product(s), the downloaded file contained products previously downloaded.
UC25 Update Availability status	MAH UI	149816	When select to download a second time after previously selecting a product and then deselecting one or more products - the download file still contained the deselected products.
UC25 Update Availability status	MAH UI	83433	Download Product data file: The 'Availability Status' column in the downloaded Product data file might have shown zero for the RMS Term

			code if no default 'Availability Status' value had been populated at the time the product or package was created.
UC28 View VNRA	NCA UI	145289	View VNRA submissions screen sometimes showed highlighted VNRA incorrectly to CA who was not the decision maker.
UC28 View VNRA	NCA UI & MAH UI	83091	Sometimes when selecting to view a submission the display is incomplete (empty boxes for combination of VNRA code & product). Viewing the submission at another time is successful. Potentially only an issue when also experience issues searching products due to timeouts in the UI. This ticket has been closed as reported issue is no longer reproducible.
UC28 View VNRA	MAH UI	150814	When MAH user viewed submission the decision maker field was filled in with MAH user Organisation name.
UC28 View VNRA	NCA UI	152323	DCP/MRP/SRP products only: The VNRA card was not always highlighted for the decision maker user.
UC28 View VNRA	NCA UI	152369	For DCP/MRP/SRP products only: When there was a submission for two or more variations and one can be approved by the CA, but the other cannot be approved, both variations were highlighted. Only the variation that the logged-on CA can approve (based on their role as RMS/CMS) should have been highlighted.
UC28 View VNRA	NCA UI	83242	NCA Germany only for DCP/MRP/SRP where National Data has been populated with Responsible Authority of either PEI or the BVL. Where VNRA Submission made for product: Both PEI and the BVL can view and approve the submission and they should only be able to view those submissions where they are the Responsible authority. Only where National Data has not been populated and Responsible Authority is the default value of EMA both PEI and the BVL should be able to view a VNRA submission. This ticket has been closed as it is assumed that affected legacy data which was corrected and no new issues were reported by both NCAs.
UC33 Manage Third Country Product Names	MAH UI	150127	Download file for Third Country Product Names contained an extra column at the end of each row for a product with value of "null". If submission file based on the download file contained this extra column the submission would fail with an error.
UC33 Manage Third Country Product Names	MAH UI	150681	Download Third Country Product Names file: the Delete column was filled with "null " values and new column added with no header and with "null" values.
UC33 Manage Third Country Product Names	MAH UI	142332	A user affiliated with two or more Organisations did not see data values added by another MAH user who was only affiliated with one of those

			Organisations. The issue affected both Third Country Product Names and Products Grouping.
UC33 Manage Third Country Product Names **UC38 Products Grouping**	MAH UI	151721	If the logged on MAH has more than 10,000 products, the download files for Third Country Product Names and Products Grouping only contain the first 10,000 products. Issue would not be fixed as this is not a reasonable problem to be faced by any MAH.
UC33 Manage Third Country Product Names	MAH UI	150635	The downloaded file had null value in "Delete" column and an extra trailing empty column.
UC34 Bulk Upload	NCA UI	150848	Bulk upload of documents to CAP would fail for products with pre-existing documents.
All UC	MAH UI	82803	All Other Post-Authorisation Data screens where MAH searches by Product Owner: if the Location in search criteria is for an Organisation that the user has no UPD role for, the screen is blocked with the progress control. User needs to refresh the page to get out of this. The search should return a message of no results found.

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	API & NCA UI	158033	When creating a product from an existing one, the user can select a product that is not under their responsibility, and that should not be allowed by the system. A user shall be able to select only products under his/her responsibility.	
UC01 Create product	API & NCA UI	157738	Create NAP from existing product - import product does not clear cache. When creating a product from an existing one, if the user repeats the process selecting different products, the second time the system will display the information retrieved from the first product.	The user needs to refresh the page in order to get the correct information of the product.

