Union Product Database (UPD) release notes

Referring to version 1.6.25

Release date: 5 June 2023

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

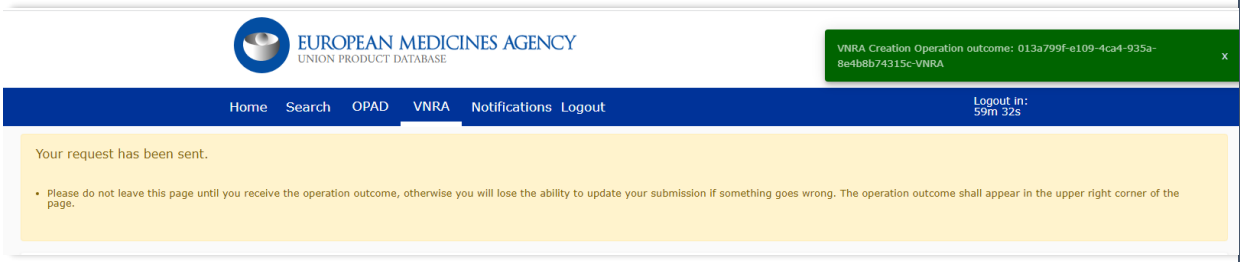
Overview of key changes:

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 (**1.6.22**, released on 17 April 2023), new functionalities (detailed information in section 2.1) are available and **58** defects (detailed information in section 2.2) have been considered resolved.

Overview of new functionality(ies):

- NCA UI user can now easily create new veterinary medicinal product by selecting a product that already exists in the UPD and using it as a baseline.
- NCA UI user can now upload in UPD multiple product documents, provided that the MAH follows new naming convention specified in the **revised** Annex 2 of Chapter 2 of the Implementation Guide on VMP data in the UPD (for completeness provided as Annex 4 in this document) and the revised User guide on how to generate PDF versions of the product information - veterinary. The new naming convention also removes the MAH burden to amend multiple PDFs specifying the product identifier in the custom tab each time.
- NCA UI: Transfer Marketing Authorisation for products under any procedure – released again
- MAH UI: Submit Availability status - released again, but please note outstanding issue
- MAH UI: Submit VNRA – for large submissions the banner may now contain a message advising that request has been sent,, but to remain on the page until Operation outcome has been received. If submission is successful the Operation outcome ID will be displayed in a dialog on upper right corner of the page.



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

Note:
Please note that the new MAH functionality to group essentially similar products together (hereafter called 'Products Grouping') functionality has not been fully released and should not yet be used.

For information:
EMA has recently 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 Nullify product
    - Search/view product (data and documents)
- 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 Nullify product
    - NCA can Bulk Upload Documents
    - NCA can Transfer Marketing Authorisation
    - Search/view/export products (data and documents)
    - Notifications for Create and Update of products and OPAD actions
    - View Volume of Sales information
    - View and Approve/Reject VNRA submissions
    - EMA and EC staff can update CAP products

- MAH UI:
    - Search/view/export products (data and documents)
    - Notifications for Create and Update of products and OPAD actions
    - Download, Submit, and View Volume of Sales information
    - Submit VNRA and View VNRA submissions
    - Submit updates for Marketing authorisation status
    - Download and Submit updates for Availability status
- Authorisation for NCA & MAH UI:
    - Integration with EMA Account Management (EAM) system for CA and Industry (MAH) roles
    - CA users may search and view all Vet products
    - MAH users may search and view only products under the responsibility of the organisations the user represents

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.

Products Grouping:

Please note that the new Products Grouping functionality for MAH has not been fully released and **should not yet be used.**

1.2. Functionality not included in this release

The following functionality is not included in this release.

NCA UI:

- none

MAH UI:

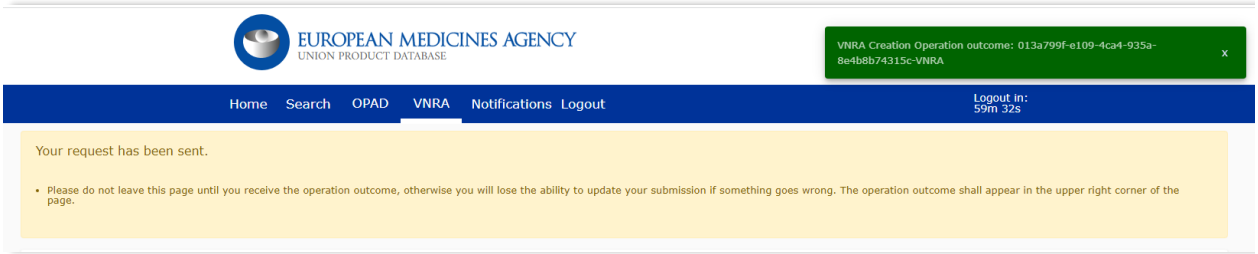
- **UPD-BR-126 - MAH ability to group essentially similar products together:**

- Menu items and screens exist in this release related to Product Grouping.
- However, due to outstanding bugs **this new functionality is not being fully released and should not be used.**

2. Changes made compared with 1.6.22

2.1. New or re-released functionality

- **NCA UI: Transfer Marketing Authorisation for products under any procedure.** UPD-12726 has been resolved and therefore this functionality can be used in this release.
- **MAH UI: Submit updates for Availability status:** There had been three issues affecting the submission of Availability status.UPD-13458 affects products under DCP/MRP/SRP where RMS product was always incorrectly updated – this issue has been resolved; UPD-13635 affecting the submission of updates for CAP products – this issue has been resolved; 85589 affects any submission where day within date provided is being ignored and availability status date in updated product is always the first day of the provided month/year – outstanding issue.
- **UPD-BR-043 Create a product from an existing one (via UI)**
  - NCA may now create a NAP or a DCP from an existing product.
- **UPD-BR-156 Bulk upload - Ability to upload one document to several products**
  - The custom property within the PDF is no longer used to indicate the Product Identifier for the new/updated document.
  - Instead the new file naming convention for files is used to indicate product(s) for the new/updated document.
  - Vet EU IG Chapter 2 has been published with a revised Annex 2 that includes the new file naming convention to be used. That Annex has been also included in this document for completeness. Please refer to Annex 4.
  - 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.
- **MAH UI: Submit VNRA** – for large submissions the banner may now contain a message advising that request has been sent but to remain on the page until Operation outcome has been received. If submission is successful the Operation outcome ID will be displayed in a dialog on upper right corner of the page.



2.2. Resolved issues

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

Use Case	Affects API and/or UI	Issue reference (Old JIRA)	Issue reference (New ADO)	Vet EUIG Chapter 2 section	Resolved issues
All UC	NCA UI & MAH UI	UPD-13282	92720		BR-169: An expired session warning message may have been displayed before current timer had run out. This issue has been resolved
UC01 Create product	API & NCA UI	UPD-13702	92790		Create MRP – were not able to create MRP from NAP where Marketing Authorisation number is populated at Package Level. The submission of the Create MRP was successful but the transaction did not complete successfully
UC01 Create product	API	UPD-12272	92576		Create Parallel Trade via API where referenced product has Authorisation status that is not equal to "Valid" : the response code was Error 500 with no meaningful validation error message
UC01 Create product	NCA UI	UPD-12904	81193		Create SRP: the RMS should not be able to delete any National Document from the RMS/CMS product retrieved. The delete button was enabled and shouldn't have been enabled
UC01 Create product	NCA UI	UPD-13523	79981		Create SRP where RMS product has National document: the National document for the RMS product was being added for the new CMS products and is now only Common Documents output for the new CMS products
UC01 Create product	NCA UI	UPD-13241	92709		When creating a product and using the Validate button: the delete button from the manufactured item section disappeared
UC01 Create product UC08 Update product	NCA UI	UPD-13782	92798		Create or Update DCP/SRP/MRP: if there was a validation error, the correct validation error message was not being displayed. For example expect validation error to contain "No manufacturer responsible for batch certification (100000160407) found." or "The value of Authorisation Status should be one of pending, valid, surrendered, suspended, revoked, and expired from the list Regulatory Entitlement Status" for example. Instead "Invalid mime type

Use Case	Affects API and/or UI	Issue reference (Old JIRA)	Issue reference (New ADO)	Vet EUIG Chapter 2 section	Resolved issues
					"application/json,text/plain,*/*; charset=utf-8": Invalid token character ',' in token "json,text/plain,*/*"" was being displayed as the error message.
UC01 Create product UC08 Update product	API	UPD-13485	80348		Create or Update of NAP - there should have been a validation error if payload does not have Legal Status of Supply at either Product or Package level. The product had incorrectly been created/updated.
UC01 Create product UC08 Update product	NCA UI	UPD-7971	82620	1.11.5 (Attached document) content type	System allowed Word .doc/.docx type document to be attached and this should not have been valid
UC01 Create product UC08 Update product	API & NCA UI	UPD-12406	92610		When processing a Create or Update to product an error occurred on one of the servers "No buffer space available". This resulted in the create or update being Queued and was never subsequently processed
UC03 Search product	NCA UI & MAH UI	UPD-13845	83373		The Active Substance and Strength columns displayed "0, N/A N/A" between the substance name and the free text value when only free text was provided for strength while creating the product
UC05 View product	NCA UI & MAH UI	UPD-13324	83282		CAP products - some products did not have any Substance name displayed. This issue affected only a few products
UC05 View product	NCA UI & MAH UI	UPD-13836	92816		If Substance strength or reference strength contains free text fields, these were not displayed correctly on view product screen
UC05 View product	NCA UI & MAH UI	UPD-13494	92755		Pharmaceutical products section: Withdrawal period information was not being listed beside the correct Target species
UC05 View product	NCA UI & MAH UI	UPD-13510	92757		View product which has PSMF populated: PSMF Address was not displayed and had N/A
UC05 View product	NCA UI & MAH UI	UPD-13631	80351		When view previous version for a product it displayed manufacturer for Ingredient based on the current version of the product; and not the value that existed in that version
UC06 Submit VNRA	MAH UI	UPD-13810	92806		Change: add a delete option for the VNeeS file so that MAH can remove file attached in error if there should be no VNeeS for the submission. If the wrong

