Union Product Database (UPD) release notes

Referring to version 1.6.22

Release date:17 April 2023

Version 2

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 (**1.6.20**, released on 13 March 2023), new functionalities (detailed information in section 2.1) are available and **28** defects (detailed information in section 2.2) have been considered resolved.

Overview of new functionality(ies):

- Create/update product:
    - For veterinary medicinal products for which it is not possible to provide the 'strength' or the 'reference strength' in a structured way, NCAs can now provide these as a free text as outlined in the relevant parts of the dossier and the SPC.
- Volume of sales:
    - It is now possible to provide a dose factor as a number with up to 4 decimal digits.

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

Changes made in revised version of release notes:

- **It has been confirmed that** issue **UPD-13842 has been resolved in PROD with release 1.6.22 and is now listed as a 'Resolved Issue'.**
- Authorisation statuses "***Valid - Renewed/Varied***" or "***Valid - Transferred marketing authorisation***" are not compliant with EU Vet IG Chapter 2 section "2.5 Authorisation Status. A valiattion rule applies for 'Create or Update product' (see UPD-5674 listed as a 'Resolved Issue'). Products with these statuses will amended with datafix by the UPD team.

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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~~ Due to UPD-12726 this functionality cannot be used in this release
    - 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
    - There are three issues affecting the submission of Availability status. UPD-13458 affects products under DCP/MRP/SRP where RMS product is always incorrectly updated and UPD-13635 affects the submission of updates to CAP products. 85589 affects any submission where the date provided is ignored and status date is always updated with first day of the month/year provided.

- 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 severe delay in processing the VNRA's.

1.2. Functionality not included in this release

The following functionality is not included in this release.

NCA UI:

- Transfer Marketing Authorisation for products under any procedure: Due to UPD-12726 this functionality cannot be used in this release

MAH UI:

- Submit updates for Availability status: There are three issues affecting the submission of Availability status. UPD-13458 affects products under DCP/MRP/SRP where RMS product is always incorrectly updated; UPD-13635 affecting the submission of updates for CAP products.

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.

2. Changes made compared with 1.6.20

2.1. New or re-released functionality

- UPD-BR-178 Ability to provide either the Strength or the Reference Strength as free-text
    - The strength (quantitative composition) or reference strength of a substance should be provided with structured data based on a numerator and denominator value and unit. This could be expressed as either presentation strength or concentration strength
    - As **an exception** for those ingredients where it is not possible to provide structured data, the strength or reference strength may now be provided as free-text as outlined in the relevant parts of the dossier and the SPC
    - It is also possible to provide both structured data and free-text
    - An updated version of Vet EU IG Chapter 2 that includes these new attributes will be published
    - For API users:
        - This is not a breaking change and payloads that have been used to-date using only structured data are still valid
        - An additional example file for the Create of a NAP has been provided
- UPD-13468 Enhancement for Submission of Volume of Sales: Dose factor accepts a number with up to 4 decimal digits

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.

The following issue was resolved in PROD on 27 March 2023 (release 1.6.20):

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Resolved issues
UC28 View VNRA	NCA UI & MAH UI	UPD-13812		When selecting "View VNRA Submissions" from the menu, or entering some search criteria and Submit: there may be a timeout error displayed. This does not happen for all users and to-date has only been observed for some MAHs. As a workaround enter additional search criteria to reduce the number of search results to be returned.
UC28 View VNRA	NCA UI & MAH UI	UPD-13320		This bug had included three different issues and they have now been split into separate tickets. This ticket is for searching for VNRA on the "View VNRA Submissions" page, and the timeout errors were resolved as part of UPD-13812. Ticket UPD-14043 has been logged for timeout error received when Downloading a PDF or Viewing a Submission. Ticket UPD-14047 has been logged for timeout error received when Submitted a VNRA.

The following issues have been resolved in this release 1.6.22:

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Resolved issues
UC01 Create product UC08 Update product	API & NCA UI	UPD-5674	2.5 Authorisation status	Create or Update product for any procedure type: validation has now been implemented to only accept the six values specified in Vet EU IG Chapter 2 from the RMS list Regulatory Entitlement Status.
UC01 Create product UC08 Update product	NCA UI	UPD-12586		Document of type "Public Assessment Report" was not saved in the created or updated product
UC01 Create product	API	UPD-13501		All procedure types: Error message of "Failed to generate snapshot" may have occurred for one or more products in the GET OperationOutcome response. That product was not created.
UC01 Create product	NCA UI	UPD-13523		Create SRP where RMS product has National document: the National document for the RMS product was being added for the new CMS products and should only be Common Documents
UC03 Search product	NCA UI & MAH UI	UPD-12590		If search results require two or more pages, and the last page of search results should contain 51 or more products: the last page of search results was always displaying 100 products.
UC05 View product	NCA UI & MAH UI	UPD-13628		Package information was not displaying Manufactured item information
UC06 Submit VNRA	MAH UI	UPD-11596		If Submission Comment exceeded limit of 4000 characters a meaningful error message was not displayed. Instead it displayed an error of "undefined" in the banner (with red background). The expected error message is now displayed.
UC06 Submit VNRA	MAH UI	UPD-13808		VNRA submission for variation code A.1.a : when MAH searched for the proposed MAH and selected a different LOC-ID to the existing LOC-ID from their own Organisation, after clicking Accept the selected location was not displayed in the VNRA Submission screen and therefore the VNRA was not able to be submitted. If the existing LOC-ID was selected as the proposed MAH LOC-ID this was successfully displayed in VNRA submission screen and the VNRA was able to be submitted.
UC06 Submit VNRA	MAH UI	UPD-13778		When submitting VNRA and error displayed of "System error: try again in a few minutes": on some occasions the message may have been misleading as the Submission had been successful and was available with