UC01 Create product	API & NCA UI	162071	When cancelling the creation of a product, confirmation modal is not being presented to the user. User is directed into the Home page.	
UC01 Create product	NCA UI	166397	When retrieving a product that has documents on the creation of MRP or DCP, these are not visible on the create form.	New products will still have the expected common documents. They would just not be listed on the create form.
UC01 Create product UC08 Update product	API	160889	It is possible to add duplicate product name for same Country/Language during Create and update of NAP product, which is not valid.	
UC05 View product	NCA UI & MAH UI	165520	Navigating from older versions of the product to most recent, QPPV information may be incorrectly displayed.	
UC06 Submit VNRA	MAH UI	155448	Submit VNRA - The fields on the VNRA level are not changed when products have different values C1/C5/C6 codes.	
UC06 Submit VNRA	MAH UI	161519	Foreseen Decision Maker dropdown list is not displaying all countries (options).	User should type in the desired country, matching options to the user input will then be presented, even if not initially visible.
UC07 Submit Volume of Sales	MAH UI	155860	Frequent timeouts when trying to download list of packages.	
UC07 – Download Packages and Submission of Volume Sales via Form	MAH UI	158743	Surrendered packages are included in the downloaded VoS csv file.	
UC08 Update product	API & NCA UI	161214	Update button not disabled when mandatory field Authorized Pharmaceutical Form is removed.	
UC08 Update product	NCA UI	166257	When the RMS deletes and adds a new national document, the common documents are removed from the CMS.	Problem only replicated when removing and adding a different national document. Doing the update of a new version of the existing documents does not raise any problem.

UC08 Update product	NCA UI	167180	RMS National data update will raise an error if a package has been deleted on a previous Common Update.	Is possible to update the product via API with the correct payload.
UC09 Approve/Reject VNRA	NCA UI	168118	Decision table is not updated if information is added at VNRA level.	
UC09 Approve/Reject VNRA	NCA UI	169536	In the VNRA form for approval/rejection of VNRA A.4, the label 'To/Proposed values' displays as well incorrectly the RMS code of the VNRA that has to be treated.	
UC21 Manage Notifications	NCA UI	159088	VNRA Notifications & VNRA View – An NCA User without permission to see VNRA has available the link to access the submission and is advised to try again later on error raised.	
UC21 Manage Notifications	NCA UI & MAH UI	161905	Back to search results button clears applied filter options.	
UC21 Manage Notifications	NCA UI & MAH UI	167823	Notification Action field is being wrongly populated with "*UPDATE, Upload Document*" for Nullify, Marketing status update, Transfer of ownership and Availability status actions	
UC21 Manage Notifications	NCA UI & MAH UI	167943	Notification is wrongly displayed as "*UPDATE, Upload Document*" for Update Product.	
UPD-UC25 - Update availability status and placing on the market via UI	MAH UI	160241	Surrendered packages are included in the downloaded AVS csv file.	
UC27 View Volume of Sales	NCA UI & MAH UI	157903	Reset button not working as expected, not all search fields are cleared, and result table defaults to "No results found"	Refreshing the page to start a new search.
UC28 View VNRA	NCA UI & MAH UI	162882	All queries on VNRA search take the value of Submission Status = PENDING	User can set an explicit value on Submission Status filter to get the expected results
UC28 View VNRA	API & NCA UI	162898	NCA - DCP/SRP - The Decision Maker, RMS and CMS checkboxes view working only when CMS	

			option was selected (should be OR instead of AND logic)
UC33 Manage Third Country Product Names	MAH UI	159277	Submission of Third country data of the DCP/SRP Product will fail if one of the CMS products is nullified or has a CMS which has marketing status set to suspended.
UC33 Manage Third Country Product Names	MAH UI	129500	3rd Country Data-Industry Search/View User not able to view and access download 3rd country data file and view submission of 3rd country data Menu