Use Case	Affects API and/or UI	Issue reference (Old JIRA)	Issue reference (New ADO)	Vet EUIG Chapter 2 section	Resolved issues
					VNeeS has been selected, clicking on the zip filename and selecting the correct zip file will overwrite the incorrect file
UC06 Submit VNRA	MAH UI	UPD-13634	92768		If submitted VNRA for an automated variation code for a product that has Marketing authorisation number populated at package level there was a validation error "Unable to find matching profile for PackagedProductDefinition/" displayed and were not able to submit VNRA as expected.
UC06 Submit VNRA	NCA UI	UPD-11278	92355		Issue affected EMA/EC users only: When VNRA is submitted, the VNeeS files was not reaching the Common Repository for some submissions
UC06 Submit VNRA	MAH UI	UPD-13483	92750		When submitting VNRA there may have been a timeout error message displayed
UC06 Submit VNRA	MAH UI	UPD-13953	83414		VNRA submission for multiple variation codes with multiple products shows failed in notification, however subsequently able to successfully submit VNRA for same combination of variation codes and products. Issue logged to review if was one-off issue due to some environmental issue in the test system; occurred one time and have not been able to reproduce. We were not able to reproduce this issue in this release in our test environments, therefore has now been recorded as closed.
UC08 Update product	NCA UI	UPD-13678	79961		All procedure types: it was not possible to update an existing document and upload a document with size > 2MB
UC08 Update product	NCA UI	UPD-12726	92648		Bulk Transfer of ownership - Incorrect validation error did not allow NCA to submit any update. This issue has been resolved.
UC08 Update product	API & NCA UI	UPD-13273	92713		For National Procedure (NAP) products that had a Data Quality issue and have been loaded without a value for Legal status of supply: when updated to add value was submitted and processed, the new value for Legal status of supply had not been saved in the updated version of the product.

Use Case	Affects API and/or UI	Issue reference (Old JIRA)	Issue reference (New ADO)	Vet EUIG Chapter 2 section	Resolved issues
UC08 Update product	NCA UI	UPD-13996	83434		Transfer Of Ownership - were not able to change the ownership for DCP/MRP/SRP product as failed with validation error "The user is not responsible for the product". This issue has been resolved.
UC08 Update product	NCA UI	UPD-13334	92736		UC08 Update CAP – were not able to add multiple Public Assessment Report documents
UC08 Update product	API & NCA UI	UPD-13815	92808		Update Common Data DCP/MRP/SRP – it was not possible to update common data when Authorisation number is provided at package level for RMS product - Failed with error
UC08 Update product	API & NCA UI	UPD-13113	92693		Update Common Data DCP/MRP/SRP - it was not possible to add an additional package if the RMS product had a national package description for existing package - BAD_REQUEST error message was displayed. This issue has been resolved.
UC08 Update product	API & NCA UI	UPD-13114	92694		Update Common Data DCP/MRP/SRP - there was an ERROR 500 if the product had Authorisation number at Package level
UC08 Update product	NCA UI	UPD-13486	92753		Update National Data DCP/MRP/SRP - a CMS was able to delete a Package and this should not be possible.
UC08 Update product	NCA UI	UPD-13484	92751		Update National Data DCP/MRP/SRP - if strength has a numerator of zero, there was an incorrect validation error when attempting to update the product
UC08 Update product	API & NCA UI	UPD-13791	92798		Update National Data DCP/MRP/SRP – were not able to update National Data when Marketing Authorisation number provided at package level. There was a validation error
UC08 Update product	NCA UI	UPD-13829	92814		Update National Data DCP/MRP/SRP where no Pack size specified for a package: when update submitted the page remained with progress control and product was not updated
UC08 Update product	NCA UI	UPD-13148	83262		Update National Data for DCP/MRP/SRP where product doesn't have Pack Size populated: there was a validation error when populated Marketing Authorisation Number at Package Level
UC08 Update product	NCA UI	UPD-13430	92742		Update package where pack size has not been populated: an incorrect validation error related to pack size was being displayed and therefore this

Use Case	Affects API and/or UI	Issue reference (Old JIRA)	Issue reference (New ADO)	Vet EUIG Chapter 2 section	Resolved issues
					prevented any update to the package. This affects NAP and also Update of National Data DCP/MRP/SRP to edit national package description
UC08 Update product	NCA UI	UPD-13672	80353		Update Parallel Trade : It was not possible to add new documents
UC08 Update product	API & NCA UI	UPD-12933	80347		Update Parallel Trade product: it was not possible to update a product as there was error. This issue has been resolved and now able to update Parallel trade products
UC18 Manage document	API	UPD-12249	92557		Create or Update of Document via API - infrequently the POST failed with response code 500 Internal server error. This was an intermittent issue as POST of the same payload was subsequently successful. This was an issue only observed in PROD environment
UC19 Nullify product	API & NCA UI	UPD-13989	83430		Nullification for MRP product was not successful. This issue has been resolved and are now able to nullify MRP products
UC21 Manage Notifications	NCA UI & MAH UI	UPD-12334	92592		The Notification for Update NAP without document showed action as "Update, Upload Document" and is now correctly shown as "Update". This change will only be effective for notifications from updates in this and subsequent releases. The action in existing notifications will not be corrected.
UC21 Manage Notifications	NCA UI & MAH UI	UPD-13288	92725		UC19 Nullify: the notification card for "Nullify" did not include the "Date of Action"
UC21 Manage Notifications	NCA UI & MAH UI	UPD-12591	92637		VNRA Submitted action: the notification card had incorrect labels. Decision Comment should be Submission Comment. Date of Decision should be Date of Submission. Date of Implementation was not displayed. The correct values of the submission date and submission comment were displayed.
UC21 Manage Notifications	NCA UI & MAH UI		93226		Product Owner field now allows user to search for a LOC-ID. However the resulting search of notifications is not applying the selected LOC-ID and therefore does not return the expected results. This is a known limitation in the current implementation of Search Notifications functionality. This issue will be resolved when requirement BR-118 is implemented when search notifications functionality will be enhanced. Therefore, this issue is now closed.

Use Case	Affects API and/or UI	Issue reference (Old JIRA)	Issue reference (New ADO)	Vet EUIG Chapter 2 section	Resolved issues
UC25 Update Availability status	MAH UI	UPD-12934	92684		Availability Status Date format of YYYY-MM was not accepted though Chapter 7 states it should
UC25 Update Availability status	MAH UI	UPD-10637	92202		If Submission of Availability status file contained invalid data where the Country term code had inadvertently been changed to some other value was displaying the wrong validation error. The correct validation error of "ERR.05: Package identifier provided doesn't belong to the country selected" is now displayed
UC25 Update Availability status	MAH UI	UPD-13467	92747		Submission of Availability Status – validation was missing for ERR.02 (product status is Current or Provisional)
UC25 Update Availability status	MAH UI	UPD-13458	92745		Submission of Availability status for CMS product under DCP/MRP/SRP was incorrectly updating the RMS product with the new availability status and not the CMS product specified in the csv file.
UC25 Update Availability status	MAH UI	UPD-13988	92833		When searching products to download file for Availability status, the Permanent identifier number incorrectly had type of search icon. This should not have been included as not able to search using starts with or contains options for this field
UC25 Update Availability status	MAH UI	UPD-13481	92748		When selected to download file the search products grid had an incorrect column heading for "Marketing authorisation status" field where it had column heading of "Marketing status". Column heading has been corrected.
UC25 Update Availability status	MAH UI	UPD-13635	92769		Were not able to submit availability status for migrated CAPs
UC27 Submit Volume of Sales	MAH UI		94988		Submission for CAP product has error: "ERR.05: Package identifier provided doesn't belong to the country selected;". This issue has been resolved and able to submit for CAP products
UC28 View VNRA	NCA UI & MAH UI	UPD-13673	80354		New search criteria of date displayed the date in the wrong format. It was displayed as mm-dd-yyyy instead of dd-mm-yyyy. The value specified was correctly applied when searching and the search results did match the selected date(s)
UC28 View VNRA	NCA UI & MAH UI	UPD-13850	80362		VNRA PDF file - information on variation codes count differed from UI and was not correct if the same variation code has been included more than once

Use Case	Affects API and/or UI	Issue reference (Old JIRA)	Issue reference (New ADO)	Vet EUIG Chapter 2 section	Resolved issues
UC28 View VNRA	NCA UI & MAH UI	UPD-13805	92802		Where submission search results are listed on 2 or more pages (based on the number of records per page that has been selected) and user views a submission from page 2 or some subsequent page: when select "Back to search results" the first page of search results was displayed and not the page the user had been viewing.
UC28 View VNRA	NCA UI & MAH UI	UPD-14043	85271		View VNRA Submission with many products & variation codes - there was a timeout error downloading the PDF and timeout errors flickered on the screen when View Submission page loaded. These issues have been resolved.
UC34 Bulk Upload for Documents	NCA UI	UPD-13677	83338		Bulk Upload was not accepting file for document type pllab
UC34 Bulk Upload for Documents	NCA UI	UPD-10699	92226		For CAP products - EPAR document type was not available. As agreed this issue will not be fixed and any legacy documents will be loaded as PuAR documents
UC34 Bulk Upload for Documents	NCA UI	UPD-13641	92770		Validation was not being applied when there are two or more documents in the same submission for a product for same Document type/Country/Language. Except for document type PuAR for a CAP product, it should not be possible for a product to have more than one document for combination of Document type/Country/Language. This validation has now been included.