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Resolved issues
				Submission ID. Therefore, duplicate submissions may be inadvertently created if submission had been retried. There should no longer be errors received of “System error: try again in a few minutes”
UC06 Submit VNRA	MAH UI	UPD-13483		When submitting VNRA there may have been a timeout error message displayed. One of the causes of this timeout has been resolved. Please note: UPD-14047 is a know open issue where Submission of VNRA may still fail with a timeout error where there are many products and/or variation codes.
UC06 Submit VNRA	MAH UI	UPD-13842		After selecting products to add to submission and click Accept, the retrieve product dialog is closed but the selected products are not carried over to the submissions page screen (issue occurs in Production only) Note: this issue was listed as a New known issue in the first version of these release notes. A change was made in release 1.6.22 that may have resolved this issue. Since we were not able to reproduce this issue in the test environments we were checking if this was still an issue in PROD. It has been confirmed that this issue has been resolved in PROD and is now listed as a Resolved Issue.
UC07 Submit Volume of Sales		UPD-10637		If Submission of Volume of Sales 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.
UC07 Submit Volume of Sales	MAH UI	UPD-13467		Submission of Volume of Sales - validation was missing for ERR.02 (product status is Current or Provisional) & ERR.15 (Species Split should be between zero and 100).
UC08 Update product	API	UPD-9031	1.6 Legal status of supply 5.4	If Legal status of supply had been specified at Package level and submit an update to populate at Product level and remove from the package:

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Resolved issues
			Legal status of supply	the updated product still had the previous value at Package as well as the new value at Product level.
UC08 Update product	API & NCA UI	UPD-11476	1.6 Legal Status 5.4 Legal status of supply	Update National Data DCP/MRP/SRP: if product does not have Legal status of supply populated at either product or package level there should is now a validation error.
UC08 Update product	API	UPD-11235	2.6 Date of authorisation status change	Update National Data DCP/MRP/SRP or Update NP/Registered Homeopathic/Parallel Trade - if no Date of Authorisation status change attribute populated in payload were getting validation error based on Legacy/Chapter 4 rules. This is now optional for Legacy product.
UC08 Update product	NCA UI	UPD-13140		Update Common Data DCP/MRP/SRP - after successful submission and processing of an update to remove withdrawal period notes, the updated version of the product still contained the notes.
UC08 Update product	NCA UI	UPD-13335		Update Common Data DCP/MRP/SRP - It was possible to remove a Manufactured item that is still referenced from a Package and this should not be allowed.
UC08 Update product	NCA UI	UPD-13875		Update National Data for DCP/MRP/SRP: NCA user for UK (Northern Ireland) was not able to Update National Data for product where is UK (Northern Ireland) is CMS. This issue has been resolved and they are now able to edit national data.
UC08 Update product	NCA UI	UPD-13274		Update National Procedure (NAP) to remove an Ingredient. In the updated version of the product the Ingredient data for the one that remained was corrupted. The Ingredient that had been removed still existed in the product but did not contain reference to the Pharmaceutical product. A new Data fix ticket has been logged to try and identify products that had been affected by this bug: UPD-14038. In the meantime, if you are blocked from updating a product and you believe it has been corrupted due to this bug please log a User Support ticket so that data in that product can be corrected so that the product is able to be updated.

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Resolved issues
UC08 Update product	NCA UI	UPD-8401	4 Ingredient	When updating a product, user is not able to remove an Ingredient that is still referenced in a Manufactured Item or referenced in Pharmaceutical product.
UC21 Manage notifications	MAH UI	UPD-13676		MAH user who is not the Product owner may have been able to view notifications for VNRA Approved and VNRA Rejected for a VNRA Submission for another Product owner. The MAH who is not the product owner was not able to view the VNRA Submission or the product. This issue has been resolved for new VNRA submissions. Existing notifications that had been created in error for existing VNRA submissions will remain.
UC21 Manage Notifications	NCA UI & MAH UI	UPD-13137		When submission of Bulk Upload has failed: the Notification card did not match the definition documented in "UPD - Notifications in processes". This has been corrected.
UC27 View Volume of Sales	NCA UI & MAH UI	UPD-13294		View Volume of Sales - changing search results from default of 20 products per page didn't always change number of products in Search results table; and may also have affected navigation through search result page.
UC27 View Volume of Sales	MAH UI	UPD-13292		View Volume of Sales (MAH users only) MAH products with submitted values for Volume of Sales were not being displayed as expected and needed to paginate through search results to see list of all products that have had sales data loaded.
UC28 View VNRA	NCA UI & MAH UI	UPD-13817		If filtered and searched using Classification code and viewed a Submission, when selecting to return back to search results the Classification code was listed as filter criteria but was not being used as part of the search. This issue has been resolved.
UC28 View VNRA	NCA UI & MAH UI	UPD-13779		If submit a search using Product name as search criteria (either default of starts with or select contains) and view a submission from search results: when you returned to the search results screen the search field included a suffix of "&productNameContains". This suffix needed to be

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Resolved issues
				removed from the end of the product name in order to be able to submit a subsequent search using that same name.
UC28 View VNRA	NCA UI & MAH UI	UPD-12627		Returning back to VNRA Search submissions page after viewing a submission was not retaining the number of records per page to display if you had changed from default of 100 submissions per page.
UC28 View VNRA	NCA UI	UPD-13452		When NCA views a VNRA submission where one of more products in that submission were included in some other submission: the warning message listing pending VNRA was incorrectly including submission ID that have been approved or rejected. It is now only listing pending VNRA.
UC34 Bulk Upload for Documents	NCA UI & MAH UI	UPD-10698		After successful Bulk Upload of one or more documents, 'Date of Action' and 'Version number' were not populated in Notification card when viewing Notification.
UC39 UPD Usability aspects	NCA UI & MAH UI	UPD-13270		The expected warning message when 5 minutes of active session are left was not displayed.

