Union Product Database (UPD) release notes
Referring to version 1.6.34

Release date: 3 October 2023

Version 2

Changes made in revised version 2 of release notes:

- NCA able to use **API to search/retrieve and approve/reject variations not requiring assessment (VNRA)**:
    - This is now available for use in PROD as well as in UAT and UPD CA API role may now be requested.
- NCA able to use **API to retrieve Volume of Sales (VoS) data**:
    - This is now available for use in PROD as well as in UAT and UPD CA API role may now be requested.
    - **The** Endpoint **for PROD has been corrected. The link contained the correct value but the display value was incorrect. Correct link is: https://spor.azure-api.net/upd/api/vos/v3/vos-sales-json**

- Issue **132450 has been resolved** and is now listed as a 'Resolved Issue'
    - **If MAH Product Group Identifier contained a comma in a valid submission, when Products grouping was downloaded the comma was incorrectly changed to be a semi-colon. Any submission of an update for that entry where submission file contained the original comma value failed.**
    - Issue affected UC38 Products Grouping and UC33 **Manage third country Product names** download files.

- Issue **133755 has been resolved** and is now listed as a 'Resolved Issue'
    - **This issue had not been reported as a known issue in the previous version of these release notes.**
    - **UC38 Products Grouping and submission of a file without the product name was incorrectly giving a validation error "ER. 08 Product name cannot be empty".**
    - **Product name is not a mandatory field and there is no longer a validation error if not populated in the submission file.**

- Issue **101205 has been resolved** and is now listed as a 'Resolved Issue'
    - **Intermittent issue where for some products there were two or more rows listed when searched for products to be able to download the submitted sales data values.**
    - **6 products were affected by this issue for two MAH. The issue with the duplicate rows has been corrected. The two MAH affected will be contacted with details of their products that were affected by this issue.**

- New issues have been added in Section 2.3 and Appendix 2:
    - **133434 UC28 View VNRA**
    - **134632 UC07 Submit Volume of Sales, UC25 Update Availability status, UC33 Manage third country Product names, UC38 Products Grouping**

- **New issues have been added in section 2.4 and Appendix 2 for UC33 Manage third country Product names**
    - **135321 133338 134632**

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.

Compared to the previous UPD version (**1.6.30**, released on 7 August 2023), new functionalities (detailed information in section 2.1) are available and **40** defects (detailed information in section 2.2) have been considered resolved.

Overview of new functionality(ies):

- NCA are able to **save and resume draft product submissions**.

- NCA able to create and update **products intended for animals which are exclusively kept as pets (Article 5(6) of Regulation (EU) 2019/6)**.

- NCA able to use **API to search/retrieve and approve/reject variations not requiring assessment (VNRA)**:

    - ~~NCA VNRA API is currently only available for use in the UAT environment~~

    - ~~EMA will advise when request of the API role and use of this API is available in PROD~~.

- NCA able to use **API to retrieve Volume of Sales (VoS) data**:

    - ~~NCA VoS API is currently only available for use in the UAT environment~~

    - ~~EMA will advise when request of the API role and use of this API is available in PROD.~~

- MAH able to maintain **Third Country Product Name**.

- MAH able to **validate VoS submission files as a stand-alone functionality**.

- **Create & Update NAP, CAP, DCP/MRP/SRP: it is now mandatory to populate pack size** (both numeric value and term code for Unit of Presentation) **for all packages**.

- **When MAH & NCA download a VNeeS file for a VNRA, a pop-up File save dialog is opened to allow them** to select **where to save the file in their file system**.

- EMA can maintain messages to appear **in the UPD portal informing users about downtime on the UPD UAT and PROD environments and the system unavailability**.

Issues that have been resolved:

- **Bug 106851** Workaround no longer required to remove and re-add VNeeS file if validation error was received when submitting VNRA.

Functionality not available in this release due to bug:

- **Bug 132758 Nullify product via API. It is not possible to use GET OperationOutcome/ID** to check the status of the nullification. The product is updated and nullified.

For full, complete information please refer to section 2 of this document.

Notes:

- Regarding the MAH UI user functionality to group essentially similar products together (hereafter called 'Products Grouping'), released with version 1.6.28 on 7 July 2023), It is strongly recommended that MAHs wait for the specific training webinar, scheduled for 18 September 2023, before they start using the MAH Products Grouping functionality. Further information on the webinar is available on the event's page.

- Whilst an improvement in the UI to avoid having to clean the browser's cache after update is ongoing, those users who experience problems accessing the data after new releases in UPD UAT and PROD, please follow this recommendation:

  - Make sure you do the following steps only in UPD supported browsers (Chrome / Edge)

    1) Clear the cache memory of browser. To clear your browser cache memory:

       On your browser page, press Ctrl+Shift+Delete

       In Chrome, select Basic and All Time and tick all three boxes.

       In Edge, tick all the boxes except the Passwords and click Delete.

    2) Close all browser windows.

    3) Log in to UPD in Chrome or Edge and retry with only one instance of UPD (tab / window) open.

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.

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1. Overview of functionality and business value

1.1. 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~~   Not fully functional due to bug 132758
  - NCA can Search/view product (data and documents)
  - NCA can Search, View and Approve/Reject VNRA
  - NCA can View Volume of Sales data
- NCA UI:
  - RMS can create DCP products (data and documents)
  - RMS can create MRP products (data and documents)
  - RMS can create SRP products (data and documents)
  - RMS and CMS can complement DCP/MRP/SRP products with national DCP/MRP data (including documents)
  - RMS can update Common data for DCP/MRP/SRP products (data and documents)
  - NCA can create and update NAP products (data and documents)
  - NCA can create & update Registered Homeopathic products (data and documents)
  - NCA can create & update Parallel Trade products (data and documents)
  - NCA can create & update Pet products (data and documents)
  - NCA can 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)

- o Notifications for Create and Update of products and OPAD actions

- o View Volume of Sales information

- o View and Approve/Reject VNRA submissions

- o EMA and EC staff can update CAP products

- MAH UI:

  - o Search/view/export products (data and documents)

  - o Notifications for Create and Update of products and OPAD actions

  - o Download, Submit, and View Volume of Sales information

  - o Submit VNRA and View VNRA submissions

  - o Submit updates for Marketing authorisation status

  - o Download and Submit updates for Availability status

  - o Submit Products Grouping

  - o Submit 3rd country product names

- MAH Validation UI:

  - o Validate Volume of Sales submission file

- Authorisation for NCA & MAH UI:

  - o Integration with EMA Account Management (EAM) system for CA and Industry (MAH) roles

  - o CA users may search and view all Vet products

  - o MAH users may search and view only products under the responsibility of the organisations the user represents

- Banner for UPD UI:

  - o EMA can maintain messages to appear in banner of UPD UI

This release is based on FHIR version R5 Preview #2, http://hl7.org/fhir/2020May/resourcelist.html.

The sections below contain all the required information to register for the usage of the UI or API, connect to the API or UI, and use the available functionality.

More functionality and additional components will be made gradually available in the next releases.

Technical grouping:

Please note that the Technical grouping functionality for VNRAs involves a certain complexity, but the learning curve will be less steep if we can rely on the collaboration between all competent authorities (CAs) and marketing authorisation holders (MAHs). With this in mind, **we strongly recommend MAHs to only combine MRP/DCP and national VNRAs in such technical groupings, where only one RMS/NCA is responsible for the approval/reject action**. Combining several NCA is technically possible, but strongly discouraged as it would lead to great obstructions and significant delay in processing the VNRA's.

1.2. Functionality not included in this release

The following functionality is not included in this release.

NCA API:

- **Bug** 132758 Nullify product via API. **It is not possible to use GET OperationOutcome/ID to check the status of the nullification. The product is updated and nullified**.

NCA UI:

- **F156 Bulk upload - Ability to upload one document to several products**
  - Please note that in this release it is only possible to use the Bulk upload to add new documents. Update of an existing document is not working due to bug 102918.
  - There is a known limitation in this release where it is not possible for the system to load documents if the Procedure number in the product has lower case letters. This will mostly only impact Portugal where approx. 200 products contain lowercase letters.
  - The bulk upload functionality is being redesigned to address the issues related to documents not added/updated on product and missing notifications. This is expected by the end of Q4 2023.

MAH UI:

- None

2. Changes made compared with 1.6.30

2.1. New or re-released functionality

- **F031 Save and resume draft product submissions**
  - NCA is now able to save and retrieve draft when creating products for NP, DCP, Parallel Trade, Registered Homeopathic and Pets.
  - MRP and SRP product have been excluded from this functionality because the current process in UPD allow NCAs to create these products easily while protecting the integrity of their identifiers, especially the Product Identifier.
  - Product name and Responsible authority are mandatory to be entered before draft can be saved. For DCP also Responsible Member State.
  - Due to bug 129052 draft functionality for Parallel Trade should not be used in this release.

- **F059 Provision of Third Country Product Name**
  - MAH is now able to add the non-EEA product name related to an authorised product stored in UPD to support Veterinary Pharmacovigilance activities.
  - Refer to version 1.6 of Vet EU IG Chapter 7.

- **F063 - VNRA - API for Competent Authorities and the European Commission**
  - NCA API user now able to use API to retrieve information related to VNRAs (data + VNeeS) and to approve/reject those VNRAs.
  - Refer to section 6. UPD API for VNRA of this document for information on API Registration and use of this API.

- **F100 - Creation and maintenance of products intended for animals which are exclusively kept as pets (Article 5(6) of Regulation (EU) 2019/6)**

  o NCA is now able to create and update products for Pets via API or NCA UI.

  o Supplementary functionalities related to these Products (*Availability status, Volume of sales, VNRA submissions, Transfer of ownership*) is out of the scope of this Requirement.

  o Refer to the updated section 5. UPD API to Maintain Products and Product Documents of this document for information on this procedure type for API users.

- **F109 – MAH possibility to validate in PROD environments the .csv files for volume of sales as a stand-alone functionality**

  o MAH is able using their own user account to login in https://upd-portal-prod-validation.azurewebsites.net and validate the volume of sales .csv files, as a stand-alone functionality, before submitting volume of sales data in PROD to be recorded.

  o Refer to section 9. MAH Validation UI for Volume of Sales Submission.