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)	Vet EUIG Chapter 2 section	New Issue description
All UC	NCA UI & MAH UI		95526		When Create a product, or Search or View an existing product: the preferred name for a Substance should be displayed

Use Case	Affects API and/or UI	Issue reference (Old JIRA)	Issue reference (New ADO)	Vet EUIG Chapter 2 section	New Issue description
UC01 Create product	NCA UI		92619		Create MRP - After retrieving a product the Edit and Delete icons for RMS National product name are enabled after adding the Common product name
UC01 Create product	API & NCA UI		85286		Create SRP - any surrendered CMS product is being updated and should be ignored at the time of Create SRP to add another CMS. No updates should be made to Common Data for CMS products that have been surrendered
UC01 Create product	NCA UI		95523		The pop-up confirmation dialog box displays "update product" and not "create product" within the confirmation message
UC01 Create product UC08 Update product	API		92879		Create or Update NAP via API only - if Package identifier is provided in the create product payload this should be ignored and instead system generated value output. If package identifier is provided for a new package as part of the update product payload, this should be ignored and instead system generated value output. Note: If update product payload has no package identifier for any existing package, or contains a change to the package identifier for any existing package the Update payload is rejected with a Validation error. This issue on Update of product only applies to package identifier for any new package that has been added.
UC03 Search product	NCA UI & MAH UI		93219		Submit any search and then click Reset button, and submit a second search then navigate to the second page. The second page of results displays the same products as on the first page of results
UC03 Search products	NCA UI & MAH UI		102523		If have submitted a search of products without inputting any search criteria and select to view a product from search results, when you return to the search results screen it will not display the

Use Case	Affects API and/or UI	Issue reference (Old JIRA)	Issue reference (New ADO)	Vet EUIG Chapter 2 section	New Issue description
					previous search results. A new search will need to be submitted
UC03 Search products	NCA UI & MAH UI		102530		If search by product name and have a space in that search field and view a product from search results, when you return to sesarch results the space within the search field has been replaced with "%20" and the search now shows no results found. As a workaround "%20" can be replaced with a space and search submitted.
UC03 Search products	NCA UI & MAH UI		102526		If search by Product owner and view a product from search results, when you return back to the search results screen the selected LOC-ID has not been retained and instead is attempting to search by a LOC-ID with no value. Therefore search results returns no values. The product owner LOC-ID will have to be re-selected in order to be able to view the same search results
UC05 View product	NCA UI & MAH UI		101462		If withdrawal period does not contain any free-text notes, the view product screen is now displayed "N/A" after the Tissue name and withdrawal period numeric and term details. "N/A" should not be displayed
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
UC06 Submit VNRA	MAH UI	UPD-14047	83470		VNRA Submission may fail with timeout if there are many products and variation codes
UC08 Update product	API		93509		Update Common Data DCP/MRP/SRP via API has validation error in OperationOutcome when new package added and user has input value for Package identifier - POST should give validation

Use Case	Affects API and/or UI	Issue reference (Old JIRA)	Issue reference (New ADO)	Vet EUIG Chapter 2 section	New Issue description
					error or the Package Identifier provided be ignored
UC08 Update product	NCA UI		101063		Update Common Data DCP/MRP/SRP - when a CMS product has Legal Status of Supply specified at Package level, after submitting the update the page hangs with the progress control displayed and submission is not possible
UC08 Update product	API & NCA UI		100337		Update product 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.
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		93612		Update National Data DCP/MRP/SRP via API has validation error in OperationOutcome when new package is added with the package identifier for the new package provided in the payload. Since package updates are Common Data only, the Post should be rejected
UC08 Update product	NCA UI		96473		Update product where Route of administration has more than one Target species and different Withdrawal periods for multiple Tissues in each Target species: when attempt to add another Withdrawal Period for different Tissue type, the submission of the update is not successful and page remains greyed out with progress control
UC08 Update product	API & NCA UI		81576		Update Registered Homeopathic product under Chapter 4 Legacy rules is not possible as

Use Case	Affects API and/or UI	Issue reference (Old JIRA)	Issue reference (New ADO)	Vet EUIG Chapter 2 section	New Issue description
					validation error is displayed regarding missing PSMF
UC09 Approve/Reject VNRA	NCA UI		84163		CMS NCA is able to select Approve/Reject checkbox when viewing a VNRA, although the Submit button correctly remains disabled
UC21 Manage Notifications	NCA UI & MAH UI		83835		Bulk Upload notification is displaying Product Identifier as N/A in the search results table. The Notification card does not have Date of action populated and also includes an extra label of Date of Submission
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		85589		If Availability Status date has been populated as yyyy-mm-dd in the submitted file, the day in that date is being ignored and first day of the month used instead in the updated product
UC25 Update Availability status	MAH UI		85598		The Error report for submission of Availability status should contain all of the fields that were populated in the submission file. At present the error file only contains the mandatory fields from the submitted file
UC25 Update Availability status	MAH UI		85314		The submitted file for Availability Status updates should give a validation error if the new Availability status date is more than the current date + 1. This future status date is being accepted and updated into the product
UC27 View Volume of Sales	NCA UI & MAH UI		92992		In the View Volume of sales screen, sorting by Country is not working
UC27 View Volume of Sales	NCA UI & MAH UI		101205		Intermittent issue where for some products there are two rows listed when search for products to be able to download the submitted sales data values. This does not happen for many products.

Use Case	Affects API and/or UI	Issue reference (Old JIRA)	Issue reference (New ADO)	Vet EUIG Chapter 2 section	New Issue description
					Depending on the row selected, different sales data may be downloaded in the csv file.
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

2.4. Known issues for new functionality in this release

This table is ordered by Use Case number.

New functionality	Use Case	Affects API and/or UI	Issue reference (Old JIRA)	Issue reference (New ADO)	New Issue description
BR-043	UC01 Create product	NCA UI		81499	BR-043 - When create product from an existing one, the messages displayed after a successful submission can be confusing. After submission a pop-up dialog box displays the Operation Outcome ID of the create that has been successfully created; aloing with the question if user would like to create another product. Options are Create and Cancel. If the user does not want to create another product, and selects Cancel, the pop-up dialog is closed and the Create page is displayed and again the same Operation Outcome ID from the successfully submitted Create is displayed. The users now leaves the create page by selecting some menu option, and is asked if user sure as data will be lost. This is not true, as the create of the product has already been submitted and no data is being lost.
BR-043	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
BR-156	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"

New functionality	Use Case	Affects API and/or UI	Issue reference (Old JIRA)	Issue reference (New ADO)	New Issue description
BR-156	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
BR-156	UC34 Bulk Upload for Documents	NCA UI & MAH UI		100730	When uploading many documents via Bulk Upload or loading documents to many products for a Procedure number (DCP/MRP/SRP/CAP) - a notification is not being created for each document that has been successfully loaded
BR-156	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'"
BR-156	UC34 Bulk Upload for Documents	NCA UI		93902	Validation on the fourth fixed part of the file name (being Product name or procedure type) is not being applied correctly. File names for DCP/MRP/SRP/NAP products are being accepted without "mr" or "np" on indicate the procedure type.
BR-156	UC05 View product	NCA UI & MAH UI	UPD-14051	83472	The country name is not being displayed for Common document files that have been added using Bulk Upload. Instead the country code is displayed as N/A. The country code in DocumentReference resource has been populated
BR-156	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
BR-156	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

New functionality	Use Case	Affects API and/or UI	Issue reference (Old JIRA)	Issue reference (New ADO)	New Issue description
					updated. This issue is only occurring in PROD and was successful in test environments
BR-156	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
BR-156	UC34 Bulk Upload for Documents	NCA UI		103141	If the file name contains a language code that is not one of the EEA languages, the file is not being rejected with a validation error. Instead the document is being loaded. On the View product screen the language is displayed as N/A

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 April 2023
- **Chapters 1, 3, 5, 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
  - Scenario 1 Create Product – NAP & Registered Homeopathic – Manual Key In
  - Scenario 2 Create Product – Decentralised Procedure – Manual Key In
  - Scenario 3 Create Product – MRP & SRP
  - Scenario 4 Create Product – Parallel Trade
  - Scenario 5 Cancel Create Product
  - 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
    - Scenario 1 Transfer of ownership
    - 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)
    - Scenario 3 Update Common Data for products under DCP/MRP/SRP (data and documents)
    - Scenario 4 Update Parallel Trade
    - Scenario 5 Cancel Update Product
    - Able to update products based on Chapter 4 Legacy or Chapter 2 Validation rules
- UPD UC19 Nullify Product
- UPD UC21 Manage Notifications via UI
    - 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 UC34 Bulk Upload of Documents
- UPD UC27 View Submissions of Volume Sales via Form
    - 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

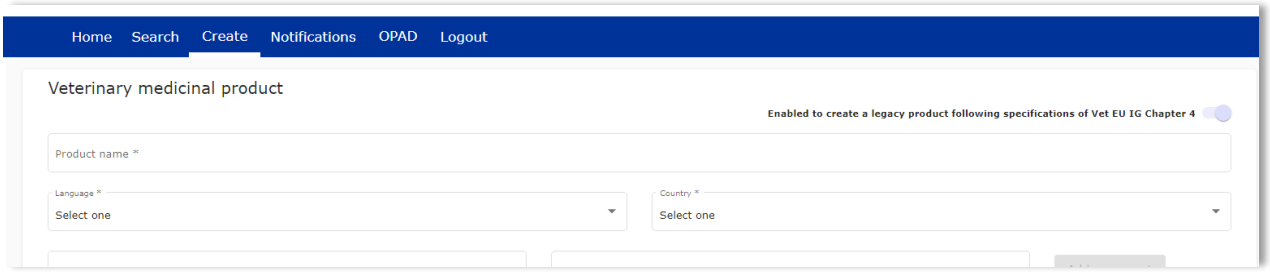
Supported browsers for the NCA UI are Chrome and Edge.

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
UPD-4863	5.6.4 Ingredient	This should not be mandatory for Legacy products.