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	Vet EUIG Chapter 2 section	New Issue description
UC01 Create product	NCA UI	UPD-13880		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 UC08 Update product	NCA UI	UPD-13782		Create or Update DCP/SRP/MRP: if there is a validation error, the correct validation error message is not being displayed. For example: expect validation error to contain "No manufacturer responsible for batch

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	New Issue description
				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 "application/json,text/plain,*/*; charset=utf-8": Invalid token character ',' in token "json,text/plain,*/*"" is being displayed as the error message.
UC01 Create product UC08 Update product	NCA UI	UPD-13874		Parallel trade product only: the wrong pop up message is displayed for the Authorisation/registration/entitlement number field
UC01 Create product	NCA UI	85286		Create SRP - a CMS product with Authorisation status of Surrendered is being validated and updated. If there had been a previous Update Common Data to remove or add a package, the CMS Surrendered product is no longer aligned with RMS product and therefore fails with error on subsequent Create SRP.
UC03 Search product	NCA UI & MAH UI	UPD-13908		Active substance and strength is displayed as N/A if strength of Active Ingredient is Concentration single value
UC03 Search products	NCA UI & MAH UI	UPD-13814		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
UC04 Export	NCA UI & MAH UI	UPD-13723		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

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	New Issue description
				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-13870		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	NCA UI & MAH UI	UPD-14051		The country name is not being displayed for document type "Combined file of all documents " for a document added using Bulk Upload
UC06 Submit VNRA	MAH UI	UPD-13810		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 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-13883		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-13953		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
UC06 Submit VNRA	MAH UI	UPD-14047		Submission on VNRA may fail with a timeout error if there are many products and/or many variation codes
UC08 Update product	API & NCA UI	UPD-13959		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-13672		Update Parallel Trade : It is not possible to add new documents
UC08 Update product	API & NCA UI	81576		Update Registered Homeopathic based on Chapter 4/Legacy validation rules: validation errors are received if PSMF is not populated. This should

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	New Issue description
				be optional under Chapter 4 rules. If PSMF is populated the update will be successful.
UC09 Approve/Reject VNRA	NCA UI	UPD-13795		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	84163		For product under DCP/MRP/SRP, a CMS user has Approve/Reject checkboxes enabled and they shouldn't. If they do attempt to select Accept/Reject the Submit button does still remains disabled
UC19 Nullify product	API	UPD-13877		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
UC21 Manage Notifications	MAH UI	UPD-13984		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-13820		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
UC24 Marketing authorisation status	MAH UI	UPD-13847		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
UC25 Update Availability status	MAH UI	UPD-13766		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

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	New Issue description
UC25 Update Availability status	MAH UI	UPD-13900		Format of value for Availability status date column is not as expected in download file; and validation not being applied as expected to this value in submission file
UC25 Update Availability status	MAH UI	UPD-13988		When searching products to download file for Availability status, the Permanent identifier number incorrectly has type of search icon. This should not be included as not able to search using starts with or contains options
UC25 Update Availability status	MAH UI	85589		The day within availability status date in submitted file is being ignored and first day of the month always used instead when updating the product
UC27 View Volume of Sales	NCA UI & MAH UI	UPD-13650		If an attempt is made to download Volume of Sales for a product with "Year from" less than or equal to 2016 the progress control is displayed for a period of time and then a server error displayed. A change will be made so that only sales volumes from 2022 onwards can be downloaded
UC27 View Volume of Sales	MAH UI	84524		Some MAH users: when select to download Volume of Sales there is an error "server encountered an error" and user is not able to download existing VoS that had been loaded prior to release or new submission made in this release. Some MAH users and NCA users are able to successfully download VoS
UC28 View VNRA	NCA UI & MAH UI	UPD-13802		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-13850		VNRA PDF file - information on variation codes count differs from UI and is not correct if the same variation code has been included more than once
UC28 View VNRA	NCA UI & MAH UI	UPD-13854		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

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	New Issue description
UC28 View VNRA	NCA UI & MAH UI	UPD-14043		For a submission with many products & variation codes, there may be a timeout error downloading PDF or when viewing submission
UC34 Bulk Upload for Documents	NCA UI	UPD-13906		Loading of Public Assessment Report documents for CAP products sometimes results in duplicate documents added in UPD
UC34 Bulk Upload for Documents	NCA UI	UPD-13855		When submit a new file that should update an existing document: user advised submission of documents was successful but the documents have not been updated and there is no Notification of failure (issue only occurs in Production)

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	New Issue description
UPD-BR-178	UC01 Create product	NCA UI	UPD-13840	Free text strength values are not displayed when selecting Ingredients to link in Pharmaceutical product and Manufactured item sections
UPD-BR-178	UC01 Create product	NCA UI	UPD-13843	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
UPD-BR-178	UC03 Search product	NCA UI & MAH UI	UPD-13845	The Active Substance and Strength columns display "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
UPD-BR-178	UC05 View product	NCA UI & MAH UI	UPD-13848	If Reference strength field defined as free text this is not displayed on the view product screen
UPD-BR-178	UC05 View product	NCA UI & MAH UI	UPD-13836	If Substance strength or reference strength contains free text fields, these are not displayed correctly on view product screen

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 2022
- **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~~ Due to UPD-12726 this functionality is not able to be used in this release for any products
    - 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

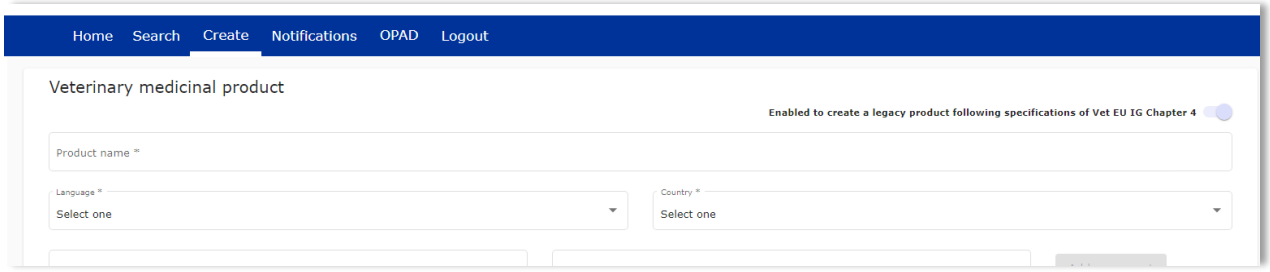
Supported browsers for the NCA UI are Chrome and Edge.

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 (in Manufactured item)	This should not be mandatory for Legacy products. An ingredient must be selected in this release for create of a NAP product. It is no longer mandatory for a DCP.