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. Registration Process for UPD (See under section 'How to register') (PDF document)
2. SPOR API Specification V2 R5 (europa.eu) API specifications for SMS and PMS, based on FHIR
3. HL7 FHIR Release 5 Preview 2: the authoritative source for the FHIR specifications used by EMA to implement SMS and PMS API
4. Referentials Management System
5. Additional information on the Referentials Management System
6. Organisations Management System
7. Additional information on the Organisations Management System

Annex 1: Overview of functionality and business value

Functionalities provided in this release

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 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

NCA UI	RMS can create DCP products (data and documents)

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

	Integration with EMA Account Management (EAM) system for CA and Industry (MAH) roles
	CA users may search and view all Vet products

Authorisation for NCA & MAH UI 	MAH users may search and view only products under the responsibility of the organisations the user represents

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

Functionality not included in this release

The following functionality is not included in this release.

NCA UI:

- None

MAH UI:

- None

Annex 2: Known issues

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

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

This table is ordered by Use Case number.

Use Case	Affects user	Issue reference (ADO)	Known Issue Description
All UC	NCA UI & MAH UI	83277	CAP products - some products with status of Withdrawn or Surrendered have been loaded into UPD from EMA's source system (SIAMED) with status of Valid.
All UC	API & NCA UI & MAH UI	143996	CAP: there are now two products for Exzolt and expected there just to be one.
All UC	API & NCA UI	92757	OMS to UPD updates: New or Updated Organisations and Locations from OMS are not available in UPD.
API Manager	API	82994	API Manager has duplicate Products listed for "UPD API" (v1 and v3 versions of EP); and exposes many EP not intended to be used by API NCA Users. There should only be the one product at this time with v1 Endpoints.
Data fix	NCA UI & MAH UI	83291	Data Fix Parallel Trade products: where Source Member State product had two or more Ingredients, the first Ingredient from that product was duplicated in the new Parallel trade product. This was due to bug UPD-13162. EMA to query existing Parallel Trade products to identify products that were affected by this issue and then assess how to correct.
UC01 Create product	API	83150	Create NAP via API: if payload contains attributes with CMS information this is accepted and the information stored. These attributes should either give validation error or be ignored as not applicable for this procedure type.
UC01 Create product	API	168950	Create Homeopathic Product via API: if payload contains attributes with CMS information this is accepted and the information stored. These attributes should either give validation error or be ignored as not applicable for this procedure type.
UC01 Create product	API	83042	Create parallel trade product via API: the GET OperationOutcome response is populating in the DCP format and it was expected would use same pattern as NAP.
UC01 Create product	NCA UI	82325	Each ingredient must be selected at least once in one of the manufactured items. This rule is not currently validated.

			If you don’t include an Ingredient in a Manufactured item the product will be created but any Ingredient not referenced may not be saved.
UC01 Create product	NCA UI	92816	Free text strength values are not displayed when selecting Ingredients to link in Pharmaceutical product and Manufactured item sections.
UC01 Create product	API & NCA UI	82830	If there has been successful rollback in MDM of a transaction when creating a product, there is still a product created (with orphaned entries).
UC01 Create product	API	144310	Validate endpoint for Create DCP is incorrectly giving a validation error related to missing Marketing authorisation number. When Create DCP payload is posted to the Create endpoint there is no validation error and products are created as expected.
UC01 Create product	API	82249	Validation in all resources of URN UUID for full URL attribute: letters allowed are only a to f to form the hexadecimal set from 0 to f pattern of 8-4-4-4-12 The post may not be rejected or may not give an error message that clearly identifies this as being the issue.
UC01 Create product UC08 Update product	NCA UI & API	154083	(Marketing authorisation application) Legal basis: Vet EU IG Chapter 2 section 1.7.1 : some terms from the RMS list are missing.
UC01 Create product UC08 Update product	API & NCA UI	147296	CA should only be able to add Availability status entry for the same country as the Authorisation country of their product.
UC01 Create product UC08 Update product	NCA UI	83327	If product contains two or more Pharmaceutical products, the labels are not properly formatted on the View product screen. The case where two or more Pharmaceutical products should link to the same Ingredient to be considered and review documentation. An Ingredient may only be linked to one Pharmaceutical product in this release.
UC01 Create product UC08 Update product	API & NCA UI	82761	The Manufactured Item Quantity will be truncated to 2 decimal places. It should be possible to enter greater precision if required of up to 8 decimal places.
UC01 Create product UC08 Update product	API & NCA UI	82570	UC01 Create & UC08 Update Product - POST should be valid where Reference Strength is populated but there is no Substance Strength; or if specify Substance Strength a Reference Substance and no Reference Substance Strength. Instead, there is a validation error and Substance Strength must always be specified.
UC01 Create product	NCA UI	82452	UC01 UC08 All procedure types - leading and trailing spaces in free-text fields should be removed by the system before validation.