Issue reference	Vet EUIG Chapter 2 section	Issue and Workaround
	(in Manufactured item)	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:
  - EAM-Test can be found at: https://register-test.ema.europa.eu/identityiq/login.jsf
  - *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
  - select *Request Access for Organizations*. Reference guide: https://register-test.ema.europa.eu/identityiq/help/requestaccess.html
  - choose your country and Organization ID.
  - use "UPD" as a search option to filter available roles
  - 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:
    - EAM Production 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 EAM Production once registration is complete to Request Access to one of the UPD NCA 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 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)

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

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
- Search and retrieve products
- Nullify product
- 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 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
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
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
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

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

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

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.

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

Procedure type	Validation rules	Example file
		UPD_1.6.5-6_DCP_Chpt2_C110_VetEUIG_AllData.JSON UPD_1.6.5-6_DCP_Chpt2_C110_VetEUIG_AllData.XML
DCP	Chapter 4 Legacy	UPD_1.6.5-6_DCP_Legacy_C2_Mandatory_VetIG.JSON UPD_1.6.5-6_DCP_Legacy_C2_Mandatory_VetIG.XML UPD_1.6.5-6_DCP_Legacy_C110_VetEUIG_AllData.JSON UPD_1.6.5-6_DCP_Legacy_C110_VetEUIG_AllData.XML
NAP	Chapter 2	2.2 Authorisation/registration/entitlement number is specified at Product level UPD_1.6.1-4_NAP_Chpt2_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel.JSON UPD_1.6.1-4_NAP_Chpt2_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel.XML UPD_1.5.1-0_NAP_Chpt2_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel.JSON UPD_1.5.1-0_NAP_Chpt2_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel.XML --- 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

Procedure type	Validation rules	Example file
		with the Marketing authorisation number for Package 2
NAP	Chapter 4 Legacy	UPD_1.6.1-4_NAP_Legacy_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel.JSON UPD_1.6.1-4_NAP_Legacy_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel.XML UPD_1.5.1-0_NAP_Legacy_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel.JSON UPD_1.5.1-0_NAP_Legacy_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel.XML
NAP	Chapter 4 Legacy	UPD_1.5.1-0_NAP_Legacy_Cx_ManyAttributesAndResources_MANumberAtMedicinalProductLevel.XML This example contains: • 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 UPD-BR-178: 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

Procedure type	Validation rules	Example file
		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

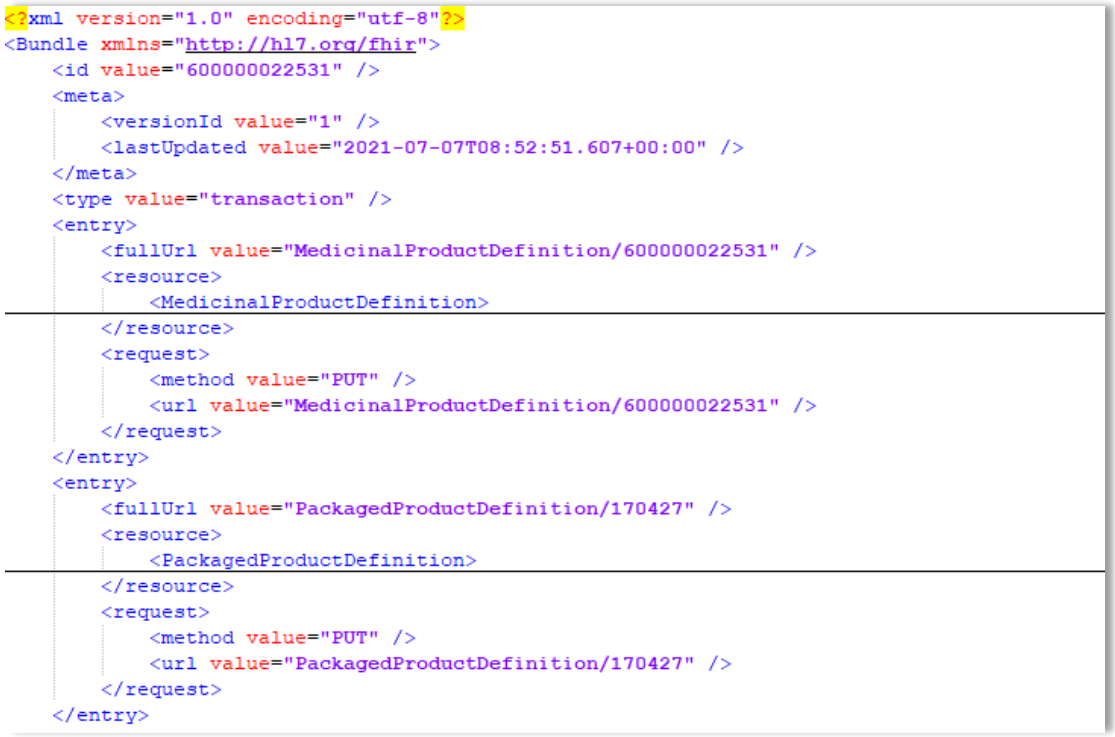
5.5.8. Recommended approach to prepare update request bundle

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 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 Bundle.entry.request.method for each resource.	Sample XML of Get Everything response used as a starting point: UPD_1.5.3-4_CreateMRP_NP_600000184179_GetEverything_version1.XML
Prepare Create MRP Bundle	• Change procedure type from NP to MRP • Add Common Name with Country = EU and Language = English • Add Reference member state and Concerned member state • Add Common package description in English (if doesn't exist)	Create MRP bundle prepared: UPD_1.5.3-4_CreateMRP_BasedOn_NP_version1.XML

Create MRP via API	POST Bundle with request headers to /upd/api/v1/mrp-bundle/ • "chapter4" = true or false for the validation rules to apply	
Check operation outcome	MSG_CREATED message expected containing Permanent identifiers for RMS NP product and products created for each CMS	
EP304 Get Product Full	RMS: • Contains the Common data that was added CMS: • Each new product is only populated with Common data, with status of Provisional	

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.

Name	Description
	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. MAH UI

6.1. 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

Supported browsers for the MAH UI are Chrome and Edge.

6.2. 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)

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.

7. 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.

8. User support

API and UI users may seek support in uploading their legacy data into UPD by contacting the VMP-Reg User Support via https://servicedesk.ema.europa.eu/jira/servicedesk/customer/portal/283/group/506.

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

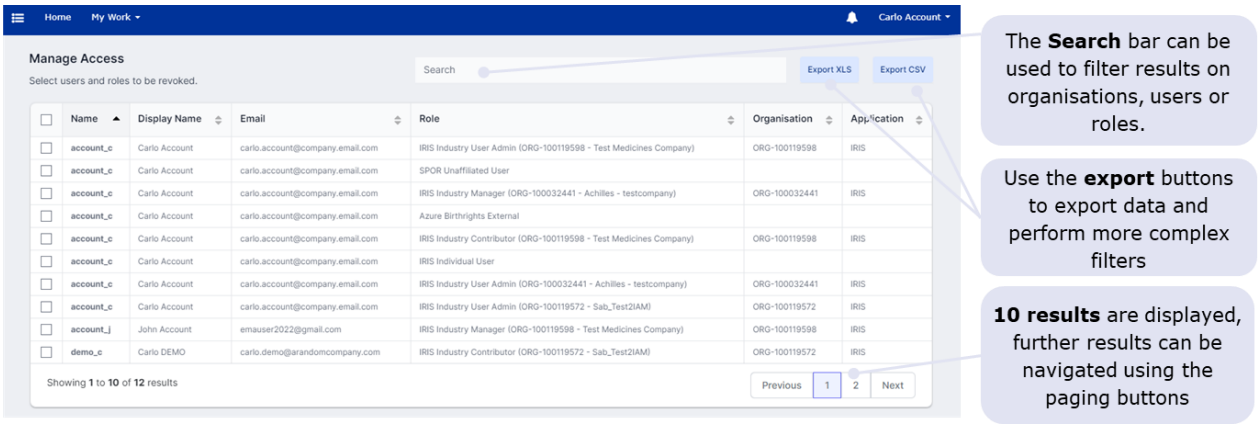
9. References

1. UPD 01.06 Registration guide - Union Product Database (UPD) 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_1.6.16_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.



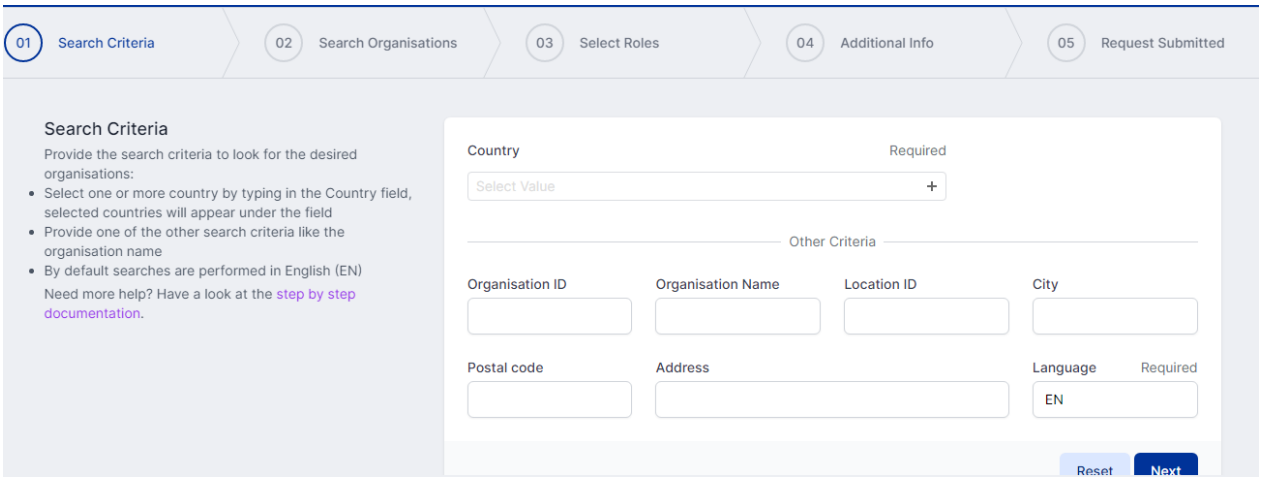
The 'Manage my access' tab, marked in red in the visual below, became obsolete, with all procedures now being managed through the 'Request Access for organisations' tab and the 'Manage Access' tab, marked in green.