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

To request access:

- If you do not already have an EMA account in the Test environment:
    - 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
Free-text substance strength and reference substance strength	New attributes to allow populated of free-text strength as an exception where it is not possible to populate structured data. Ingredient.substance.strength.presentationText Ingredient.substance.strength.concentrationText Ingredient.substance.strength.referenceStrength.strength.extension.strengthText Refer to new Create NAP example payload provided: xxx

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 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

Procedure type	Validation rules	Example file
		with the Marketing authorisation number for Package 1 • One with subject reference = 2nd PackagedProductDefinition resource; populate with the Marketing authorisation number for Package 2
NAP	Chapter 4 Legacy	UPD_1.6.1-4_NAP_Legacy_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel.JSON UPD_1.6.1-4_NAP_Legacy_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel.XML UPD_1.5.1-0_NAP_Legacy_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel.JSON UPD_1.5.1-0_NAP_Legacy_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel.XML
NAP	Chapter 4 Legacy	UPD_1.5.1-0_NAP_Legacy_Cx_ManyAttributesAndResources_MANumberAtMedicinalProductLevel.XML This example contains: • 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	Xxxx UPD-BR-178: This example contains Ingredient resources that illustrate how to specify free-text substance or reference substance strength

Procedure type	Validation rules	Example file
Registered Homeopathic	Chapter 2	UPD_1.6.1-4_HOM_Chpt2_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel.JSON UPD_1.6.1-4_HOM_Chpt2_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel.JSON
Parallel Trade	Chapter 2	UPD_1.6.8-4_PAT_Chpt2_C2_Mandatory_VetIGl.JSON UPD_1.6.8-4_PAT_Chpt2_C110_VetEUIG_AllData.JSON

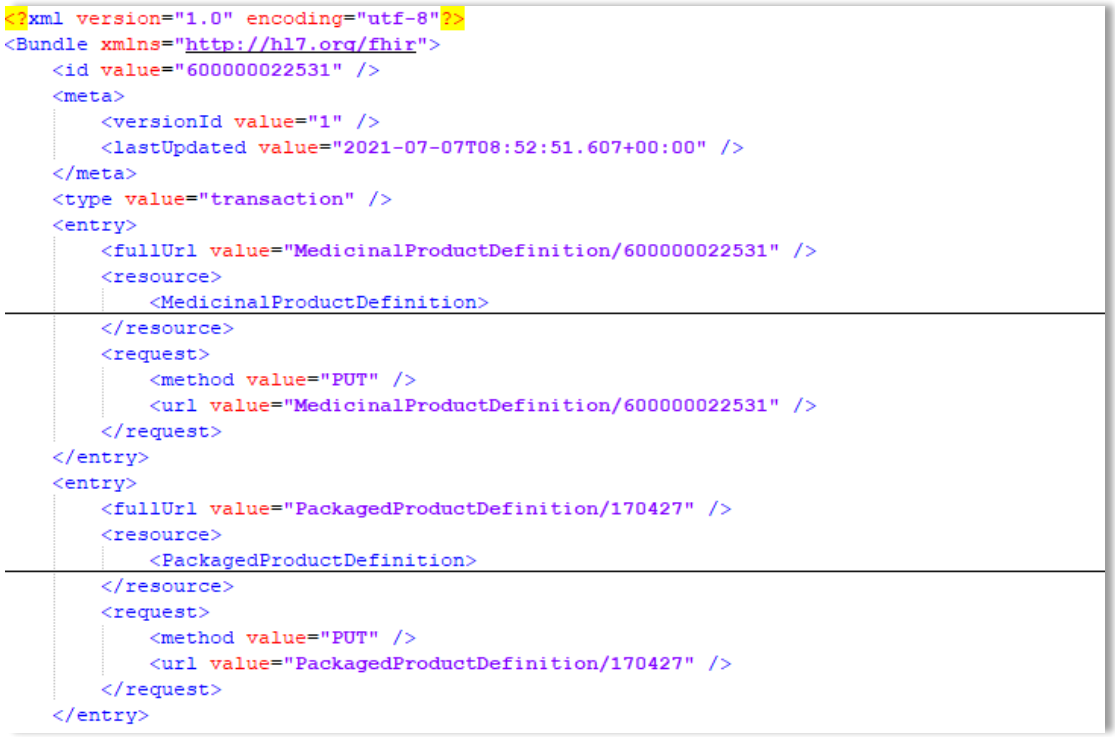
5.5.8. Recommended approach to prepare update request bundle

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
  - There are three issues affecting the submission of Availability status. UPD-13458 affects products under DCP/MRP/SRP where RMS product is always incorrectly updated and UPD-13635 affects the submission of updates to CAP products. 85589 affects any submission where the date provided is ignored and status date is always updated with first day of the month/year provided.