- **F176 - Banner in the UPD portal informing users about downtime on the UPD UAT and PROD environments and the system unavailability**

  o EMA will publish messages that will appear in the banner of the UPD UI and users do not need to be logged in to view these banner messages.

  o After logging into UPD UI, the banner messages can be closed and will not be re-displayed until the next time user log into UPD and reload the page.

  Example:

- **F202 - API for Volume of Sales**

  o NCA external system shall be able to consume (read) volume of sales data in UPD via an API.

  o Refer to section 7. UPD API for Volume of Sales Data for information on API Registration and use of this API.

- **Create & Update NAP, CAP, DCP/MRP/SRP: it is now mandatory to populate pack size** (both numeric value and term code for Unit of Presentation) **for all packages**. Pack size remains optional for Pet and Registered Homeopathic products and is not applicable for Parallel Trade. Revised versions of Vet EU IG Chapter 2 and 4 will be published in due course. This change was made following a review of the issue in bug 105143

- When MAH & NCA **download a VNeeS file for a VNRA**, a **pop-up File save dialog is opened** to allow them to select where to save the file in their file system
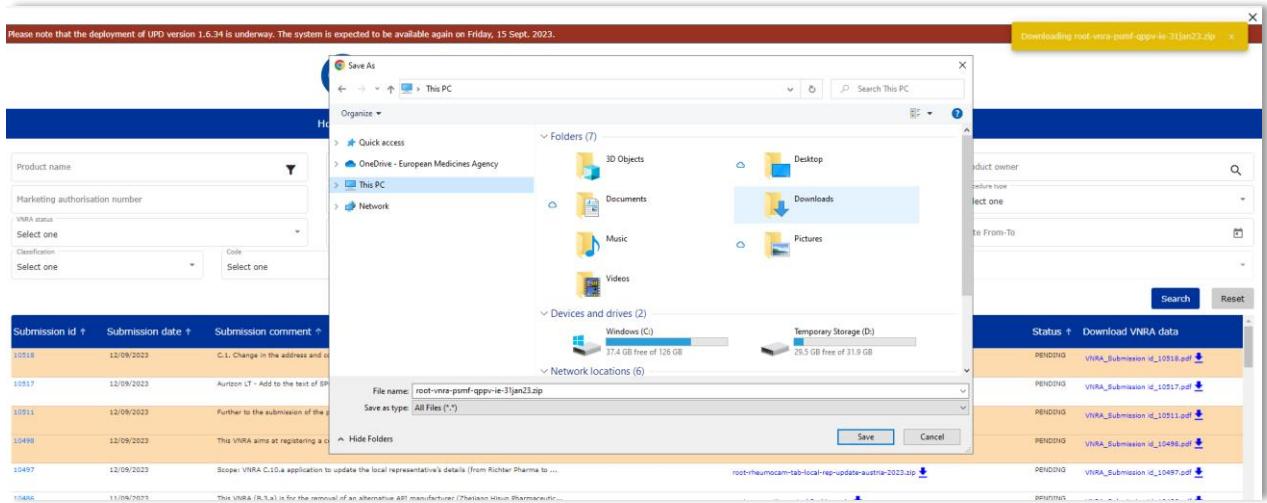
2.2. Resolved issues

Use Case	Affects API and/or UI	Issue reference (Old JIRA)	Issue reference (New ADO)	Resolved issues
UC38 Products Grouping	MAH UI		132450	**Resolved 3/10/23 in a Hotfix release:** If MAH Product Group Identifier contained a comma in a valid submission, when Products grouping was downloaded the comma was incorrectly changed to be a semi-colon. Any submission of an update for that entry where submission file contained the original comma value failed. The MAH Product Group Identifier should always be enclosed in quotes in the submission file when it contains a comma
UC33 Manage third country Product names	MAH UI		132450	**Resolved 3/10/23 in a Hotfix release:** If MAH Product Group Identifier contained a comma in a valid submission and 3rd country product name submission contains an entry for that MAH Product Group Identifier, the 3rd country name submission was incorrectly rejected as the system had changed the comma to be a semi-colon. The MAH Product Group Identifier should always be enclosed in quotes in the submission file when it contains a comma
UC38 Products Grouping	MAH UI		133755	**Resolved 3/10/23 in a Hotfix release:** This issue had not been reported as a known issue in the previous version of these release notes. UC38 Products Grouping and submission of a file without the product name was incorrectly giving a validation error "ER. 08 Product name cannot be empty".

Use Case	Affects API and/or UI	Issue reference (Old JIRA)	Issue reference (New ADO)	Resolved issues
				Product name is not a mandatory field and there is no longer a validation error if not populated in the submission file.
UC27 View Volume of Sales	NCA UI & MAH UI		101205	**Resolved 3/10/23 in a Hotfix release:** Intermittent issue where for some products there were two or more rows listed when searched for products to be able to download the submitted sales data values. This does not happen for many products. Depending on the row selected, different sales data may be downloaded in the csv file. 6 products were affected by this issue for two MAH. The issue with the duplicate rows has been corrected. The two MAH affected will be contacted with details of their products that were affected by this issue.
All UC	NCA UI & MAH UI		95526	When 'Create' a product, or 'Search' or 'View' an existing product: the preferred name for a Substance was not always displayed. Preferred name is now displayed. This issue had been reported resolved in Release 1.6.28 but found to still be an issue and therefore this bug was reopened. The outstanding issues were investigated and are now resolved.
UC01 Create product	NCA UI		103190	F043 Create NAP or Create DCP based on existing product that has Marketing authorisation number at package level was not possible. After create was submitted there was a validation error "Profile http://ema.europa.eu/fhir/definition/upd/chapter4/RegulatedAuthorization-for-PackagedProductDefinition-create, Element 'resource.id': max allowed = 0, but found 1". Issue is resolved and there is no longer this validation error.
UC01 Create product	NCA UI		108616	F043 Create NAP or DCP and Import existing information: it was possible to select a product where the NCA user was not the responsible authority or the RMS as after selecting the product the Accept button was momentarily enabled long enough for the user to click it and enable the creation
UC01 Create product UC08 Update product	NCA UI	UPD-11419	83051	Any procedure type: create or update with Document of type EPAR was able to be submitted for a CAP product. There was an exception when processing and the document was not saved on the product.

Use Case	Affects API and/or UI	Issue reference (Old JIRA)	Issue reference (New ADO)	Resolved issues
				There is now a validation error if attempting to use document type of EPAR for any procedure type and this document type is no longer listed as a valid option in Vet EU IG Chapter 2.
UC01 Create product UC08 Update product	API & NCA UI		105143	Create & Update NAP, CAP, DCP/MRP/SRP: it is now mandatory to populate pack size (both numeric value and term code for Unit of Presentation) for all packages. Pack size remains optional for Pet and Registered Homeopathic products and is not applicable for Parallel Trade. Revised versions of Vet EU IG Chapter 2 and 4 will be published.
UC01 Create product UC08 Update product	NCA UI		107739	Registered Homeopathic - the pop-up confirmation dialog contained {{Action}} in the message. This issue has been resolved and message now contains whether product is being created or updated
UC01 Create products	API & NCA UI		111922	Create MRP: Instead of just outputting the Common package description in the new CMS products, any national package description from the RMS NAP product was also incorrectly being added
UC03 Search product	NCA UI & MAH UI	UPD-12867	83241	Enter some value for search criteria in Authorisation/registration/entitlement number field and submit Search; select to view a product; and then select "Back to search results" option from the View Product page. The Authorisation/registration/entitlement number field displayed [object object] and not the value that had been input. This issue has been resolved.
UC04 Export	NCA UI & MAH UI		111977	The system message advising of the search result size that can be exported had a typo in the number of products. The limit is ten thousand products and the message had an extra zero and displayed as "10,0000". Message now displays correct limit.
UC05 View product	NCA UI & MAH UI		101462	If withdrawal period does not contain any free-text notes, the view product screen displayed "N/A" after the Tissue name and withdrawal period numeric and term details. "N/A" is no longer displayed
UC05 View product	NCA UI & MAH UI		104703	The table listing Route of Administration was sometimes incorrectly listing a Route of administration twice where it has 3 or more Target species within that Route of administration. The table now correctly lists entries in the product for Route of Administration, Target Species and Withdrawal Period.
UC06 Submit VNRA	MAH UI		103465	After submitting a VNRA it was possible to click the Submit button multiple times resulting in the creation of duplicate identical submissions.

Use Case	Affects API and/or UI	Issue reference (Old JIRA)	Issue reference (New ADO)	Resolved issues
UC06 Submit VNRA	MAH UI	UPD-7960	82616	Submit VNRA: No search results were displayed when the 'Retrieve product' search dialog was opened a second time
UC06 Submit VNRA	MAH UI		106851	VNeeS file name did not retain the original name if there had been a validation error for any product for an automated variation code in the first submit. If user submitted the VNRA again after removing the invalid products, the VNRA was submitted successfully but changed the name of the VNeeS file included in the submission. The file name displayed a system generated name that is being used internally by the system.\nThe workaround was: remove the VNeeS file and add it again before submitting for a second time (after the invalid products have been removed) to ensure that the VNeeS file name retains the MAH file name.\nThis issue has been resolved and workaround is no longer required.
UC06 Submit VNRA	MAH UI	UPD-14047	83470	VNRA Submission may have failed with timeout if there are many products and variation codes. No timeout error should not be received.
UC06 Submit VNRA	MAH UI	UPD-11617	83106	For F092 Automated A.1.a for update to MAH : only allow MAH to select LOC-ID for an Organisation that they have affiliation to.\nThis issue has been closed without any change being made to add in this additional validation.\nAfter discussion it was agreed this validation is not required as A.1.a is not used for Transfer of Ownership and MAH will always be selecting the same/other LOC-ID that is for their Organisation.
UC07 Submit Volume of Sales	MAH UI		103299	If submission file contains an invalid term code for Country, the error report displayed error message "ERR.05 - Package identifier doesn't belong to the country selected" instead of "ERR.03 - Country identifier doesn't exist in RMS list"
UC07 Submit Volume of Sales	MAH UI		110156	Submission for DCP/MRP/SRP where a CMS has been removed from the procedure with their product nullified, then the same CMS re-added via Create SRP: submission of VoS for new CMS product failed as invalid with ERR.18. The error report contained the Permanent identifier of the nullified CMS product for the same country and not the new Permanent identifier for that CMS country that was provided in the submission file. This issue has been resolved and Volume of Sales can be submitted for the re-added CMS.