UC08 Update product			
UC03 Search product	NCA UI & MAH UI	152113	After updating a product and have received Notification, the Search results screen and the Search screen product card may take many minutes before it reflects the updates made to a product. The View product screen does show the updated values.
UC03 Search product	API	123745	API user not able to search and view products and receives 403 invalid query and 403 Product is NOT in user affiliations response.
UC03 Search product	API	83332	API user only: A search of products using two parameters of _lastUpdated: the second parameter is ignored and only the first is applied.
UC03 Search product	NCA UI & MAH UI	144929	New products were not always included in search results immediately and sometimes had to wait up to 15 minutes after receiving Notification.
UC03 Search product	API & NCA UI & MAH UI	82482	Not able to search using marketing authorisation number if has been specified at package level. Affects UI and API.
UC03 Search product	NCA UI & MAH UI	83234	Search limitations due to FHIR limitation or MS FHIR limitation.
UC05 View product	NCA UI & MAH UI	83259	When View product QPPV displays as N/A even although the product does have a LOC-ID populated. This affects only some products and may be due to some Data Quality issue in the affected products.
UC06 Submit VNRA	MAH UI	104507	An intermittent issue affecting some users when attempting to Submit VNRA. Error message advises of VNRA Creation error and that VNeeS file could not be uploaded.
UC06 Submit VNRA	MAH UI	83112	If submit an automated variation that will update National Data, for example A.1.a to update MAH, for products under DCP/MRP/SRP where National Data has not been populated: the submission fails with a Validation error that the Marketing Authorisation Number has not been populated. The MAH should be able to submit a variation even if the RMS/CMS has not populated national data. As a workaround for this release the NCA will need to populate national data before the MAH can submit the VNRA.
UC06 Submit VNRA	MAH UI	83259	When View product QPPV displays as N/A even although the product does have a LOC-ID populated. This affects only some products and may be due to some Data Quality issue in the affected products.
UC08 Update product	API & NCA UI	92687	Able to submit update but does not complete successfully where product has Data Quality issue. OperationOutcome result displays ERR-1003. This is due to incomplete and orphan records for product names in the underpinning PMS MDM database. Affects about 56 products.
UC08 Update product	NCA UI	82627	Add button in Package medicinal product section needs to have more meaningful caption.
UC08 Update product	API & NCA UI	79977	All procedure types: if product does not contain any existing value for Responsible Authority or Product Owner, when an update is submitted the new LOC-ID is not saved.