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".

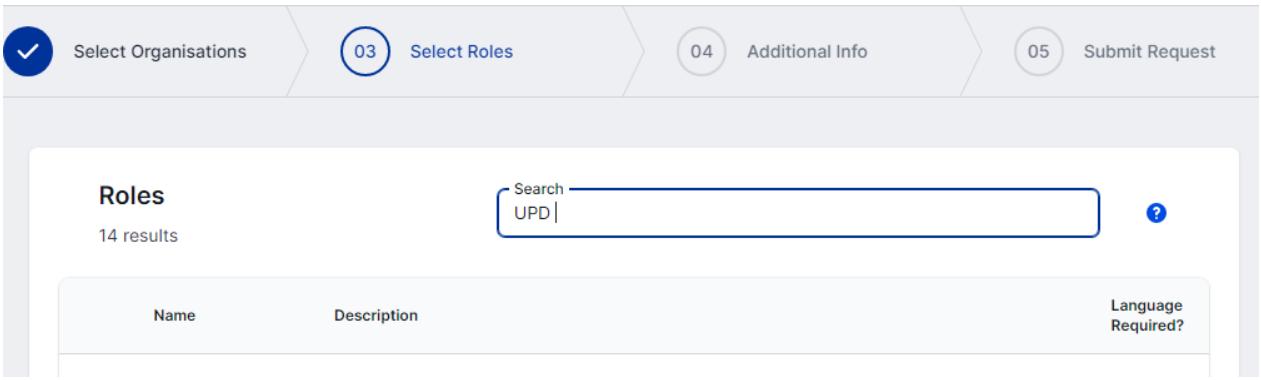
9.1. Request the Super User Role for your Organisation in UAT

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

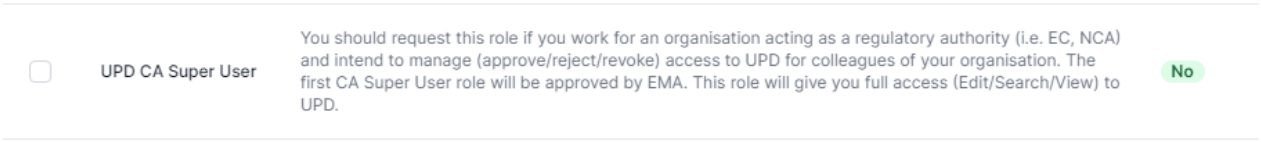
2. Go to "Request Access for Organizations" and search for your country and your ORG ID:



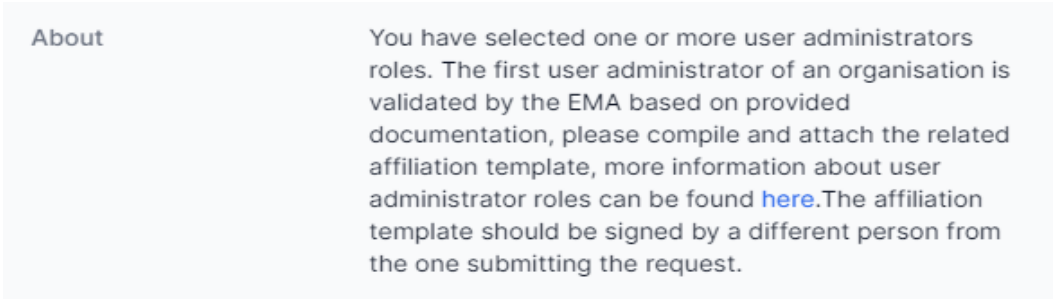
3. Select "UPD" to find the roles:



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)



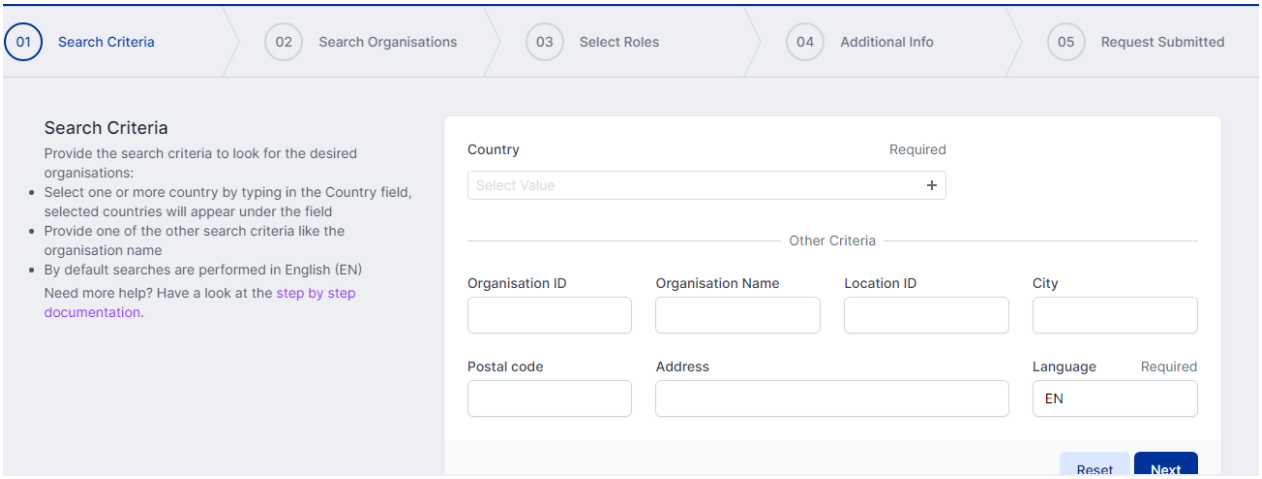
6. Click "Submit"

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

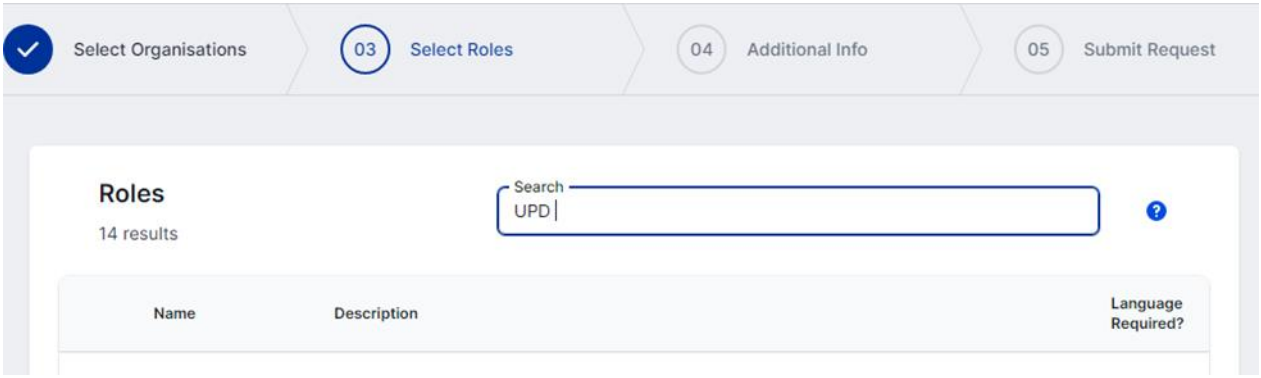
9.2. Request a Member User Role for your Organisation and Affiliate to your Organisation in UAT

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.

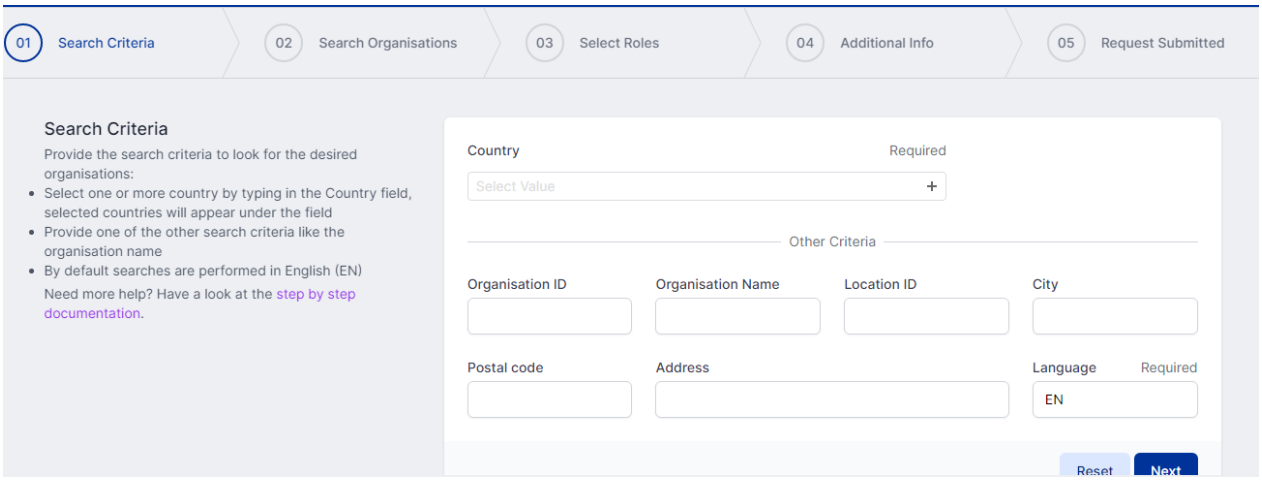
5. Submit.