Use Case	Affects API and/or UI	Issue reference (Old JIRA)	Issue reference (New ADO)	Resolved issues
UC08 Update product	NCA UI	UPD-13466	83298	If product name has been incorrectly duplicated for a language/country and you edited the product to remove one of the duplicated names, the updated product still contained both product names. This issue has been resolved and NCA will now be able to delete any duplicated product names.
UC08 Update product	NCA UI		105453	If product has 'ATC vet code not available' selected: the Update product button was not enabled (even if all other mandatory data was added). If click checkbox to de-select flag and then click again to re-select flag the Update product button was enabled. Once update was submitted the screen hung with the progress control remaining on the screen and update was not submitted. Issues have been resolved.
UC08 Update product	API & NCA UI		112958	If update failed part way through when updating the main database the transaction remained IN_PROGRESS instead of setting status to ERROR (as see in OperationOutcome for API users). No Notification was generated for this failed updated. Since the first transaction remained in progress this blocked any further update to the product. There have been no new instances of this issue in PROD. EMA User support team are making updates for all products that were affected by this issue so that a new update may be submitted.
UC08 Update product	NCA UI		103536	Update Common Data DCP/MRP/SRP or Update National Data DCP/MRP/SRP: the table did not list the Reference Member State and listed the first CMS as the RMS. The Reference member state & Concerned member states fields were OK and update to products was not affected by this issue. The table now correctly lists the RMS and CMS.
UC08 Update product	API & NCA UI		108402	Update Common Data DCP/MRP/SRP: it was not possible to delete a package if a CMS had Marketing authorisation number populated at package level. This issue has been resolved and RMS is now able to successfully remove packages whether CMS has Marketing authorisation number at product or package level
UC08 Update product	NCA UI		106517	Update National Data DCP/MRP/SRP Were not able to edit or delete a national product name - either that existed already in the product or a new name that was just added on the screen
UC08 Update product	NCA UI		130070	Update National Data DCP/MRP/SRP - if ATC vet code is populated and ATC Pending Flag set to False, the Update screen had the checkbox "ATC vet code not available"

Use Case	Affects API and/or UI	Issue reference (Old JIRA)	Issue reference (New ADO)	Resolved issues
				selected (ticked) and the CMS was not able to de-select in order to be able to submit an Update National Data. This issue has been resolved and the checkbox is no longer incorrectly checked
UC08 Update product	API	UPD-12286	83198	Update Parallel Trade via API failed with validation error messages relating to RMS and CMS (regression issue from previous release). This issue has been resolved and now able to update parallel trade products.
UC08 Update product	NCA UI		106757	Update to remove Legal status of supply from package level and populate it at product level incorrectly gave a validation error. This issue has been resolved and Legal status of supply can be switched from package to product level or vice-versa
UC09 Approve/Reject VNRA	NCA UI	UPD-13793	83351	If VNRA submission contains a product that has been nullified after the VNRA was submitted - the Decision comment entered at submission level was not being replicated into all product cards. Those product cards listed in the submission below the nullified product may not have had the decision comment populated and the field at product card level had to be populated.
UC18 Manage document	API	UPD-11460	83061	EP403 Create Document for CAP with document type of EPAR: get a validation error even although payload is valid. This bug has been closed as it is now obsolete. Decision made to no longer add CAP documents as legacy document type of EPAR and instead to use PuAR. Therefore it is correct to get a validation error when using document type of EPAR.
UC19 Nullify product	API	UPD-13877	83383	If submit Nullification via API and the previously submitted Update transaction failed: the response code to nullification is 202 Accepted with an OperationOutcome/ID, but GET OperationOutcome result is always 404 Not Found. The OperationOutcome for the nullification will now display a message that there is an update in progress and will not proceed to attempt to nullify. The issue with the update that failed will need to be corrected first and then product can be nullified.
UC21 Manage Notifications	NCA UI & MAH UI		105219	Action drop-down list did not contain the option of "VNRA automatic update failure". If update of product was not successful when an automated variation is approved, there is a notification generated and it is displayed in the search results. The drop-down list now includes this action.
UC21 Manage Notifications	NCA UI & MAH UI		102376	Bulk Upload Notification for action of Bulk Upload Docs Succeeded had incorrectly included Date of Submission in the Notification card

Use Case	Affects API and/or UI	Issue reference (Old JIRA)	Issue reference (New ADO)	Resolved issues
UC21 Notifications	NCA UI & MAH UI		102711	Intermittent issue: Create DCP/MRP/SRP and Update Common Data DCP/MRP/SRP: sometimes notifications were not listed for all products under the product identifier even although the create or update for all products was successful. Notifications are now created for all products.
UC25 Update Availability status	MAH UI		108691	Selecting to View Availability Status submissions displayed an error message for an MAH who has made no submissions
UC25 Update Availability status	MAH UI		105166	View Submissions of Availability Status: Navigating through search result pages and submitting a new search from the 2nd or subsequent page was incorrectly displaying an error message that no results found for new search, even although there are submissions that match the new search criteria
UC27 View Volume of Sales	MAH UI		108691	Selecting to View Volume of Sales submissions displayed an error message for an MAH who has made no submissions
UC27 View Volume of Sales	MAH UI		108687	Viewing Volume of Sales: when paginating through volume of sales at some point an error was displayed "Resource(s) not found, search criteria: APIM-Org-ID : ORG-XXXXXXXXX, procedureNumber : null, productIdentifier : null". This issue has been resolved and now able to paginate through all search results
UC27 View Volume of Sales	NCA UI & MAH UI		100172	Search of Volume of Sales data using Country as a filter criteria did not return the expected products
UC28 View VNRA	NCA UI		111176	F181 The highlight of submissions that contain a product where the logged on user is the 'Decision maker' was missing for NCA/EMA/EC users with only the Search/View role: 'UPD - CA Search/View', 'UPD - EMA Search/View' , 'UPD - EC Search/View'
UC28 View VNRA	NCA UI & MAH UI		110763	View VNRA Submissions page - an intermittent error observed by some users since 1.6.28 release: when selected to view submission from menu, or submit a search there were no results displayed. An error is seen in browser log of ClientConnectionFailure. This issue was only seen in PROD and was intermittent only affecting a few users; and same user may have experienced this issue and then at a later time was successfully able to search and view submissions.

Below are 2 ways to retrieve VNRAs when you get no result, with the aim of narrowing down the number of VNRA to less that the default of 100:
1. Apply search criteria filters to narrow down the number of VNRA submissions retrieved. |

Use Case	Affects API and/or UI	Issue reference (Old JIRA)	Issue reference (New ADO)	Resolved issues
				2. By replacing 100 with 20 in the URL, example of URL: example: https://upd-portal-prod.azurewebsites.net/updwebui/vnra/view?submissionStatus=PENDING&_page=0&_items=20 (changed from 100 to 20). Alternatively search notifications for VNRA submitted within a date range and view submission using link provided. Changes have been made to make the search more performant.
UC34 Bulk Upload for Documents	NCA UI		103141	If the file name contained a language code that is not one of the EEA languages, the file was not being rejected with a validation error. Instead, the document was being loaded. On the View product screen the language is displayed as N/A. This issue has been corrected and new files submitted will be rejected if the language code in the filename is not valid. A data quality check will be made to identify any documents loaded with an invalid language code so that the NCA can correct.

2.3. New known issues for functionality in previous 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 (Old JIRA)	Issue reference (New ADO)	New Issue description
UC01 Create product	API		121940	Create DCP where RMS has inadvertently included a National package description in the request payload. This national data should be silently ignored and not output in the created products for the RMS or CMS. Instead the national package description is being added in the created products

Use Case	Affects API and/or UI	Issue reference (Old JIRA)	Issue reference (New ADO)	New Issue description
UC01 Create product	NCA UI		113613	Create SRP - an intermittent issue where the update for one of the existing CMS fails with error in OperationOutcome related to DocumentProcessingException
UC01 Create product	NCA UI		113178	Create SRP product - RMS is able to select DCP/MRP/SRP where that are not the RMS and use as retrieved product for a create SRP
UC01 Create product	API & NCA UI		112858	Create SRP Product - RMS is not able to submit create SRP for a DCP/MRP/SRP where one of CMS products is nullified and not yet removed from the list of Concerned member states. As a workaround for this issue the RMS can submit an Update Common Data to remove the nullified CMS from list of CMS countries and once that update transaction has been completed proceed to create SRP
UC03 Search products	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 products	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 products	NCA UI & MAH UI		111811	The search results grid displays N/A after the substance name when the strength is only defined with free text value
UC04 Export	MAH UI		132732	MAH user affiliated to 2 or more Organisations that has searched for products for one of the Locations they are affiliated to is not able to export the product search results
UC05 View product	NCA UI & MAH UI		115230	CAP products are incorrectly displaying a value for Availability Status beside the package description. Only the table that lists Availability Status and Availability Status Date by Country should be listed for CAP products
UC05 View Product	NCA UI & MAH UI		132610	CAP products for Metacam now have some duplicated products with different Permanent identifiers. The Package identifiers in the two products are the same. Issue is still be investigated to identify cause and which product will be retained
UC05 View Product	NCA UI		133247	Registered Homeopathic, Parallel trade and Pet products - when a NCA Edit/Search/View user views a product for one of these procedure types for another Authorisation Country to that they are affiliated to the Edit product button is

Use Case	Affects API and/or UI	Issue reference (Old JIRA)	Issue reference (New ADO)	New Issue description
				incorrectly displayed and enabled. The user is able to select to edit and submit an Update
UC06 Submit VNRA UC28 View VNRA	NCA UI & MAH UI		132447	If the ATC pending vet code is set to True and VNRA is being submitted for variation code A4, the message "ATC vet code not available" is not displayed on the submission form. The VNRA can be successfully submitted but when MAH or NCA view the submission they will ne see this message in Existing value field
UC08 Update product	NCA UI		111377	All procedure types: Availability status is not updated to "Not marketed" when Authorisation status is updated to Suspended or Revoked if Product has no existing record for Availability status from when product was created
UC09 Approve/Reject VNRA	NCA UI		132424	An EC user cannot approve/reject VNRA submission of CAP products
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
UC21 Manage Notifications	NCA UI & MAH UI		100749	Updating a NAP to delete a document does not create a "Delete document" notification and there is only an "Update" notification
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.
UC28 View VNRA	NCA UI		133434	NCA user not able to view first page of pending submissions when select from menu, or are not able to navigate to second page of 100 submissions. After a period of time the screen is displayed with the message "no results found"
UC28 View VNRA UC06 Submit VNRA	NCA UI & MAH UI		132447	If the ATC pending vet code is set to True and VNRA is being submitted for variation code A4, the message "ATC vet code not available" is not displayed on the

Use Case	Affects API and/or UI	Issue reference (Old JIRA)	Issue reference (New ADO)	New Issue description
				submission form. The VNRA can be successfully submitted but when MAH or NCA view the submission they will ne see this message in Existing value field
UC28 View VNRA	NCA UI		133434	Some NCA users aere not able to view the first page of pending submissions when select to View VNRA Submission from the menu; or are not able to navigate to second page of 100. As a work-around some filter criteria needs to be applied and a new search submitted
UC07 Submit Volume of Sales UC25 Update Availability status UC33 Manage third country Product names UC38 Products Grouping	NCA UI & MAH UI		134376	If Product name or Package description comain an embedded comma, this comma is being replaced with a semi-colon in the download file ("," is changed to ";"). This issue affects the 4 download files for Volume of Sales, Availability Status, Manage 3rd Country Product Name and Manage Products Grouping

2.4. Known issues for new functionality in this release

This table is ordered by Use Case number.