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	API	82437	Change to procedure number not saved if existing inline attribute id is not included in the request body.
UC08 Update product	API	82436	Change to Responsible authority or Product Owner is not saved if existing inline attribute id is not included in the request body.
UC08 Update product	NCA UI & MAH UI	83142	For CAP products: there are examples where two products have been created and expected just one. This may occur when a new package has been added or package information has been updated. The cause of the issue will be resolved and affected products corrected.
UC08 Update product	API & NCA UI	109885	Products that had previously been affected by Bug 89511 (replacing Pharmaceutical product removed the Ingredients) cannot be further updated. EMA to investigate whether it is possible for NCA to update products to correct this issue so that products can be updated.
UC08 Update product	NCA UI	83206	The edit screen freezes and does not successfully load if the selected product has an invalid LOC-ID for the Product owner. This situation was possible in a previous release due to a bug.
UC08 Update product	API	82569	UC08 Update SC2 NAP - should reject update with validation error message if MedicinalProductDefinition.id is not populated.
UC08 Update product	API	82865	Update Common Data DCP/MRP/SRP by API only - not all expected Validation errors are displayed if Mandatory attributes are not populated in POST for Update Common.
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	83276	Update of product fails leaving product in Pending state and this blocks and subsequent update.
UC08 Update product	API & NCA UI	83203	Update of product fails with error in GET OperationOutcome of ERR-1003. An error from previous failed update with an incorrect payload prevents a subsequent update.
UC08 Update product	API & NCA UI	100337	Update of product has not completed successfully and Operation Outcome state remains In-Progress. The error seen in logs is OSB-382510. Only 7 instances observed for this over the past year but does mean that update did not complete and also blocks any subsequent update.
UC08 Update product	API & NCA UI	83205	Update product - error regarding buffer space for connections occurs on server but flag is not set to error preventing further updates and advising user that existing transaction needs to be completed before they submit another.
UC09 Approve/Reject VNRA	NCA UI	151292	Automated C1/C5/C6: Where MAH has populated new values at product level only and left fields at VNRA level empty when VNRA was submitted: when view VNRA submission the fields on the VNRA level are populated with the values of the first product card.

UC09 Approve/Reject VNRA	NCA UI	84163	CMS NCA is able to select Approve/Reject checkbox when viewing a VNRA, although the Submit button correctly remains disabled.
UC18 Manage document	API	83213	Add or Update document via API: if payload is invalid and does not conform to the JSON/XML format (for example there is an extra comma or other formatting control after an attribute) this returns a Response of 500 Internal Server error. Instead it should return Response of 400 Bad Request with details of the error.
UC19 Nullify product	API	83064	Any procedure type: After product has been nullified, able to submit a subsequent update product which is accepted and processed. There should be a Validation error
UC19 Nullify product	API	82811	API Manager Nullification endpoint: when Try It option is selected the Content-Type request header defaults to application/json and it should be application/fhir+json. Using the default value will give an error.
UC19 Nullify product	API	132758	Nullify Product via API - OperationOutcome ID now has suffix of "-Patch" which is not expected and is potentially a breaking change for API users. When submitting GET OperationOutcome/ID the response code is 499 Client Closed Request. Therefore it is not possible to nullify a product via the API in this release and NCA UI will need to be used.
UC19 Nullify product	NCA UI	82796	When you nullify a product, the confirmation message does not include the Permanent Identifier.
UC21 Manage Notifications	NCA UI & MAH UI	83254	Date format inconsistent between different actions.
UC21 Manage Notifications	NCA UI & MAH UI	83114	For CAP products, no Notification generated on successful creation or update of products from SIAMED.
UC21 Manage Notifications	NCA UI & MAH UI	131608	Responsible Authority displays the Organisation full name in Notification search results and it should display only the Acronym.
UC25 Update Availability status	MAH UI	82625	Not able to select all products to download in the one csv file if product search results are over two or more pages.
UC28 View VNRA	NCA UI	154201	Approve/Reject VNRA: When CMS enters decision for their product and before they submit, the summary table may incorrectly update the user name and decision date for some other CMS product as well as the CMS product; or may incorrectly only populate the Decision maker field on the CMS product. After decision has been submitted the status table is correctly updated and redisplayed showing updates only for the CMS variations where decision was submitted.
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.