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

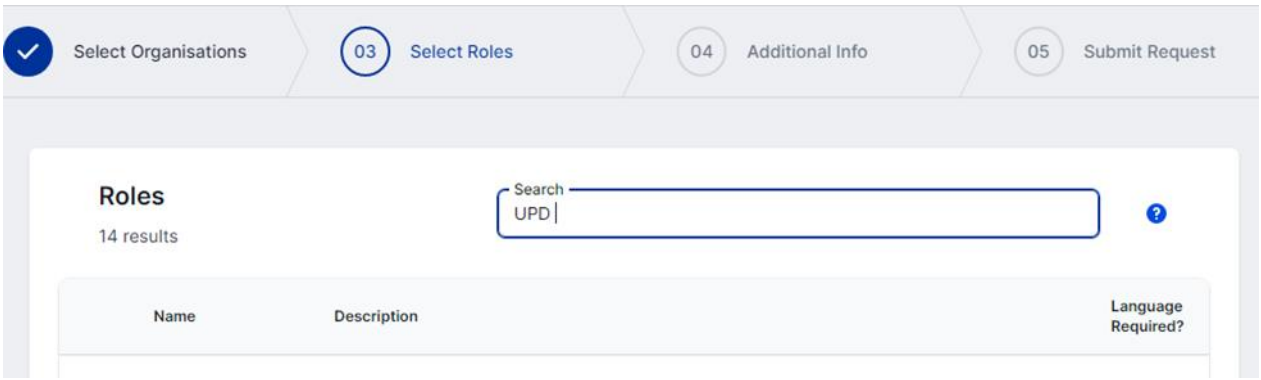
Note: This is at this point only relevant for UI usage. The model for the API accounts remains as per section 5.3. and the document referred to in section 9. .

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

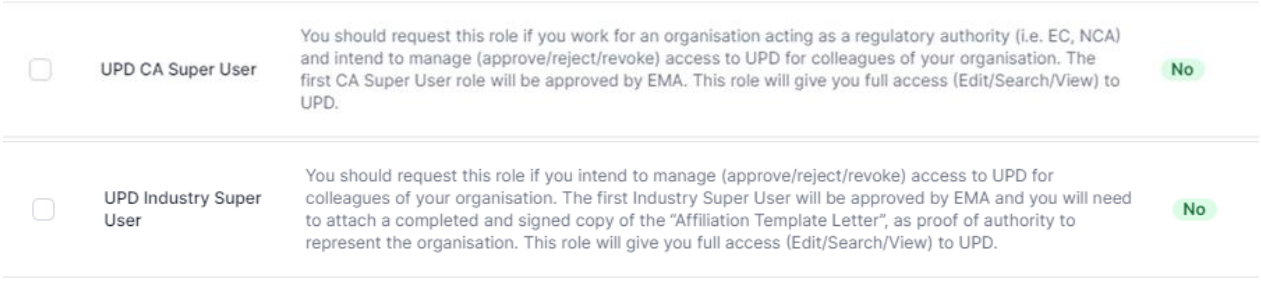
2. Go to "Request Access for Organizations" and search for your country and your ORG ID:



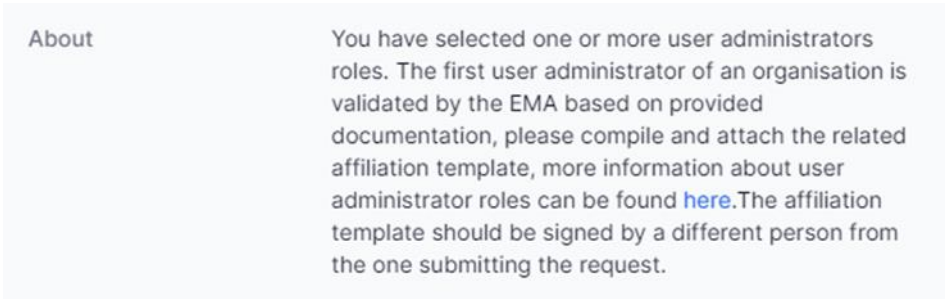
3. Select "UPD" to find the roles:



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.

9.4. 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 9. .

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

See the screenshots in section 9.2. 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)	Vet EUIG Chapter 2 section	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	2.5 Authorisation status	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
All UC	NCA UI & MAH UI		95526		When Create a product, or Search or View an existing product: the preferred name for a Substance should be displayed
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

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Vet EUIG Chapter 2 section	Known Issue Description
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		81499		BR-043 - When create product from an existing one, the messages displayed after a successful submission can be confusing. After submission a pop-up dialog box displays the Operation Outcome ID of the create that has been successfully created; aloing with the question if user would like to create another product. Options are Create and Cancel. If the user does not want to create another product, and selects Cancel, the pop-up dialog is closed and the Create page is displayed and again the same Operation Outcome ID from the successfully submitted Create is displayed. The users now leaves the create page by selecting some menu option, and is asked if user sure as data will be lost. This is not true, as the create of the product has already been submitted and no data is being lost.
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
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		92619		Create MRP - After retrieving a product the Edit and Delete icons for RMS National product name are enabled after adding the Common product name
UC01 Create product	NCA UI	UPD-9013	82733		Create MRP - when Retrieving Product Information in the search dialog, if the enter key is clicked after entering some search criteria the screen changes to be main Search product screen and user is no longer in Create MRP screen. Do not use the Enter key when searching for product
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

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Vet EUIG Chapter 2 section	Known Issue Description
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		85286		Create SRP - any surrendered CMS product is being updated and should be ignored at the time of Create SRP to add another CMS. No updates should be made to Common Data for CMS products that have been surrendered
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	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	5.6.4 Ingredient (in Manufactured item)	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

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Vet EUIG Chapter 2 section	Known Issue Description
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)
UC01 Create product	API	UPD-4726	82433	1.8.1 Veterinary medicinal product name	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	NCA UI		95523		The pop-up confirmation dialog box displays "update product" and not "create product" within the confirmation message
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

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Vet EUIG Chapter 2 section	Known Issue Description
UC01 Create product UC08 Update product	NCA UI	UPD-11419	83051		CAP procedure type: create or update with Document of type EPAR is able to be submitted. There is an exception when processing and the document is not saved on the product
UC01 Create product UC08 Update product	API		92879		Create or Update NAP via API only - if Package identifier is provided in the create product payload this should be ignored and instead system generated value output. If package identifier is provided for a new package as part of the update product payload, this should be ignored and instead system generated value output. Note: If update product payload has no package identifier for any existing package, or contains a change to the package identifier for any existing package the Update payload is rejected with a Validation error. This issue on Update of product only applies to package identifier for any new package that has been added.
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.
UC01 Create product UC08 Update product	API & NCA UI	UPD-5531	82481	1.8.2.1 Name type	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

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Vet EUIG Chapter 2 section	Known Issue Description
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	NCA UI	UPD-13874	83382		Parallel trade product only: the wrong pop up message is displayed for the Authorisation/registration/entitlement number field
UC01 Create product UC08 Update product	API & NCA UI	UPD-9338	82761	5.6.2 Manufactured item quantity	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-6910	82562	1.9.4 (PSM) File location 1.10.3 QPPV Location	The Validate button doesn't highlight PSMF or QPPV Location as missing mandatory fields if the code/contact value s populated but no location selected (PSMF for Chapter 2 only)

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Vet EUIG Chapter 2 section	Known Issue Description
UC01 Create product UC08 Update product	NCA UI	UPD-4863	82440	5.6.4 Ingredient (in Manufactured item)	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	4.3.2.1 & 4.3.2.2	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
UC01 Create product UC08 Update product	API & NCA UI	UPD-12932	94174		UPD is missing terms from SPOR (RMS) - Units of measurement list
UC01 Create product UC08 Update product	API & NCA UI	UPD-12950	92688		When create or update product with more than 1 Package and Legal status of supply is populated at Package level, there should be a validation error if Legal status of supply has not been populated for all packages. Instead the product is created/updated
UC03 Search product	NCA UI & MAH UI	UPD-13908	83403		Active substance and strength is displayed as N/A if strength of Active Ingredient is Concentration single value
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

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Vet EUIG Chapter 2 section	Known Issue Description
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 displays [object object] and not the value that had been input.
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
UC03 Search product	NCA UI & MAH UI		93219		Submit any search and then click Reset button, and submit a second search then navigate to the second page. The second page of results displays the same products as on the first page of results
UC03 Search product	NCA UI & MAH UI	UPD-13463	94175		The "Active substance and strength column" is including Ingredients that do not have role of "Active". Only Active Ingredients should have details included in this column
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

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Vet EUIG Chapter 2 section	Known Issue Description
UC03 Search products	NCA UI & MAH UI	UPD-13814	83360		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
UC03 Search products	NCA UI & MAH UI		102523		If have submitted a search of products without inputting any search criteria and select to view a product from search results, when you return to the search results screen it will not display the previous search results. A new search will need to be submitted
UC03 Search products	NCA UI & MAH UI		102530		If search by product name and have a space in that search field and view a product from search results, when you return to sesarch results the space within the search field has been replaced with "%20" and the search now shows no results found. As a workaround "%20" can be replaced with a space and search submitted.
UC03 Search products	NCA UI & MAH UI		102526		If search by Product owner and view a product from search results, when you return back to the search results screen the selected LOC-ID has not been retained and instead is attempting to search by a LOC-ID with no value. Therefore search results returns no values. The product owner LOC-ID will have to be re-selected in order to be able to view the same search results
UC04 Export	NCA UI & MAH UI	UPD-13723	83345		If search results to be exported contains free-text field that includes a comma, for example product name, the output csv file is not correctly formatted to handle this embedded comma and splits the field across 2 columns (as seen in MS Excel when viewing csv file)
UC05 View product	NCA UI & MAH UI	UPD-13848	80361		If Reference strength field defined as free text this is not displayed on the view product screen