New functionality[1]	Use Case	Affects API and/or UI	Issue reference (New ADO)	New Issue description
F031	UC26 Manage draft Products	NCA UI	129052	Parallel Trade product - able to save a draft but when return and retrieve draft the screen hangs and not able to create product from the saved draft
F031	UC26 Manage draft Products	NCA UI	113642	When a product is Created for a Saved draft, the draft has not been deleted after the creation of the product. Initial test has identified issue with draft for a NAP and still to be assess if also an issue for other procedure types

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[1] Note for information: in previous release notes the prefix for new functionalities was 'UPD-BR-xx'.

New functionality[1]	Use Case	Affects API and/or UI	Issue reference (New ADO)	New Issue description
F031	UC26 Manage draft Products	NCA UI	131326	Update Draft DCP - after retrieving a saved draft for a DCP, the product name that was in the draft is not able to be edited or deleted. As a workaround, RMS will need to use Update Common Data to edit common product name after Create DCP has been processed
F059	UC33 Manage third country Product names	MAH UI	129500	MAH user with UPD Industry Search/View role is not able to download file of 3rd country product names and is not able to view submissions
F059	UC33 Manage third country Product names	MAH UI	133338	When download submitted file from View submission page for 3rd country name submissions, the system is incorrectly adding a suffix to the filename of the downloaded file
F059	UC33 Manage third country Product names	MAH UI	135321	Submission of 3rd Country Product Name is failing with validation ERR.27 for some countries even although they have the required extended attribute of "Country Grouping: non-European Economic Area - non-EEA"
F059	UC33 Manage third country Product names	MAH UI	134632	If a 3rd Country Product Name contains an embedded comma in the submission file, this comma is being replaced with a semi-colon in the download file ("," is changed to ";")
F059	UC33 Manage third country Product names	MAH UI	133338	When download the file that was submitted from the View submission page the system is adding a suffix to the end of the filename during the download process
F100	UC01 Create product	API & NCA UI	119875	Create Pet product - In the table of Ingredients, if reference strength is added using free text there is no hyphen between the reference substance name and the free text data
F100	UC01 Create product	NCA UI	117980	Create Pet product based on Chapter 2 rules: it is possible to add a Manufactured item into the table without any of the 3 fields for the manufactured item populated. This empty manufactured item is able to be selected in a Package. Submission of the create is successful and OperationOutcome ID provided. However, the transaction fails with ERR-1002 (as seen in the GET OperationOutcome result) and the product is not created

New functionality[1]	Use Case	Affects API and/or UI	Issue reference (New ADO)	New Issue description
F109	Volume of Sales Validation Portal	MAH UI	117823	The Volume of Sales Validation portal is for use by MAH. An NCA user is able to log into the Validation portal and search and view products. There is an Edit button on the view product screen but nothing happens when this is clicked. An NCA user is not able to access any of the Volume of Sales menu entries. When issue is resolved NCA users will not be able to log into the Validation portal

3. Veterinary EU Implementation Guide versions for this release

This UPD release is based on the following Vet EU IG versions:

- **Chapter 2:** Format for the electronic submission of veterinary medicinal product information – May 2023

- **Chapter 4:** Process and format for the submission of legacy data on veterinary medicinal products – July 2021

- **Chapter 6:** Examples for submission of legacy data – December 2021

- **Chapter 7:** Submission of other post-authorisation (OPAD) data – updated version September 2023

- **Chapters 1, 3, and 5**: May 2021

3.1. Providing Strength or Reference Strength for an Ingredient

The following is an explanation of the workaround that is recommended to be used for issue UPD-7228

> UC01 Create & UC08 Update Product – this 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. In addition, if you add a Reference Substance you must always add a Reference Substance Strength.

The following table illustrates the possible combinations that should be valid and a workaround to use until this issue is resolved.

- Green tick ✓ indicates this combination is working in this release

- Red tick ✓ indicates this combination should be valid but is not working in this release.

The values in the Substance, Substance Strength, Reference Substance and Reference Substance Strength illustrate what values should be populated as a recommendation until this issue is resolved.

	(Active/Adjuvant) Substance	Substance Strength	Reference Substance	Ref. Substance Strength	Example in SPC	Working	Work around
1	✓ Amoxicillin 3H2O	✓ 300 mg/tablet			Amoxicillin 3H2O 300 mg/tablet	Yes	
2	Amoxicillin	500 mg/tablet	✓	✓	Amoxicillin 500 mg/tablet	No and not able to resolve as this is a FHIR requirement to always have substance specified	Report as substance
3	✓ Amoxicillin	500 mg/tablet	✓	✓	Amoxicillin 3H2O expressed as amoxicillin 500 mg/tablet	No – bug to fix UPD-7228	Recommendation: Report the reference substance as substance.
4	✓ Amoxicillin 3H2O	✓ 300 mg/tablet	✓		Amoxicillin 3H2O 300 mg/tablet expressed as amoxicillin	No and not able to resolve as it is a FHIR requirement to always have Reference Strength if Reference Substance is specified	Recommendation: just report the substance + strength and do not report Ref Substance
5	✓ Amoxicillin 3H2O	✓ 300 mg/tablet	✓ Amoxicillin	✓ 500 mg/tablet	Amoxicillin 3H2O 300 mg/tablet expressed as amoxicillin 500 mg/tablet	Yes	

4. NCA UI

4.1. Scope of this release for NCA UI

- UC01 Create Product via UI

    o Scenario 1 Create Product – NAP & Registered Homeopathic – Manual Key In

    o Scenario 2 Create Product – Decentralised Procedure – Manual Key In

    o Scenario 3 Create Product – MRP & SRP

    o Scenario 4 Create Product – Parallel Trade

    o Scenario 5 Cancel Create Product

    o Scenario 7 Create Product - for animals exclusively kept as pets

    o Able to create products based on Chapter 4 Legacy or Chapter 2 Validation rules

- UPD UC03 Search Product via UI

- UPD UC04 Export search results

- UPD UC05 View Product via UI

- UPD UC08 Update Product via UI

  o Scenario 1 Transfer of ownership

  o Scenario 2 Update a single Product – Common & National data for CAP, NP & Registered Homeopathic and National data for DC/MR/SR procedures (data and documents)

  o Scenario 3 Update Common Data for products under DCP/MRP/SRP (data and documents)

  o Scenario 4 Update Parallel Trade

  o Scenario 5 Cancel Update Product

  o Able to update products based on Chapter 4 Legacy or Chapter 2 Validation rules

- UPD UC19 Nullify Product

- UPD UC21 Manage Notifications via UI

  o The flags for "Show only products under my responsibility" and "Exclude products where my role is RMS" are not in scope for this release and are not implemented

- UPD UC26 Manage Draft Products

- UPD UC34 Bulk Upload of Documents

- UPD UC27 View Submissions of Volume Sales via Form

  o Scenario 1 and 3 – View and Download Volume of Sales as a CA or MAH

- UC28 View Variation not Requiring assessment via UI

- UC09 Approve/Reject Variation Not Requiring Assessment via UI

Supported browsers for the NCA UI are Chrome and Edge.

4.2. Apply Chapter 4 Legacy or Chapter 2 Validation rules

There is a flag on the top right of the Create and Update screens. This is used to indicate which validation rules are to be applied for this product.

When you select to Create from the menu or select to edit a product the flag is enabled with the message "**Enabled to create a legacy product following specifications of Vet EU IG Chapter 4**".

Click the button to toggle to use Chapter 2 validation rules.

4.3. Workarounds required to Create or Update products

There are some workarounds that are required in this release when creating products.

Issue reference	Vet EUIG Chapter 2 section	Issue and Workaround
82440 UPD-4863	5.6.4 Ingredient (in Manufactured item)	This should not be mandatory for Legacy products. An ingredient must be selected in this release for create of a NAP product. It is no longer mandatory for a DCP.

4.4. Registration process for access to the NCA UI in the UAT environment

To request access:

- If you do not already have an EMA account in the Test environment:

    o EAM-Test can be found at: https://register-test.ema.europa.eu/identityiq/login.jsf

    o *Create a new EMA account*   Reference guide: https://register-test.ema.europa.eu/identityiq/help/selfregister.html (note: links in the documentation are for the production environment)

- Log into EAM-Test once registration is complete to Request Access to one of the UPD NCA UI roles

    o select *Request Access for Organizations*. Reference guide: https://register-test.ema.europa.eu/identityiq/help/requestaccess.html

    o choose your country and Organization ID.

    o use "UPD" as a search option to filter available roles

    o select appropriate role:

        ▪ **UPD CA Super User (reminder**: **attach document** as evidence of your authority to manage users for your organisation)

        ▪ **UPD CA Edit Search View**

        ▪ **UPD CA Search View**

- Some UPD-specific screenshots can be found in Annex 1.

- The request for the first "UPD CA Super User" for your organisation will be approved by EMA. Access is only being granted to NCA staff.

- The approved "UPD CA Super User" will manage all other access requests for your organisation.