UC28 View VNRA	NCA UI & MAH UI	92808	Search results will not be correct if new search is submitted after viewing second or subsequent page of search results from previous search. In the following sequence of actions: User submits search that results in 2 or more pages of search results, navigates to second or subsequent page, enters new search criteria for results found on page 1 or previous page (with or without clicking Reset button) then the search results will not include results from page 1 or previous pages. The page number that user was on from the previous search is still being applied to the new search. Thus new search results are not correct. After navigating to the next page, please reselect the search option from the menu to correctly reset the page counter and clear previous search results.
UC31 Manage VNRA Submissions via API	API	142804	All of the all endpoints for VNRA API https://spor.azure-api.net/upd/api/vnra/v3/vnra-submission fail with 404 Resource Not Found.
UC34 Bulk Upload for Documents	NCA UI	140303	Submitting a file for a Registered Homeopathic product fails with an error "ERROR: Your organization is not the Responsible Authority of this/these product(s).".

Annex 3: Release Schedule

Environment	Closed from	Closed to	Expected to be open	Description
UAT	1 April 2024	2 April 2024	2 April 2024	Upgrade of UPD to **1.7.2416**
PROD	9 April 2024	10 April 2024	10 April 2024	Upgrade of UPD to **1.7.2416**

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"
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

SPOR API Specification v2	API Manager
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
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

Refer to the document UPD 01.03 Registration Process for UPD API in Production/UAT listed in the References section.

4.1.4. Apply Chapter 4 Legacy or Chapter 2 Validation rules

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

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

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

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

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

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

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

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

4.1.5.2. Create and Update endpoints

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

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

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

Type and Procedure	POST Endpoint	Request header Key for validation rules	Additional Request header
		parallelchapter4 - true	
Update Parallel Trade	/upd/api/v1/ptp-bundle/	parallelchapter2 = true OR parallelchapter4 - true	is update = true
Create Pet	/upd/api/v1/pet-bundle/	chapter4	
Update Pet	/upd/api/v1/pet-bundle/	chapter4	is update = true
To Validate any Create or Update bundle	/pms/api/v2/$Validate	Use appropriate request header to apply validation rules based on the procedure type	Use is update = true when validating the following bundles: • Update NP • Update Registered Homeopathic • Update Parallel Trade • 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

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

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

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

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

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

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

Attribute	Change
None	

4.1.6. API EP309 Create product example request bundles

Examples for EP309 Create Product for NP and DCP. Please note that the purpose of these examples is as illustration of the FHIR attributes to be populated.

The value for MedicinalProductDefinition as a cross referenced product is a valid permanent identifier from UAT.

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

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

Procedure type	Validation rules	Example file
		UPD_1.6.5-6_DCP_Legacy_C110_VetEUIG_AllData.JSON UPD_1.6.5-6_DCP_Legacy_C110_VetEUIG_AllData.XML
NAP	Chapter 2	2.2 Authorisation/registration/entitlement number is specified at Product level UPD_1.6.1-4_NAP_Chpt2_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel.JSON UPD_1.6.1-4_NAP_Chpt2_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel.XML UPD_1.5.1-0_NAP_Chpt2_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel.JSON UPD_1.5.1-0_NAP_Chpt2_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel.XML _____ 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

Procedure type	Validation rules	Example file
		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: • 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

Procedure type	Validation rules	Example file
		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

4.1.6.1. 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.

Refer to the document Registration guide: Union product database for veterinary medicinal products listed in the References section.

4.3. UPD API for Volume of Sales Data

4.3.1. Scope of this release for Volume of Sales API

- Retrieve Volume of Sales Data

4.3.2. Endpoint, Authorisation header, Query Parameters, Pagination

Endpoint

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

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

Request Security Header (Mandatory)
This endpoint requires a mandatory OAuth Bearer Token which is passed via the Authorization header

---

Query Parameters

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

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

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

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

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

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

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

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

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

Examples:

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

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

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

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

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

Examples:
GET https://spor-uat.azure-api.net/upd/api/vos/v3/vos-sales-json?_size=5

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.