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

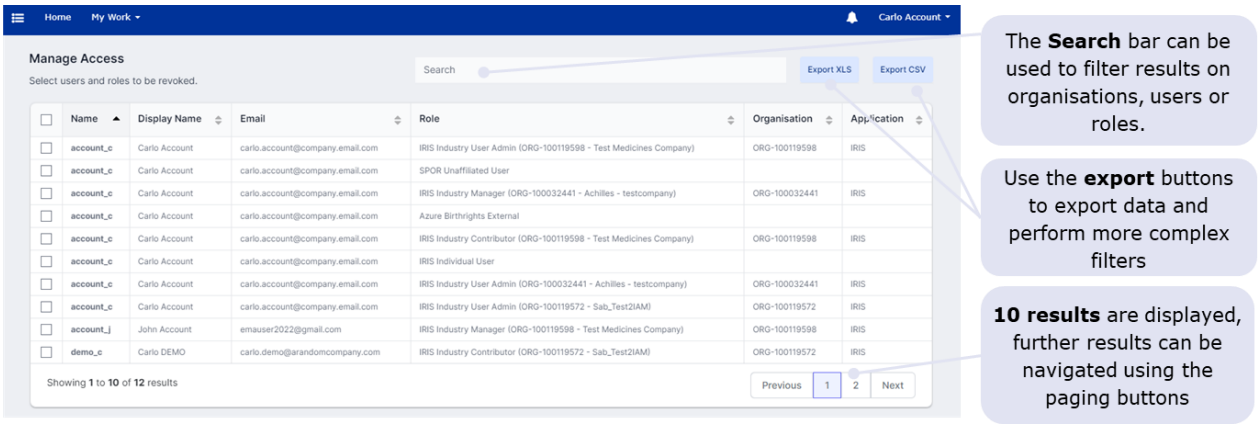
9. References

1. UPD 01.06 Registration Process for UPD API in Production (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.



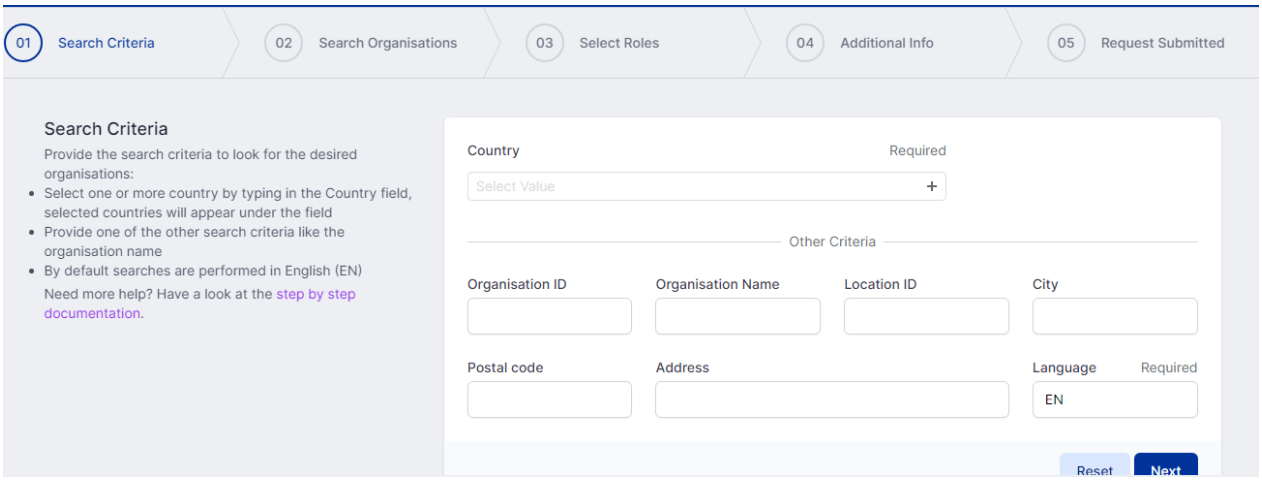
The 'Manage my access' tab, marked in red in the visual below, became obsolete, with all procedures now being managed through the 'Request Access for organisations' tab and the 'Manage Access' tab, marked in green.

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".

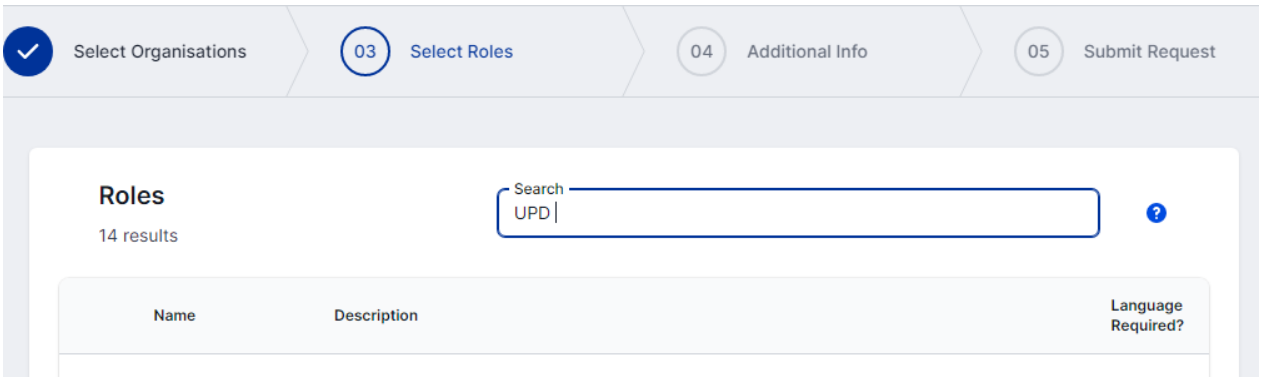
9.1. Request the Super User Role for your Organisation in UAT

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

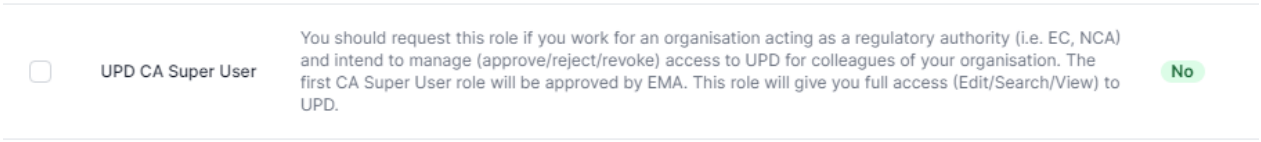
2. Go to "Request Access for Organizations" and search for your country and your ORG ID:



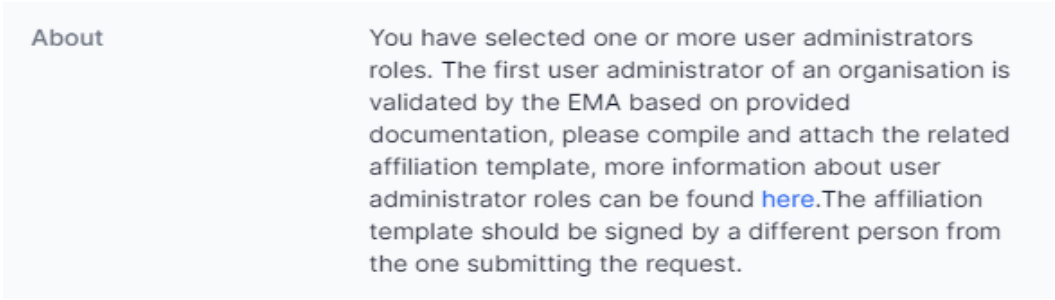
3. Select "UPD" to find the roles:



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)



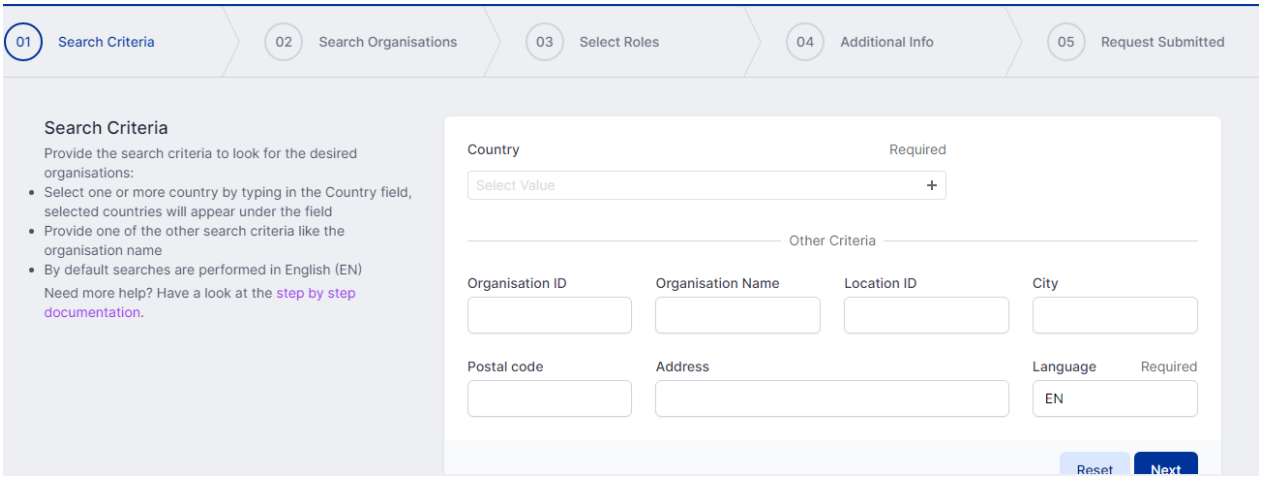
6. Click "Submit"

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

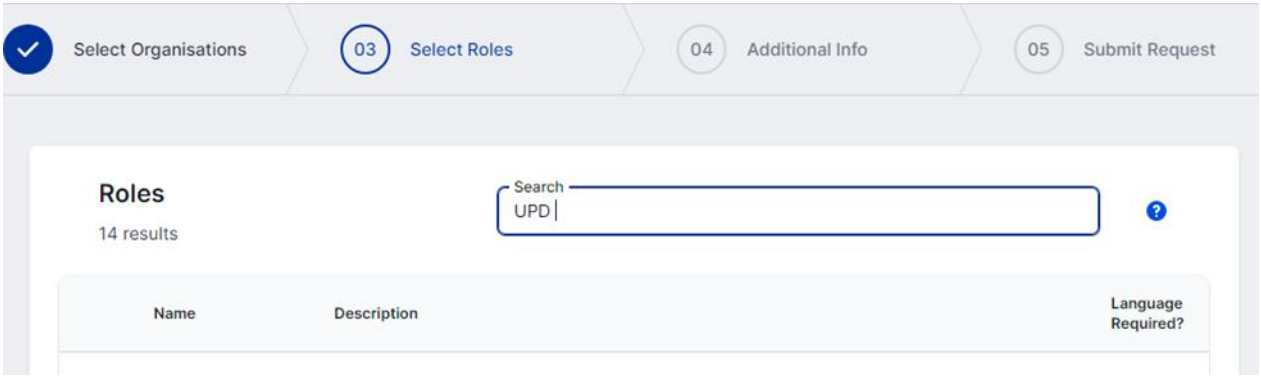
9.2. Request a Member User Role for your Organisation and Affiliate to your Organisation in UAT

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.

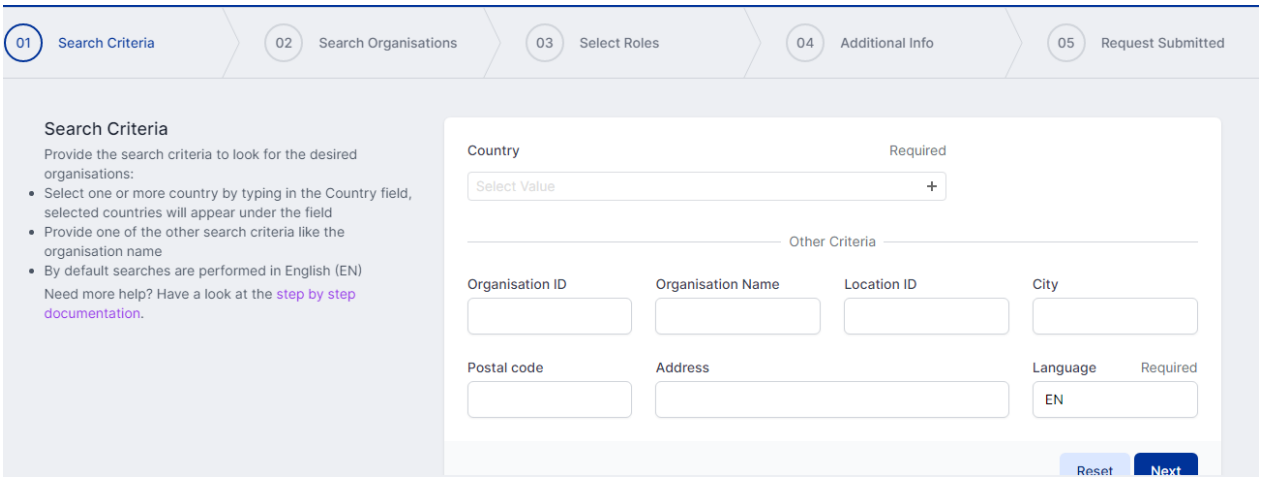
5. Submit.