- Once registered, the UI in UAT can be found at:

    Union product database (upd-portal-uat.azurewebsites.net)

If you have questions or encounter issues, contact the VMP-Reg User Support via https://servicedesk.ema.europa.eu/jira/servicedesk/customer/portal/283/group/506.

4.5. Registration process for access to the NCA UI in production (PROD) environment

We strongly recommend that before you request access to the UPD PROD environment, you have:

- Participated (viewed recording) in the training/demo on how to submit legacy data in UPD of 4 August 2021

- Carried out some testing in the UAT environment compliant with the latest version of the EU Implementation Guide.

To request access:

- If you do not already have an EMA account in the Production environment:

    o EAM Production can be found at: https://register.ema.europa.eu/identityiq/login.jsf

    o *Create a new EMA account*   Reference guide: https://register.ema.europa.eu/identityiq/help/selfregister.html

- Log into EAM Production once registration is complete to Request Access to one of the UPD NCA UI roles

    o select *Request Access for Organizations.*   Reference guide: https://register.ema.europa.eu/identityiq/help/requestaccess.html

    o choose your country and Organization ID.

    o use "UPD" as a search option to filter available roles

    o select appropriate role:

        ▪ **UPD CA Super User (reminder**: **attach** Nomination **document** as evidence of your authority to manage users for your organisation)

        ▪ **UPD CA Edit Search View**

        ▪ **UPD CA Search View**

- Some UPD-specific screenshots can be found in Annex 1.

- The request for the first "UPD CA Super User" for your organisation will be approved by EMA. Access is only being granted to NCA staff.

- The approved "UPD CA Super User" will manage all other access requests for your organisation.

- Once registered, the UI in PROD can be found at:

    [Union product database (upd-portal-prod.azurewebsites.net)](upd-portal-prod.azurewebsites.net)

If you have questions or encounter issues, contact the VMP-Reg User Support via https://servicedesk.ema.europa.eu/jira/servicedesk/customer/portal/283/group/506.

5. UPD API to Maintain Products and Product Documents

5.1. 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~~   Not fully functional due to bug 132758

- Upload, search, retrieve, and update Documents (for product under any procedure type)

5.2. 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 5.5.2. 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
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.

5.3. 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 5.2. 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.

5.4. 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

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

5.5.1. 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

5.5.2. 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 homeopathicschapter4 = true	
Update Registered Homeopathic	/pms/api/v2	homeopathicschapter2 = true OR homeopathicschapter4 = true	is update = true

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

5.5.3. 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."

5.5.4. 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
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

5.5.5. 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.

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

Attribute	Change
None	

5.5.7. API EP309 Create product example request bundles

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

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

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

Procedure type	Validation rules	Example file
DCP	Chapter 2	UPD_1.6.5-6_DCP_Chpt2_C2_Mandatory_VetIG.JSON UPD_1.6.5-6_DCP_Chpt2_C2_Mandatory_VetIG.XML UPD_1.6.5-6_DCP_Chpt2_C110_VetEUIG_AllData.JSON UPD_1.6.5-6_DCP_Chpt2_C110_VetEUIG_AllData.XML
DCP	Chapter 4 Legacy	UPD_1.6.5-6_DCP_Legacy_C2_Mandatory_VetIG.JSON UPD_1.6.5-6_DCP_Legacy_C2_Mandatory_VetIG.XML UPD_1.6.5-6_DCP_Legacy_C110_VetEUIG_AllData.JSON UPD_1.6.5-6_DCP_Legacy_C110_VetEUIG_AllData.XML
NAP	Chapter 2	2.2 Authorisation/registration/entitlement number is specified at Product level UPD_1.6.1-4_NAP_Chpt2_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel.JSON UPD_1.6.1-4_NAP_Chpt2_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel.XML

Procedure type	Validation rules	Example file
		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
NAP	Chapter 4 Legacy	UPD_1.5.1-0_NAP_Legacy_Cx_ManyAttributesAndResources_MANumberAtMedicinalProductLevel.XML

Procedure type	Validation rules	Example file
		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

5.5.8. 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
<?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

5.5.9. 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

5.5.10. 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

5.5.11. 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.

5.5.12. 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	Sample XML of Get Everything response used as a starting point:

	Bundle.entry.request.method for each resource.	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	

5.5.13. 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	

5.6. API Manage document

5.6.1. EP403 Create document

Resource Information

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

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

Query Parameters

None

Example Request

For UAT environment: POST https://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)

5.6.2. EP401 Search document

Resource Information

Endpoint	GET /pms/api/v2/DocumentReference?{ param}={value}[&{param}={value}]
Request	
Accept	application/fhir+xml application/fhir+json
Body	n/a
Content-Type	n/a
Response	

Body	Bundle of <DocumentReference>(s)
	
	e.g.
	Bundle
	  Total value=N
	  [entry
	     {DocumentReference Resource Type}
	  ] *

Path Parameters

Name	Description
Version	Service version number **Example value:** 2

Query Parameters

Name	Description
related	Permanent identifier of the product the document is related to
type	Type of document
_summary	Boolean set to true or false. If set to true, the contents of the document is not populated in the response in DocumentReference.content.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

5.6.3. EP402 Get/retrieve document

Resource Information

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

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

Path Parameters

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

Query Parameters

None

Example Request

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

5.6.4. EP404 Update document

Resource Information

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

Query Parameters

None

Example Request

For UAT environment: POST https://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

5.6.5. Changes for Create and Update document payload

- There are no changes to payload

6. UPD API for VNRA

6.1. Scope of this release for VNRA API

UPD-UC31 Manage VNRA Submissions via API

- Search and Retrieve VNRA

- Approve/Reject VNRA

6.2. UPD API supported VNRA endpoints

6.2.1. Query / Retrieve VNRA Submission

Query / Retrieve VNRA Submission	GET	*Returns the complete collection of submissions which the caller is entitled to view* /vnra-submission?permanentId={permanentId} upd/api/vnra/v3/vnra-submission?permanentId=600013438271
APIM entry point UAT		https://spor-uat.azure-api.net/upd/api/vnra/v3/vnra-submission?permanentId=600013438271
APIM entry point PROD		https://spor.azure-api.net/upd/api/vnra/v3/vnra-submission?permanentId=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": {
```

```json
      "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** | ```json
{
  "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
   }
```

6.2.2. 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"
}
```

6.2.3. 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

6.2.4. 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	<pre>{
	  "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": {}
	    }
	  ]
	}</pre>

6.3. 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.

7. UPD API for Volume of Sales Data

7.1. Scope of this release for Volume of Sales API

- Retrieve Volume of Sales Data

7.2. 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

```json
{
  "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