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Vet EUIG Chapter 2 section	Known Issue Description
UC05 View product	NCA UI & MAH UI		101462		If withdrawal period does not contain any free-text notes, the view product screen is now displayed "N/A" after the Tissue name and withdrawal period numeric and term details. "N/A" should not be displayed
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
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	2.7 Marketing authorisation date	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
UC05 View product	NCA UI & MAH UI	UPD-14051	83472		The country name is not being displayed for Common document files that have been added using Bulk Upload. Instead the country code is displayed as N/A. The country code in DocumentReference resource has been populated
UC06 Submit VNRA	MAH UI	UPD-10901	82944		After successful submission of VNRA, if click on the Cancel button the screen should be ready to input another submission. Instead the screen becomes unusable with grey background and MAH needs to refresh the browser page

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Vet EUIG Chapter 2 section	Known Issue Description
UC06 Submit VNRA	MAH UI	UPD-11617	83106		For UPD-BR-092 Automated A.1.a for update to MAH : only allow MAH to select LOC-ID for an Organisation that they have affiliation to
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
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-12908	89551		Submit VNRA for an Automated code and product that has some Data Quality issue that will prevent that product being updated. There is a validation check made on submission and validation error displayed. However the Permanent Identifier of the product that has failed validation is not listed as part of the message
UC06 Submit VNRA	MAH UI	UPD-7960	82616		Submit VNRA: No search results displayed when the 'Retrieve product' search dialog is opened a second time
UC06 Submit VNRA	MAH UI	UPD-12062	83179		The System is displaying Homeopathic products as available to select in VNRA submission and they should not be included in search results
UC06 Submit VNRA	MAH UI	UPD-11256	83036		When selecting products, a search by Product Owner doesn't work if used as criteria for second time
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

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Vet EUIG Chapter 2 section	Known Issue Description
UC06 Submit VNRA	MAH UI	UPD-14047	83470		VNRA Submission may fail with timeout if there are many products and variation codes
UC06 Submit VNRA UC28 View VNRA	NCA UI & MAH UI	UPD-10184	82821		Accented and special characters for all EU languages are not correctly displayed for Product Name and Package description. Some are OK but others aren't
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)
UC07 Submit Volume of Sales	MAH UI	UPD-13794	83352		Volume of Sales Download list of Packages - the csv file is missing a column for "Comment" data. If file is used to prepare a submission file without populating the missing column there will be a validation error on submission "ER.04: The number of columns provided is not correct"
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	API & NCA UI	UPD-12580	79977	2.4 Responsible Authority 2.8 Product Owner	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

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Vet EUIG Chapter 2 section	Known Issue Description
UC08 Update product	API	UPD-4812	82437	2.13.1 Procedure number	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	2.4 Responsible authority (organisation) 2.8 Product Owner (organisation)	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	UPD-12602	83222	1.9.4 (PSM) File location	Chapter 4/Legacy products for all procedure types: if no PSM File Location has been populated the edit screen displays a value of "undefined - undefined". If you submit the update like this there will be a validation error. Click the "X" to delete and then you will be able to Submit the update without a validation error

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Vet EUIG Chapter 2 section	Known Issue Description
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	NCA UI	UPD-13466	83298		If product name has been incorrectly duplicated for a language/country and you edit the product to remove one of the duplicated names, the updated product still contains both product names
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	5.6 Manufactured item (in Package)	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	1.4 Permanent identifier	UC08 Update SC2 NAP - should reject update with validation error message if MedicinalProductDefinition.id is not populated

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Vet EUIG Chapter 2 section	Known Issue Description
UC08 Update product	API	UPD-7273	82573	1.2 Product Record Status	UC08 Update SC2 Update National - API - UPD-UC08-AC016 - Missing Validation error when update Product Status from Current to Provisional & product has been updated
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	NCA UI	UPD-13454	94846		Update Common Data and Update National Data DCP/MRP/SRP: the edit screen displays a warning message at the top advising of Pending VNRA submissions for the product. The same warning message should also be included in the confirmation dialog after clicking the Update product button
UC08 Update product	NCA UI	UPD-13495	92756		Update Common Data DCP/MRP/SRP and remove a Common Document: a Notification for action of "Delete Document" is only being created for the RMS product and not for each of the CMS products. The RMS and CMS products have been correctly updated and the common document removed.
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		93509		Update Common Data DCP/MRP/SRP via API has validation error in OperationOutcome when new package added and user has input value for Package identifier - POST should give validation error or the Package Identifier provided be ignored
UC08 Update product	NCA UI		101063		Update Common Data DCP/MRP/SRP - when a CMS product has Legal Status of Supply specified at Package level, after submitting the update the page hangs with the progress control displayed and submission is not possible

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Vet EUIG Chapter 2 section	Known Issue Description
UC08 Update product	API & NCA UI		100337		Update product 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.
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	NCA UI	UPD-12239	89511		Update NAP - deletion of existing Pharmaceutical product and addition of a new Pharmaceutical product removed the existing Ingredients from the updated product
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		93612		Update National Data DCP/MRP/SRP via API has validation error in OperationOutcome when new package is added with the package identifier for the new package provided in the payload. Since package updates are Common Data only, the Post should be rejected
UC08 Update product	NCA UI	UPD-10287	82829		Update National DCP/MRP/SRP - the confirmation modal message lists all RMS and CMS countries, and should just be the authorisation country from the product that is being updated
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	UPD-12286	83198		Update Parallel Trade via API fails with validation error messages relating to RMS and CMS (regression issue from previous release)

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Vet EUIG Chapter 2 section	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	NCA UI	UPD-8399	82651	3.1 Ingredient	Update product that has more then one Pharmaceutical product. There will be a validation error when update is submitted if one of the Pharmaceutical Product has no linked Ingredients. Workaround is to ensure at least one Ingredient is linked for each Pharmaceutical Product
UC08 Update product	NCA UI		96473		Update product where Route of administration has more than one Target species and different Withdrawal periods for multiple Tissues in each Target species: when attempt to add another Withdrawal Period for different Tissue type, the submission of the update is not successful and page remains greyed out with progress control
UC08 Update product	API & NCA UI		81576		Update Registered Homeopathic product under Chapter 4 Legacy rules is not possible as validation error is displayed regarding missing PSMF
UC08 Update product	NCA UI	UPD-8246	82636	1.3 Product identifier	Update SRP National data - The Product identifier is displaying [object Object], [object Object]
UC08 Update product	API	UPD-5192	82466	1.6 Legal status of supply 5.4 Legal status of supply	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.

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Vet EUIG Chapter 2 section	Known Issue Description
UC09 Approve/Reject VNRA	NCA UI		84163		CMS NCA is able to select Approve/Reject checkbox when viewing a VNRA, although the Submit button correctly remains disabled
UC09 Approve/Reject 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
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 is 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 will need to be populated
UC09 Approve/Reject VNRA	NCA UI	UPD-11052	83001		UC09 Approve/Reject VNRA NCA - When the user views a Pending submission and clicks on Cancel button empty blank cards are showing on the screen
UC09 Approve/Reject VNRA	NCA UI	UPD-13795	83353		When view submission for variation code A4 Change in ATCvet code, the label for the current value of ATC Vet code shows as " "A4-ATC-VetCodeCurrent". The label should be "Value in UPD at the time of the submission"
UC09 Approve/Reject VNRA	NCA UI	UPD-13497	92757		Where VNRA submission contains two or more Variation codes, and the NCA approves each variation in a separate submission: when the second and subsequent variations are being approved a "VNRA approved" notification is also being created for the variation codes that had already been approved.
UC18 Manage document	API	UPD-12477	83213	1.11 Attached Document	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.
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

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Vet EUIG Chapter 2 section	Known Issue Description
UC19 Nullify product	API	UPD-13659	96465		After successful POST of nullification, the initial response to GET OperationOutcome/ID is 404 not found. Subsequent GET are OK and show the status of the nullification transaction. This is not an issue for any of the Create or Update POSTs. As a workaround, a delay of few seconds should be included prior to submission of the first GET OperationOutcome, or handle response of 404 not found and resubmit
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
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
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 correctly displayed for Product Name and Package description. Some are OK but others aren't
UC21 Manage Notifications	NCA UI & MAH UI		83835		Bulk Upload notification is displaying Product Identifier as N/A in the search results table. The Notification card does not have Date of action populated and also includes an extra label of Date of Submission
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

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Vet EUIG Chapter 2 section	Known Issue Description
UC21 Manage Notifications	MAH UI	UPD-13984	80365		MAH user only : for products under DCP/MRP/SRP - for Create and Upload document are not seeing all notifications for all products under the procedure where they are the MAH. Missing notification could be for RMS or CMS product. User is able to search and view all products via Search product screen
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
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	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"
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-12888	83243		Sorting of the product search results table by any column does not work

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Vet EUIG Chapter 2 section	Known Issue Description
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
UC25 Update Availability status	MAH UI	UPD-13766	92791		Download file for Availability Status: the quotation marks in the file are not correct. There is a missing quotation mark at the end of the first line and the beginning of the second line. Therefore file is not able to be viewed in MS Excel without first correctly using a text editor
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-13487	80349		Download product data file and select all products from several pages may result in a timeout error
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		85589		If Availability Status date has been populated as yyyy-mm-dd in the submitted file, the day in that date is being ignored and first day of the month used instead in the updated product
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

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Vet EUIG Chapter 2 section	Known Issue Description
UC25 Update Availability status	MAH UI		85598		The Error report for submission of Availability status should contain all of the fields that were populated in the submission file. At present the error file only contains the mandatory fields from the submitted file
UC25 Update Availability status	MAH UI		85314		The submitted file for Availability Status updates should give a validation error if the new Availability status date is more than the current date + 1. This future status date is being accepted and updated into the product
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	NCA UI & MAH UI		92992		In the View Volume of sales screen, sorting by Country is not working
UC27 View Volume of Sales	NCA UI & MAH UI		101205		Intermittent issue where for some products there are two rows listed when search 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.
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

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Vet EUIG Chapter 2 section	Known Issue Description
UC27 View Volume of Sales	NCA UI & MAH UI	UPD-13814	83360		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
UC27 View Volume of Sales	MAH UI	UPD-13321	83281		View Submissions of volume of sales - clicking the Reset button doesn't clear the search results table of previous search results
UC27 View Volume of Sales	NCA UI & MAH UI	UPD-13796	83354		When download file to view submitted Volume of sales for a product, the downloaded csv file has not populated the column for "Creation date of product"
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	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.