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

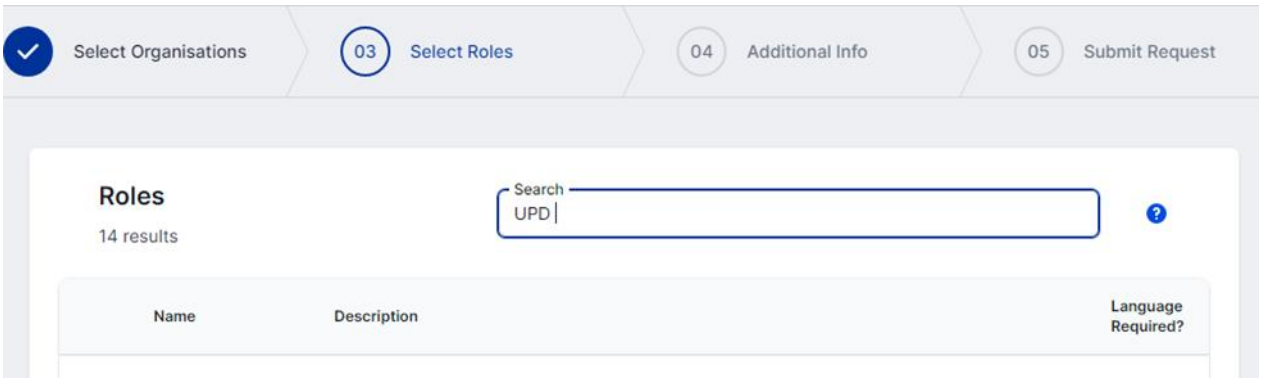
Note: This is at this point only relevant for UI usage. The model for the API accounts remains as per section 5.3. and the document referred to in section 9. .

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

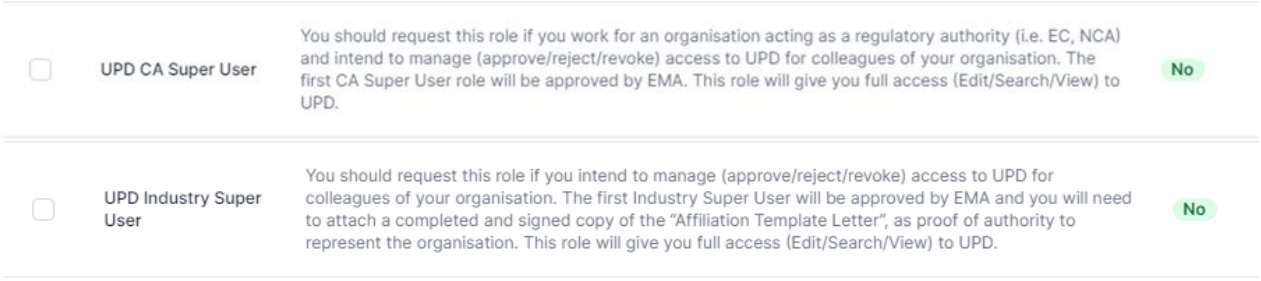
2. Go to "Request Access for Organizations" and search for your country and your ORG ID:



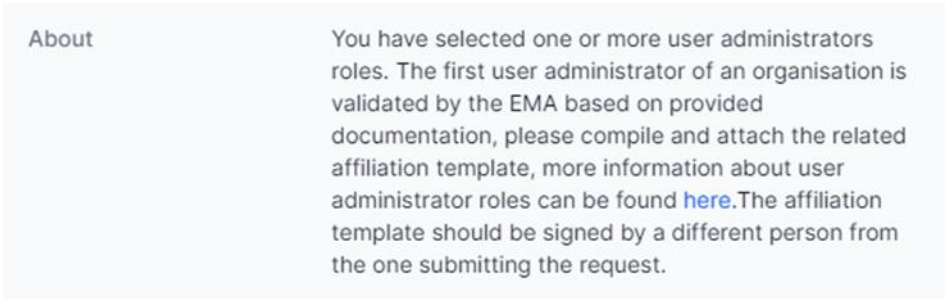
3. Select "UPD" to find the roles:



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	Vet EUIG Chapter 2 section	Known Issue Description
All UC	MAH UI	UPD-9896		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	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		OMS to UPD updates: New or Updated Organisations and Locations from OMS are not available in UPD
API Manager	API	UPD-10952		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		Data Fix Parallel Trade products: where Source Member State product had two or more Ingredients, the first Ingredient from that product was duplicated in the new Parallel trade product. This was due to bug UPD-13162. EMA to query existing Parallel Trade products to identify products that were affected by this issue and then assess how to correct
UC01 Create product	NCA UI	UPD-13465		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	API & NCA UI	UPD-11038		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	API & NCA UI	UPD-13702		Create MRP - not able to create MRP from NAP where Marketing Authorisation number is populated at Package Level. The submission of the Create MRP is successful but the transaction does not complete successfully

Use Case	Affects user	Issue reference	Vet EUIG Chapter 2 section	Known Issue Description
UC01 Create product	NCA UI	UPD-9013		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		Create MRP : the "Add Package" button remains disabled after entering values for the addition of a package
UC01 Create product	API	UPD-11849		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		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	UPD-12272		Create Parallel Trade via API where referenced product has Authorisation status that is not equal to "Valid" : the response code is Error 500 with no meaningful validation error message
UC01 Create product	NCA UI	85286		Create SRP - a CMS product with Authorisation status of Surrendered is being validated and updated. If there had been a previous Update Common Data to remove or add a package, the CMS Surrendered product is no longer aligned with RMS product and therefore fails with error on subsequent Create SRP.
UC01 Create product	NCA UI	UPD-13271		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-12904		Create SRP : the RMS should not be able to delete any National Document from the RMS/CMS product retrieved. The delete button is enabled and shouldn't be
UC01 Create product	NCA UI	UPD-3346	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.