```json
{
  "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
}
```

7.3. 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.

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

8. MAH UI

8.1. Scope of this release for MAH UI

- UPD UC03 Search Product via UI

- UPD UC04 Export search results

- UPD UC05 View Product via UI

- UPD UC21 Manage Notifications via UI

- UPD-UC07 Download Packages and Submission of Volume Sales via Form

- UPD-UC27 View Submissions of Volume Sales via Form

  - Scenario 1 and 3 – View and Download Volume of Sales as a CA or MAH

  - Scenario 2 – View Submissions as MAH

- UC06 Submit VNRA via UI

- UC28 View Variation not Requiring assessment via UI

- UC24 Submit updates for Marketing authorisation status

- UC25 Download and Submit updates for Availability status

- UC33 Manage third country Product names (Name, Country, and Language)

- UC38 Manage Products grouping

Supported browsers for the MAH UI are Chrome and Edge.

8.2. Registration process for access to the MAH UI in production (PROD) environment

To request access:

- If you do not already have an EMA account in the production environment:

  - EAM can be found at: https://register.ema.europa.eu/identityiq/login.jsf

  - *Create a new EMA account* Reference guide:
    https://register.ema.europa.eu/identityiq/help/selfregister.html

- Log into EMA Production once registration is complete to Request Access to one of the UPD MAH UI roles

  - select *Request Access for Organizations.* Reference guide:
    https://register.ema.europa.eu/identityiq/help/requestaccess.html

  - choose your country and Organization ID.

  - use "UPD" as a search option to filter available roles

  - select the appropriate role:

    - **UPD Industry Super User (**reminder: attach document as evidence of your authority to manage users for your organisation)

    - **UPD Industry Edit Search View**

    - **UPD Industry Search View**

- Some UPD-specific screenshots can be found in Annex 1.

- The request for the first "UPD Industry Super User" for your organisation will be approved by EMA.

- The approved "UPD Industry Super User" will manage all other access requests for your organisation.

- Once registered, the UI in the production environment can be found at:

  [Union product database (upd-portal.azurewebsites.net)](upd-portal.azurewebsites.net)

If you have questions or encounter issues, contact the VMP-Reg User Support via [EMA Service Now: https://support.ema.europa.eu/](https://support.ema.europa.eu/).

9. MAH Validation UI for Volume of Sales Submission

There is a separate Validation UI available for MAH users to use to validate submission files for Volume of Sales.

Validation portal URL https://upd-portal-prod-validation.azurewebsites.net

Scope for Validation portal

- The Validation UI will 'Download packages' originating from the **same** store as the normal MAH UI

- The Validation UI 'Submit submission' goes to a **separate validation store**

- The Validation UI 'View Submissions' retrieves data from the **separate validation store**

- Submission to the validation store or normal store **are completely independent.** Therefore submissions made in Validation UI will not be seen in the normal MAH UI and vice-versa.

10. Known issues

Please refer to Annex 2.

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.

11. User support

API and UI users may seek support in uploading their legacy data into UPD, by contacting the User Support via [EMA Service Now: https://support.ema.europa.eu/](https://support.ema.europa.eu/).

For the technical team to address your query in a timely manner, please include the following information as appropriate:

- UI: Print screen of the information entered to create a veterinary product (go to your browser settings, select Print (or press Control + P) and "Save as PDF" on your computer

- API: Operational outcome of the unsuccessful task; the request URL and request headers; and for a Create or Update the request body

12. References

1. [Registration guide - Union Product Database for veterinary medicinal products](#) (PDF document)

2. UPD 01.03 [Registration Process for UPD API in UAT](#) (PDF document)

3. [SPOR API Specification V2_R5 (europa.eu)](#) API specifications for SMS and PMS, based on FHIR

4. [HL7 FHIR Release 5 Preview 2: the authoritative source for the FHIR specifications used by EMA to implement SMS and PMS API](#)

5. [Referentials Management System](#)

6. [Additional information](#) on the Referentials Management System

7. [Organisations Management System](#)

8. [Additional information](#) on the Organisations Management System

9. UPD_1.6.34_ReleaseNotes_ExampleFilesForAPI (zip file)

10. Nomination letter for EAM CA Super user role

Annex 1: UPD-Specific Screenshots for Registration for an Account for the UI

The overall aim of the new access request workflow is to **better guide our users through the entire process**, **minimise the number of rejections** and to ensure that users can **access EMA's applications and systems** in a swift and efficient manner.

Furthermore a new "**Manage Access**" tab allows users and users administrators to list and revoke access for themselves and for the users of the organisation they manage.
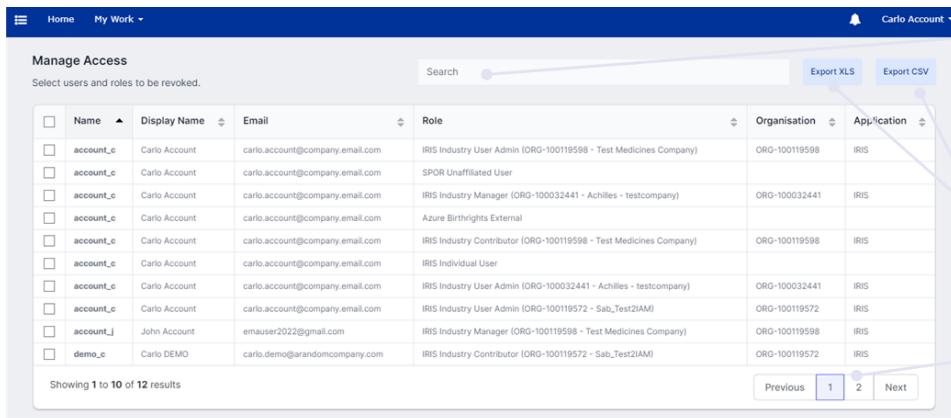
The Search bar can be used to filter results on organisations, users or roles.

Use the export buttons to export data and perform more complex filters

10 results are displayed, further results can be navigated using the paging buttons

The 'Manage my access' tab, marked in red in the visual below, became obsolete, with all procedures now being managed through the 'Request Access for organisations' tab and the 'Manage Access' tab, marked in green.

Further information on access-management aspects and procedures for requesting and managing access to EMA applications can be found in the recording of the "EMA Account Management training webinar".

12.1. Request the Super User Role for your Organisation in UAT

1. Connect to EMA test: https://register-test.ema.europa.eu/identityiq/login.jsf?prompt=true

2. Go to "Request Access for Organizations" and search for your country and your ORG ID:

3. Select "UPD" to find the roles:

4. Choose the UPD CA Super User role:

5. In the next screen, upload a document to show your affiliation to your organisation. For now, just upload any document (We'll need the formal document later and will also need this for production)

6. Click "Submit"

7. An EMA Super User Approver will now review your request and approve asap or get back to you for more information.

12.2. Request a Member User Role for your Organisation and Affiliate to your Organisation in UAT

1. Connect to EMA test: https://register-test.ema.europa.eu/identityiq/login.jsf?prompt=true

2. Go to "Request Access for Organizations" and search for your country and your ORG ID:

3. Select "UPD" to find the roles:

4. Choose the UPD CA Edit/Search/View or the UPD CA Search/View role.

5. Submit.

12.3. Request the Super User Role for your Organisation in Production

Note: This is at this point only relevant for UI usage. The model for the API accounts remains as per section 5.3. and the document referred to in section 12. .

1. Connect to EMA production: https://register.ema.europa.eu/identityiq/login.jsf?prompt=true

2. Go to "Request Access for Organizations" and search for your country and your ORG ID:

3. Select "UPD" to find the roles:

4. Choose the UPD CA Super User role (NCA) or the UPD Industry Super User role (MAH):

5. In the next screen, upload the nomination letter to show your affiliation to your organisation.

6. Submit.

7. An EMA Super User Approver will now review your request and approve asap or get back to you for more information.

12.4. Request a Member User Role for your Organisation and Affiliate to your Organisation in Production

Note: This is at this point only relevant for UI usage. The model for the API accounts remains as per section 5.3. and the document referred to in section 12. .

1. Connect to EMA production: https://register.ema.europa.eu/identityiq/login.jsf?prompt=true

See the screenshots in section 12.2. in this annex.

Contact the Super User of your organisation if in doubt on which the correct organisation ID is for your organisation.

Annex 2: Known issues

This table is ordered by Use Case number.

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Known Issue Description
All UC	MAH UI	UPD-9896	82803	All OPAD 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
All UC	NCA UI & MAH UI	UPD-13297	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	UPD-13623	92757	OMS to UPD updates: New or Updated Organisations and Locations from OMS are not available in UPD
API Manager	API	UPD-10952	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	UPD-13448	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	NCA UI	UPD-13465	83297	All procedure types: when adding second Ingredient, the Reference strength "Unit of measurement" drop-down list does not display list of terms so select a value. Second ingredient must first be added and then select Edit to be able to select required Unit of Measurement term
UC01 Create product	NCA UI		81410	Create a product from an existing one - "Retrieve Existing information": When NCA user is affiliated to more than one NCA organization, it is not possible to select products that belong to these organizations

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Known Issue Description
UC01 Create product	API		121940	Create DCP where RMS has inadvertently included a National package description in the request payload. This national data should be silently ignored and not output in the created products for the RMS or CMS. Instead the national package description is being added in the created products
UC01 Create product	API & NCA UI	UPD-11038	92292	Create DCP: submission is successful but when check transaction status using GET OperationOutcome there is an error "Failed to generate snapshot". The product is not created and there is no Notification. This is an intermittent issue that infrequently occurs.
UC01 Create product	NCA UI	UPD-11832	92479	Create MRP : the "Add Package" button remains disabled after entering values for the addition of a package
UC01 Create product	API	UPD-11849	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	UPD-11277	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	API & NCA UI		119875	Create Pet product - In the table of Ingredients, if reference strength is added using free text there is no hyphen between the reference substance name and the free text data
UC01 Create product	NCA UI		117980	Create Pet product based on Chapter 2 rules: it is possible to add a Manufactured item into the table without any of the 3 fields for the manufactured item populated. This empty manufactured item is able to be selected in a Package. Submission of the create is successful and OperationOutcome ID provided. However, the transaction fails with ERR-1002 (as seen in the GET OperationOutcome result) and the product is not created
UC01 Create product	NCA UI		113613	Create SRP - an intermittent issue where the update for one of the existing CMS fails with error in OperationOutcome related to DocumentProcessingException

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Known Issue Description
UC01 Create product	NCA UI	UPD-13271	83271	Create SRP - in some situations, the create transaction does not complete. When checking the status using OperationOutcome ID the status remains IN_PROGRESS indefinitely. Issue is still to be investigated but may be related to a large Common product document(s) that exist for the RMS
UC01 Create product	NCA UI		113178	Create SRP product - RMS is able to select DCP/MRP/SRP where that are not the RMS and use as retrieved product for a create SRP
UC01 Create product	API & NCA UI		112858	Create SRP Product - RMS is not able to submit create SRP for a DCP/MRP/SRP where one of CMS products is nullified and not yet removed from the list of Concerned member states. As a workaround for this issue the RMS can submit an Update Common Data to remove the nullified CMS from list of CMS countries and once that update transaction has been completed proceed to create SRP
UC01 Create product	NCA UI	UPD-13829	92814	Create SRP where no Pack size specified for a package: when create submitted the page remained with progress contol and product was not created
UC01 Create product	NCA UI	UPD-3346	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	UPD-13840	92816	Free text strength values are not displayed when selecting Ingredients to link in Pharmaceutical product and Manufactured item sections
UC01 Create product	NCA UI	UPD-13843	83371	If free text strength for an Ingredient is entered before selecting the Substance code, add button remains disabled. As a workaround for this minor issue: remove the free-text substance strength after selecting the substance code and then re-enter
UC01 Create product	API & NCA UI	UPD-10293	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)

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Known Issue Description
UC01 Create product	API	UPD-4726	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 will be corrected in a future release.
UC01 Create product	API	UPD-4723	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. This will be corrected in a future release.
UC01 Create product	NCA UI	UPD-13880	83385	Registered Homeopathic based on Legacy/Chapter 4 validation rules: the asterisk mark to indicate a mandatory field is not displayed on Tissue field
UC01 Create product	API	UPD-11587	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	API	UPD-2765	82249	Validation in all resources of URN UUID for fullURL 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	UPD-7997	82628	Create/Update of a Product - Error Messages need to be more meaningful
UC01 Create product UC08 Update product	NCA UI	UPD-7964	82617	Date field may give an erroneous value when you click on the date picker widget after entering some partial value manually.