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Vet EUIG Chapter 2 section	Known Issue Description
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	UPD-13802	83358		View submission for Variation codes for QPPV and PSMF C1, C5, C6: the Location fields in the product card for the existing value are empty
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
UC34 Bulk Upload for Documents	NCA UI	UPD-12937	92685		Can´t submit file using Bulk Upload for Registered Homeopathic product as receive validation error "ERROR: Your organization is not the Responsible Authority of this/these product(s)."
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)	Vet EUIG Chapter 2 section	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	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		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		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 & MAH UI		100730		When uploading many documents via Bulk Upload or loading documents to many products for a Procedure number (DCP/MRP/SRP/CAP) - a notification is not being created for each document that has been successfully loaded
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-13906	83401		Loading of Public Assessment Report documents for CAP products sometimes results in duplicate documents added in UPD

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Vet EUIG Chapter 2 section	Known Issue Description
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		93902		Validation on the fourth fixed part of the file name (being Product name or procedure type) is not being applied correctly. File names for DCP/MRP/SRP/NAP products are being accepted without "mr" or "np" on indicate the procedure type.
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		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
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
UC34 Bulk Upload for Documents	NCA UI		103141		If the file name contains a language code that is not one of the EEA languages, the file is not being rejected with a validation error. Instead the document is being loaded. On the View product screen the language is displayed as N/A

Annex 3: Release Schedule

	Environment	From	To	Description
5	~~UAT (TBC)~~	~~05 Apr 23~~	~~05 Apr 23~~	~~Upgrade of UPD to 1.6.23~~
6	~~PROD (TBC)~~	~~17 Apr 23~~	~~17 Apr 23~~	~~Upgrade of UPD to 1.6.23~~
7	~~UAT (TBC)~~	~~20 Apr 23~~	~~20 Apr 23~~	~~Upgrade of UPD to 1.6.24~~
8	~~PROD (TBC)~~	~~02 May 23~~	~~02 May 23~~	~~Upgrade of UPD to 1.6.24~~
9	UAT	4 May 23	5 May 23	Upgrade of UPD to 1.6.25
10	PROD	~~15 May 23~~ 30 May 23	~~16 May 23~~ 5 June 23	Upgrade of UPD to 1.6.25

Annex 4: UPD-BR-156 Bulk Upload revised filename

The following is an extract of Annex 2 from the revised Vet EU IG Chapter 2 that contains the new file naming convention to be used for Bulk Upload following implementation of UPD-BR-156.

Vet EU IG Chapter 2 Annex 2: Product information documents requirements

This section aims to describe the requirements that apply to the product information documents to be uploaded to the Union Product Database (UPD), including the naming convention.

All documents should be submitted using PDF file format. The file size limit is 10MB.

The name of the document should not contain any 'special' characters; only alphanumeric characters (lower case characters a-z, digits 0-9) and hyphens are allowed. Do not include blank spaces in the file name.

Likewise, the structure of the file name is fixed and should be respected in order to successfully perform bulk uploads of documents. It should be composed of five fixed parts, with an optional variable part in between. Examples will follow afterwards.

- **Country**: is the initial **fixed** part, defined by the 2-letter ISO code, as referenced in the RMS list: 100000000002 and 100000000003, from SPOR system:
    - Source of information: 2-letter ISO 3166-1 Codes for the representation of names of countries and their subdivisions - ISO 3166-1 alpha-2.
    - Exceptions:
        - For centrally authorised products = "ema".
        - For the common the English version of the product information concerning mutual recognition/decentralised/subsequent recognition procedures = "eu".
- **Document type**: is the second **fixed** part.
    - Applicable RMS lists: Product information Document Type & Regulating Authority Submission Unit Type:

List ID	List Name	Term Name	SPOR Attribute	Document Type Value	Term ID
100000155531	Product Information Document Type	Package Leaflet and Labelling	Other names	pllab	200000017121
100000155531	Product Information Document Type	Summary of Product Characteristics	Other names	spc	100000155532
100000155531	Product Information Document Type	Labelling	Other names	lab	100000155535
100000155531	Product Information Document Type	Package Leaflet	Other Name	pl	100000155538
100000155531	Product Information Document Type	Combined File of all Documents	Short name	combined	100000155539
100000155552	Regulating Authority Submission Unit Type	Public Assessment Report	Other names	puar	200000017122

- **Procedure number or permanent identifier:** is the third **fixed** part. The use of one or the other value, depends on the type of procedure to which the veterinary medicinal product belongs to.
    - For CAPs = Procedure number: the procedure number shall not be added with format defined in Chapter 2 from the Vet EU IG (emea/v/c/nnnnnn) section **Error! Reference source not found.**, but with the following format: "vnnnnnn" (where "v" represents veterinary medicinal product and "n" represents EMEA six digits procedure number). In cases where the EMEA six digits procedure number starts with "0's", they shall be removed from the file name. For example, for the procedure number "emea/v/c/000033", the following must be added in the third part of the file name: "v33".

- For DCP/SRP/MRP = Procedure number: the procedure number shall be added with format defined in Chapter 2 from Vet EU IG but without the slashes. For example, for the procedure number "es/v/0190/001" the following must be added in the third part of the file name: "esv0190001".
- For NAPs, parallel traded, registered homeopathic and pet products. = Permanent identifier.

- **Product name** or procedure type: is the fourth **fixed** part and the use of one or the other value, depends on the type of procedure to which the veterinary medicinal product belongs to.
  - For CAPs = Product name: the veterinary medicinal product name shall be provided based on the definition facilitated in Reg 2019/6: Article 4.21. This fixed part of the file name is not validated by the system. If the name of the veterinary medicinal product contains two or more words, they shall be separated by hyphens.
  - For DCP/SRP/MRP = Procedure type: to identify the veterinary medicinal products under decentralised, subsequent, or mutual recognition procedure, the value "mr" (mutual recognition) shall be added in this part of the file name.
  - For NAPs, parallel traded, registered homeopathic and pet products. – Procedure type: to identify the veterinary medicinal products under national procedure, the value "np" (national procedure) shall be added in this part of the file name.
- Additional (**variable**) information can be included only after the Product Name or Procedure type, e.g, target species, internal identifier and/or date, as deemed useful by the user to distinguish between different file versions.
- **Language**: is the last **fixed** part, defined by the 2-letter ISO code, as referred in the RMS list: 100000072057, from SPOR system.
  - Source of information: ISO 639-1 Codes for the representation of names of languages - ISO 639-1.

Examples of valid document name for files to be uploaded in the UPD:

Example for centralised procedures:

- ema-combined-v33-hydrocortisone-aceponate-ecuphar-dog-pt.pdf

  This name corresponds to the Combined file of all documents in Portuguese for a product that has been authorised under centralised procedure, where the target species is the solely variable part provided.

country=ema, document type=combined, procedure number=v33, product name= hydrocortisone-aceponate-ecuphar, variable part=dog, language=pt

Example for national procedures:

- es-lab-600010551208-np-amoxicilina-maymo-cattle-es.pdf

This name corresponds to a Labelling document in Spanish for a product that has been authorised under national procedure, where the product name and the target species is the variable part provided.

country=es, document type=lab, permanent identifier=600010551208, procedure type=np, variable part=amoxicilina-maymo-cattle, language=es

Example for mutual recognition/decentralised/subsequent recognition procedures:

- eu-spc-esv0190001-mr-boflox-cattle-en.pdf

  This name corresponds to a common SPC document in English from a product that could be authorised under mutual recognition/decentralized/subsequent recognition procedures, where the product name and the target species is the variable part.

  country=eu, document type=spc, procedure number= esv0190001, procedure type=mr, variable part=boflox-cattle, language=en

- xi-spc-esv0190001-mr-boflox-en.pdf

  This name corresponds to a national SPC document in English from a product that could be authorised under mutual recognition/decentralized/subsequent recognition procedures, where the product name is the solely variable part.

  country=xi (United Kingdom (Northern Ireland)), document type=spc, procedure number= esv0190001, procedure type=mr, variable part=boflox, language=en

Example for VRA centralised procedures:

- ema-combined-v1234-metacam-vra0005-pt.pdf
  This name corresponds to the combined file of all documents in Portuguese for a centrally authorised product undergoing a variation requiring assessment procedure (VRA), where the variation type/counter is the solely variable part.

  country=ema, document type=combined, procedure number=v1234, product name=metacam, variable part=vra0005, language=pt

Example for VNRA centralised procedures:

- ema-combined-v745-superdrug-vnra-a3-2022-02-01-pt.pdf
  This name corresponds to the combined file of all documents in Portuguese for a centrally authorised product undergoing a variation not requiring assessment procedure (VNRA), where the variation type/counter and date are the variable parts.

  country=ema, document type=combined, procedure number=v745, product name=superdrug, variable part=vnra-a3-2022-02-01, language=pt

- ema-combined-v99-purevaxrcpchfelv-rim-ref-1234-it.pdf
  The name corresponds to the combined file of all documents in Italian for a centrally authorised product undergoing a variation not requiring assessment procedure (VNRA), where an internal company identifier is the solely the variable part.

  country=ema, document type=combined, procedure number=v99, product name= purevaxrcpchfelv, variable part=rim-ref-1234, language=it

To summarise, the product information documents should meet the following conditions:

a) The file format is pdf.

b) The file size does not exceed 10MB.

c) No capitals, special characters nor blank spaces are allowed in the file name.

d) The file name is compliant with the *naming convention*, as specified.

For information, the maximum length accepted for the file's name varies depending on the Window's version installed.

- Latest/newest Window's versions accepts until 255 characters.
- All information can be found in the following link https://docs.microsoft.com/en-us/windows/win32/fileio/naming-a-file