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Known Issue Description
UC01 Create product UC08 Update product	API & NCA UI	UPD-5531	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
UC01 Create product UC08 Update product	API	UPD-11621	83108	For any product where Reference Strength Denominator has a term from Unit of Measurement list with List ID specified as Unit of Presentation, or vice-versa, there should be a validation error
UC01 Create product UC08 Update product	NCA UI	UPD-13632	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	UPD-9338	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	NCA UI	UPD-4863	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.
UC01 Create product UC08 Update product	API & NCA UI	UPD-7228	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 UC08 Update product	NCA UI	UPD-5114	82452	UC01 UC08 All procedure types - leading and trailing spaces in free-text fields should be removed by the system before validation

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Known Issue Description
UC01 Create products	API & NCA UI		111611	Create SRP - if there is an update already in progress for an existing CMS product when the Create SRP transaction is processed, the new CMS and any other common data updates are only applied to the RMS and other CMS products. Any CMS product that has an update in progress is not being updated. New CMS products are being created. For API users an error is seen in the GET OperationOutcome response like "An update request is already in progress for Bundle: 600000000000". The current datafix for DCP/MRP/SRP products to align the list of Concerned Members Status in each CMS product with the list in the RMS product will correct for any existing products affected by this issue. Once this bug is resolved we will re-run the datafix to align the list of Concerned member states. This datafix will not align any other common data updates that may have been made as part of the Create SRP.
UC03 Search product	API	UPD-13658	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	MAH UI	UPD-12230	83191	If search products filtering by Product owner for Location that MAH user is not affiliated to - Error 403 Permission denied message is displayed instead of expected "Results not found"
UC03 Search product	API & NCA UI & MAH UI	UPD-5538	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	UPD-10219	82825	Reset button does not clear existing search criteria from "Authorisation Country"
UC03 Search product	NCA UI & MAH UI	UPD-12748	83234	Search limitations due to FHIR limitation or MS FHIR limitation
UC03 Search product	API & NCA UI & MAH UI	UPD-140	82034	Sort of search results does not work

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Known Issue Description
UC03 Search product UC05 View Product	API & NCA UI & MAH UI	UPD-13461	83294	The 'Organisation Name' from OMS is not always displayed for a Product Owner on the Search and View Product screens
UC03 Search products	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 products	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 dusplayed on the page overlapping the drop down for the number of products to display per page
UC03 Search products	NCA UI & MAH UI		111811	The search results grid displays N/A after the subtance name when the strength is only defined with free text value
UC04 Export	MAH UI		132732	MAH user affiliated to 2 or more Organisations that has searched for products for one of the Locations they are affiliated to is not able to export the product search results
UC05 View product	NCA UI & MAH UI		115230	CAP products are incorrectly displaying a value for Availability Status beside the package description. Only the table that lists Availability Status and Availability Status Date by Country should be listed for CAP products
UC05 View Product	NCA UI & MAH UI		132610	CAP products for Metacam now have some duplicated products with different Permanent identifiers. The Package identifiers in the two products are the same. Issue is still be investigated to identify cause and which product will be retained
UC05 View product	NCA UI	UPD-13441	79980	NCA User affiliated to both PEI & BVL does not have Edit Buttons as expected
UC05 View product	NCA UI & MAH UI	UPD-13870	83380	Parallel trade product with more than one Route of Administration lists the term names without a space and separator between each term

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Known Issue Description
UC05 View Product	NCA UI		133247	Registered Homeopathic, Parallel trade and Pet products - when a NCA Edit/Search/View user views a product for one of these procedure types for another Authorisation Country to that they are affiliated to the Edit product button is incorrectly displayed and enabled. The user is able to select to edit and submit an Update
UC05 View product	API & NCA UI & MAH UI	UPD-13993	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	UPD-13125	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
UC05 View product	NCA UI & MAH UI	UPD-12279	83197	When view product, dates are different according to browser timezone
UC05 View product	NCA UI & MAH UI	UPD-10185	82822	When view product, there has been an example where Marketing authorisation date shows differently for MAH and NCA user. Issue is still being investigated but is thought to occur infrequently and examples have differed by 1 day
UC06 Submit VNRA UC28 View VNRA	NCA UI & MAH UI		132447	If the ATC pending vet code is set to True and VNRA is being submitted for variation code A4, the message "ATC vet code not available" is not displayed on the submission form. The VNRA can be successfully submitted but when MAH or NCA view the submission they will ne see this message in Existing value field
UC06 Submit VNRA	MAH UI	UPD-11632	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

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Known Issue Description
UC06 Submit VNRA	MAH UI	UPD-8440	82652	Overall Date of submission shows red outline if it had been populated, then value removed and individual values added for each variation for each product
UC06 Submit VNRA	MAH UI	UPD-13883	80363	Submission of VNRA fails with notification that failed due to a technical error. The error message seen in server logs is SQL Error: 547 "The INSERT statement conflicted with the FOREIGN KEY constraint". We have not been able to reproduce this issue in the UAT environment and not able to provide any additional information at this time as to combination of circumstances causing this issue
UC06 Submit VNRA	MAH UI	UPD-13125	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 UC28 View VNRA	NCA UI & MAH UI	UPD-10184	82821	Accented and special characters for all EU languages are not always correctly displayed (could be Product Name, Package description, Submission Comment, Decision comment). Some are OK but others aren't. This is an issue on the UI screen and also in the PDF
UC07 Submit Volume of Sales	MAH UI	UPD-9868	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)
UC08 Update product	API & NCA UI	UPD-10288	92114	A Product stuck in 'pending' state from a previously failed update transaction cannot be updated
UC08 Update product	API & NCA UI	UPD-12949	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	UPD-7996	82627	Add button in Package medicinal product section needs to have more meaningful caption
UC08 Update product	NCA UI		111377	All procedure types: Availability status is not updated to "Not marketed" when Authorisation status is updated to Suspended or Revoked if Product has no existing record for Availability status from when product was created

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Known Issue Description
UC08 Update product	API & NCA UI	UPD-12580	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	UPD-4812	82437	Change to procedure number not saved if existing inline attribute id is not included in the request body
UC08 Update product	API	UPD-4811	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	UPD-11819	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	UPD-12399	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	NCA UI	UPD-9023	82735	The quantity and units of presentation are not shown in package table for Manufactured Item. The values are displayed if the package is edited. This is only issue with display of information on the UI and no data has been lost from the product
UC08 Update product	NCA UI	UPD-7247	82571	UC08 - Update DCP SC2 National data - Able to add a new Pharmaceutical Product which is a Common data; advised successful but Get OperationOutcome has Validation error
UC08 Update product	API	UPD-7148	82569	UC08 Update SC2 NAP - should reject update with validation error message if MedicinalProductDefinition.id is not populated
UC08 Update product	API	UPD-7273	82573	UC08 Update SC2 Update National - API - UPD-UC08-AC016 - Missing Validation error when update Product Status from Current to Provisional & product has been updated

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Known Issue Description
UC08 Update product	API	UPD-9709	82786	Update Common Data - the response to Get OperationOutcome in some circumstances does not contain the status of the POST and instead has "Failed to parse JSON encoded FHIR content: Content does not appear to be FHIR JSON, first non-whitespace character was: '<' (must be '{')". This issue only arises for some instances where there has been a failure processing the update. It is not expected that this will occur frequently.
UC08 Update product	API	UPD-10607	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		93900	Update NAP - POST fails with Validation error but can't identify offending data based on error message provided. Believe this only occurs for some older products where Authorisation number is specified at Package level where there are 2 or more packages
UC08 Update product	API & NCA UI	UPD-13959	80364	Update National Data DCP/MRP/SRP - it is possible to edit Common description of a package and change the language from English to another language. It should not be possible to update this common data
UC08 Update product	NCA UI	UPD-12905	83246	Update National Data DCP/MRP/SRP - Visually looks like can delete a CMS as has "x". However, CMS can't be removed as nothing happens when click on "x"
UC08 Update product	API & NCA UI	UPD-13296	83276	Update of product fails leaving product in Pending state and this blocks and subsequent update
UC08 Update product	API & NCA UI	UPD-12385	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 sucessfully and Operation Outcomce states 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.

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Known Issue Description
UC08 Update product	API & NCA UI	UPD-12396	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
UC08 Update product	API	UPD-5192	82466	When updating product to change from specifying Legal status of supply at product level to package level, when you retrieve the updated product the previous value is still populated at the product level.
UC09 Approve/Rej ect VNRA	NCA UI		132424	An EC user cannot approve/reject VNRA submission of CAP products
UC09 Approve/Rej ect VNRA	NCA UI		84163	CMS NCA is able to select Approve/Reject checkbox when viewing a VNRA, although the Submit button correctly remains disabled
UC09 Approve/Rej ect VNRA	NCA UI	UPD-9866	82800	If an NCA is affiliated with two or more Organisations, they should only be able to view and approve/reject VNRA for submissions of NP products where they are the Responsible Authority; or DCP/MRP/SRP where they are RMS/CMS
UC18 Manage document	API	UPD-12477	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	UPD-11471	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	UPD-10057	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

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Known Issue Description
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	UPD-9830	82796	When you nullify a product, the confirmation message does not include the Permanent Identifier
UC21 Manage Notifications	NCA UI & MAH UI	UPD-10184	82821	Accented and special characters for all EU languages are not always correctly displayed (could be Product Name, Package description, Submission Comment, Decision comment). Some are OK but others aren't
UC21 Manage Notifications	NCA UI & MAH UI	UPD-13049	83254	Date format inconsistent between different actions
UC21 Manage Notifications	NCA UI	UPD-8340	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
UC21 Manage notifications	NCA UI & MAH UI	UPD-11827	83144	Not able to search notifications using Procedure number
UC21 Manage Notifications	NCA UI & MAH UI	UPD-13820	83361	Notification for VNRA Approved : Date of Decision in notification card has date in wrong format : has mm-dd-yyyy and should be dd-mm-yyyy
UC21 Manage Notifications	NCA UI	UPD-13811	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
UC21 Manage Notifications	NCA UI & MAH UI	UPD-12454	83211	Notifications are sometimes missing for some actions. For example Create DCP - only notifications received for some CMS even although transaction has been completed successfully and products have been created

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Known Issue Description
UC21 Manage Notifications	NCA UI & MAH UI	UPD-13656	83330	Search of notifications with filter of "VNRA Rejected" and Authorisation Country "Romania" displays a system error. This is the only Authorisation country that displays an error for Action of "VNRA Rejected". Filtering by just "VNRA Rejected" or "Romania" does list notifications
UC21 Manage Notifications	NCA UI & MAH UI		100749	Updating a NAP to delete a document does not create a "Delete document" notification and there is only an "Update" notification
UC21 Manage Notifications	NCA UI & MAH UI	UPD-13135	92701	When submission of VNRA has Failed: The notification card for action of "VNRA failed" does not match the definition documented in "UPD - Notifications in processes"
UC21 Notifications	NCA UI & MAH UI		101016	After entering search criteria and click the "Enter" key, the search results should be displayed as if the Search button had been clicked. Instead nothing happens and no results are displayed. After submitting a search clicking the Reset button should clear all search criteria and the search results table. Product owner search criteria field is not being cleared; and search results table is not cleared.
UC24 Marketing authorisation status	MAH UI	UPD-13847	83374	If select DCP/MRP/SRP where Product status Provisional, the UI screen remains hung with in-progress control. There should be a validation error displayed that marketing authorisation status can only be updated if product status is Current
UC24 Marketing authorisation status	MAH UI	UPD-12092	83188	When MAH selects to update a product that has some data quality issue, the screen hangs on submission due to a validation error. This validation error is not shown to the user. The submission should fail with validation error displayed to the user.
UC25 Update Availability status	MAH UI	UPD-13491	83305	After searching for products, selecting products and download file: when click on the Reset button any search criteria in Product name and Permanent Identifier fields is not being cleared

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Known Issue Description
UC25 Update Availability status	MAH UI		101204	After submitting a search to view submissions for Availability Status and click the Reset button: only the search criteria are being cleared but the search results table remains populated with previous search results. The search results table should also be cleared
UC25 Update Availability status	MAH UI	UPD-13995	83433	Download Product data file : the 'Availability Status' column may have zero for the RMS Term code if no default Availability status value has been populated at the time the product or package was created
UC25 Update Availability status	MAH UI	UPD-13900	83397	Format of value for Availability status date column is not as expected in download file; and validation not being applied as expected to this value in submission file
UC25 Update Availability status	MAH UI	UPD-7980	82625	Not able to select all products to download in the one csv file if product search results are over two or more pages
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.
UC26 Manage draft Products	NCA UI		129052	Parallel Trade product - able to save a draft but when return and retrieve draft the screen hangs and not able to create product from the saved draft
UC26 Manage draft Products	NCA UI		113642	When a product is Created for a Saved draft, the draft has not been deleted after the creation of the product. Initial test has identified issue with draft for a NAP and still to be assess if also an issue for other procedure types
UC26 Manage draft Products	NCA UI		131326	Update Draft DCP - after retrieving a saved draft for a DCP, the product name that was in the draft is not able to be edited or deleted. As a workaround, RMS will need to use Update Common Data to edit common product name after Create DCP has been processed

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Known Issue Description
UC27 View Volume of Sales	NCA UI & MAH UI	UPD-13650	92777	If an attempt is made to download Volume of Sales for a product with "Year from" less than or equal to 2016 the progress control is displayed for a period of time and then a server error displayed. A change will be made so that only sales volumes from 2022 onwards can be downloaded
UC27 View Volume of Sales	MAH UI		84524	MAH user only: Download Volume of Sales sales data - get "server encountered an error" - not able to download for either existing Volume of Sales that had been loaded prior to release 1.6.22 or new submission made in 1.6.22 release
UC27 View Volume of Sales	MAH UI		101204	After submitting a search to view submissions for Volume of Sales and click the Reset button: only the search criteria are being cleared but the search results table remains populated with previous search results. The search results table should also be cleared
UC28 View VNRA	NCA UI & MAH UI		103494	Accented and special characters for all EU languages are not always correctly displayed (could be Product Name, Package description, Submission Comment, Decision comment). Some are OK but others aren't. Issue in PDF (similar issue to 82821)
UC28 View VNRA	NCA UI	UPD-13717	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	UPD-9866	82800	If an NCA is affiliated with two or more Organisations, they should only be able to view and approve/reject VNRA for submissions of NP products where they are the Responsible Authority; or DCP/MRP/SRP where they are RMS/CMS
UC28 View VNRA UC06 Submit VNRA	NCA UI & MAH UI		132447	If the ATC pending vet code is set to True and VNRA is being submitted for variation code A4, the message "ATC vet code not available" is not displayed on the submission form. The VNRA can be successfully submitted but when MAH or NCA view the submission they will ne see this message in Existing value field

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Known Issue Description
UC28 View VNRA	NCA UI	UPD-12886	83242	NCA Germany only for DCP/MRP/SRP where National Data has been populated with Responsible Authority of either PEI or BVL. Where VNRA Submission made for product: Both PEI and 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 BVL should be able to view a VNRA submission.
UC28 View VNRA	NCA UI		133434	NCA user not able to view first page of pending submissions when select from menu, or are not able to navigate to second page of 100 subnissions. After a period of time the screen is displayed with the message "no results found"
UC28 View VNRA	NCA UI & MAH UI	UPD-13814	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
UC28 View VNRA	NCA UI & MAH UI	UPD-11574	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
UC28 View VNRA	MAH UI	UPD-10911	82958	View partially approved VNRA and message is displayed "System error: try again in a few minutes". Waiting some time and retrying will not work and it will always fail to display
UC28 View VNRA	NCA UI & MAH UI		103545	VNRA PDF - the term code for the Variation code is displayed instead of term name in the downloaded PDF file for new codes B.24.a B.24.b and B.12.h

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Known Issue Description
UC28 View VNRA			103505	When select to view a submission that contains many products and/or variation codes : there may be a timeout error downloading PDF; and timeout error viewing submission or information takes long to appear on screen but does eventually load
UC28 View VNRA	NCA UI & MAH UI	UPD-13854	83375	When view an old VNRA submission that contains more than one variation code, only one variation code as header is displayed and counted. This means that NCA is not able to partially approve/reject combinations for product/variation code. The correct variation code and product details are listed in each product card
UC28 View VNRA	NCA UI		133434	Some NCA users aere not able to view the first page of pending submissions when select to View VNRA Submission from the menu; or are not able to navigate to second page of 100. As a work-around some filter criteria needs to be applied and a new search submitted
UC07 Submit Volume of Sales UC25 Update Availability status UC33 Manage third country Product names UC38 Products Grouping	NCA UI & MAH UI		134376	If Product name or Package description comain an embedded comma, this comma is being replaced with a semi-colon in the download file ("," is changed to ";"). This issue affects the 4 download files for Volume of Sales, Availability Status, Manage 3rd Country Product Name and Manage Products Grouping

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Known Issue Description
UC33 Manage third country Product names	MAH UI		129500	MAH user with UPD Industry Search/View role is not able to download file of 3rd country product names and is not able to view submissions
UC33 Manage third country Product names	MAH UI		135321	Submission of 3rd Country Product Name is failing with validation ERR.27 for some countries even although they have the required extended attribute of "Country Grouping: non-European Economic Area - non-EEA"
UC33 Manage third country Product names	MAH UI		134632	If a 3rd Country Product Name contains an embedded comma in the submission file, this comma is being replaced with a semi-colon in the download file ("," is changed to ";")
UC33 Manage third country Product names	MAH UI		133338	When download the file that was submitted from the View submission page the system is adding a suffix to the end of the filename during the download process
UC34 Bulk Upload for Documents	NCA UI		102555	After Submit files may get error message displayed of "Document Upload Error: Document could not be uploaded.", with no validation error listed for any of the files. Based on investigations to-date believe this occurs when loading of files is slow due to load on the system. On subsequent attempt to load the files at a later time this has been successful
UC34 Bulk Upload for Documents	NCA UI	UPD-13642	80352	CAP product only for Document type PuAR: if PDF filename is the same as an existing document for PuAR there will be two documents show but both will have content of the most recent document that was loaded for that filename

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Known Issue Description
UC34 Bulk Upload for Documents	NCA UI	UPD-13298	92730	Documents have been successfully added to the product but a Notification has not been created for each of the documents that were successfully loaded
UC34 Bulk Upload for Documents	NCA UI		101825	For CAP products only: intermittent issue where load of documents for Procedure number where there are more than 10 products for that procedure number - not all of the documents are added for each of the products
UC34 Bulk Upload for Documents	NCA UI		101585	For CAP products only: issue where documents are not able to be submitted when there are many products under the procedure. Believe this only affects the 1 procedure that has more than 15 products. Error message received: "Document upload error: Document could not be uploaded"
UC34 Bulk Upload for Documents	NCA UI	UPD-11376	83046	For CAP products only: review document types that can be loaded as only expected PuAR, EPAR and Combined to be valid
UC34 Bulk Upload for Documents	NCA UI		94231	If CMS attempts to load a National Document for some other CMS the wrong validation error message is being displayed. The error messages displayed are: "ERROR: Product doesn't belong to the country provided ERROR: File naming convention is not respected ERROR: Invalid procedure number or product identifier provided in the file´s name ERROR: Your organization is not the Responsible Authority of this/these product(s)"; and it should be "ERROR: NCA users who play the role of CMS, are able to upload only National documents for the products approved under 'DCP', 'MRP' and 'SRP'"
UC34 Bulk Upload for Documents	NCA UI	UPD-12182	79983	Notifications are not all generated after uploading multiple documents using the bulk upload functionality (files have been added to the product)
UC34 Bulk Upload for Documents	NCA UI		102918	Submit a file where there is an existing document for that country, document type & language. Advised that the file has been submitted but there is no Notification suceeded/failed and document has not been updated. This issue is only occurring in PROD and was successful in test environments

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Known Issue Description
UC34 Bulk Upload for Documents	NCA UI		102996	Submit files and a message advisiing of the progress of loading the files is displayed. One or more files may be successful and one or more may have error. Files that were sucessfully loaded will have a green background and those with an error will have red background. There is no other error message in banner or on the page but can see in logs that there has been a timeout error. A subsequent load of those files at a later time is successful unless there is still a timeout error
UC38 Products Grouping	MAH UI		101204	After submitting a search to view submissions for Products grouping and click the Reset button: only the search criteria are being cleared but the search results table remains populated with previous search results. The search results table should also be cleared
UC38 Products Grouping	MAH UI		108430	MAH user with role "UPD Industry Search/View" is not able to download list of products or view list of submissions as there is no menu option listed
UC38 Products Grouping	MAH UI		109153	MAH user with role "UPD Industry Super User" is not able to download list of products. The in-progress control remains on the screen and there is an error "404 Not Found" (only seen in background and not displayed on the screen). MAH users with "UPD Industry Edit/Search/View" role are able to download list of products
Volume of Sales Validation Portal	MAH UI		117823	The Volume of Sales Validation portal is for use by MAH. An NCA user is able to log into the Validation portal and search and view products. There is an Edit button on the view product screen but nothing happens when this is clicked. An NCA user is not able to access any of the Volume of Sales menu entries. When issue is resolved NCA users will not be able to log into the Validation portal

Annex 3: Release Schedule

Environment	From	To	Description
UAT	6 September 2023	8 September 2023	Upgrade of UPD to 1.6.34
PROD	13 September 2023	15 September 2023	Upgrade of UPD to 1.6.34
UAT	18 October 2023	20 October 2023	Upgrade of UPD to 1.6.37
PROD	25 October 2023	27 October 2023	Upgrade of UPD to 1.6.37
UAT	29 November 2023 (tbc)	1 December 2023 (tbc)	Upgrade of UPD to 1.6.40
PROD	6 December 2023 (tbc)	8 December 2023 (tbc)	Upgrade of UPD to 1.6.40