Use Case	Affects user	Issue reference	Vet EUIG Chapter 2 section	Known Issue Description
UC01 Create product	NCA UI	UPD-13840		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		If free text strength for an Ingredient is entered before selecting the Substance code, add button remains disabled. As a workaround for this minor issue: remove the free-text substance strength after selecting the substance code and then re-enter
UC01 Create product	API & NCA UI	UPD-10293		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	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		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		Registered Homeopathic based on Legacy/Chapter 4 validation rules: the asterisk mark to indicate a mandatory field is not displayed on Tissue field
UC01 Create product	API	UPD-11587		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		Validation in all resources of URN UUID for fullURL attribute: letters allowed are only a to f to form the hexadecimal set from 0 to f pattern of 8-4-4-4-12 The post may not be rejected or may not give an error message that clearly identifies this as being the issue
UC01 Create product	NCA UI	UPD-13241		When creating a product and using the Validate button: the delete button from the manufactured item section disappears

Use Case	Affects user	Issue reference	Vet EUIG Chapter 2 section	Known Issue Description
UC01 Create product UC08 Update product	NCA UI	UPD-11419		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	NCA UI	UPD-13782		Create or Update DCP/SRP/MRP: if there is a validation error, the correct validation error message is 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 "application/json,text/plain,*/*; charset=utf-8": Invalid token character ',' in token "json,text/plain,*/*"" is being displayed as the error message.
UC01 Create product UC08 Update product	API	UPD-13485		Create or Update of NAP - there should be a validation error if payload does not have Legal Status of Supply at either Product or Package level. At present the product is incorrectly being created/updated. Once this issue is resolved we will identify products that do not have Legal status of supply populated so that they can be corrected
UC01 Create product UC08 Update product	NCA UI	UPD-7997		Create/Update of a Product - Error Messages need to be more meaningful
UC01 Create product UC08 Update product	NCA UI	UPD-7964		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	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		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	Vet EUIG Chapter 2 section	Known Issue Description
UC01 Create product UC08 Update product	NCA UI	UPD-13632		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		Parallel trade product only: the wrong pop up message is displayed for the Authorisation/registration/entitlement number field
UC01 Create product UC08 Update product	NCA UI	UPD-7971	1.11.5 (Attached document) content type	System allows Word .doc/.docx type document to be attached and this should not be valid
UC01 Create product UC08 Update product	API & NCA UI	UPD-9338	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	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)
UC01 Create product UC08 Update product	NCA UI	UPD-4863	5.6.4 Ingredient (in Manufactured item)	This should not be mandatory for Legacy products. An ingredient must be selected in this release for 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	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		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		UPD is missing terms from SPOR (RMS) - Units of measurement list

Use Case	Affects user	Issue reference	Vet EUIG Chapter 2 section	Known Issue Description
UC01 Create product UC08 Update product	API & NCA UI	UPD-12950		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
UC01 Create product UC08 Update product	API & NCA UI	UPD-12406		When processing a Create or Update to product an error occurs on one of the servers "No buffer space available". This results in the create or update being Queued and is never subsequently processed
UC03 Search product	NCA UI & MAH UI	UPD-13908		Active substance and strength is displayed as N/A if strength of Active Ingredient is Concentration single value
UC03 Search product	API	UPD-13658		API user only: A search of products using two parameters of _lastUpdated: the second parameter is ignored and only the first is applied
UC03 Search product	NCA UI & MAH UI	UPD-12867		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		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		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		Reset button does not clear existing search criteria from "Authorisation Country"
UC03 Search product	NCA UI & MAH UI	UPD-12748		Search limitations due to FHIR limitation or MS FHIR limitation
UC03 Search product	API & NCA UI & MAH UI	UPD-140		Sort of search results does not work

Use Case	Affects user	Issue reference	Vet EUIG Chapter 2 section	Known Issue Description
UC03 Search product	NCA UI & MAH UI	UPD-13463		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	NCA UI & MAH UI	UPD-13845		The Active Substance and Strength columns display "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
UC03 Search product UC05 View Product	API & NCA UI & MAH UI	UPD-13461		The 'Organisation Name' from OMS is not always displayed for a Product Owner on the Search and View Product screens
UC03 Search products	NCA UI & MAH UI	UPD-13814		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
UC04 Export	NCA UI & MAH UI	UPD-13723		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-13324		CAP products - some products do not have any Substance name displayed. This issue affects only a few products
UC05 View product	NCA UI & MAH UI	UPD-13848		If Reference strength field defined as free text this is not displayed on the view product screen
UC05 View product	NCA UI & MAH UI	UPD-13836		If Substance strength or reference strength contains free text fields, these are not displayed correctly on view product screen
UC05 View product	NCA UI	UPD-13441		NCA User affiliated to both PEI & BVL does not have Edit Buttons as expected

Use Case	Affects user	Issue reference	Vet EUIG Chapter 2 section	Known Issue Description
UC05 View product	NCA UI & MAH UI	UPD-13870		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	NCA UI & MAH UI	UPD-13494		Pharmaceutical products section: Withdrawal period information is not being listed beside the correct Target species
UC05 View product	NCA UI & MAH UI	UPD-14051		The country name is not being displayed for document type "Combined file of all documents " for a document added using Bulk Upload
UC05 View product	NCA UI & MAH UI	UPD-13510		View product which has PSMF populated: PSMF Address is not displayed and has N/A
UC05 View product	NCA UI & MAH UI	UPD-13631		When view previous version for a product it displays manufacturer for Ingredient based on the current version of the product; and not the value that existed in that version
UC05 View product	NCA UI & MAH UI	UPD-13125		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		When view product, dates are different according to browser timezone
UC05 View product	NCA UI & MAH UI	UPD-10185	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
UC06 Submit VNRA	MAH UI	UPD-10901		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
UC06 Submit VNRA	MAH UI	UPD-13810		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 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-11617		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

Use Case	Affects user	Issue reference	Vet EUIG Chapter 2 section	Known Issue Description
UC06 Submit VNRA	MAH UI	UPD-11632		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-13634		If submit VNRA for an automated variation code for a product that has Marketing authorisation number populated at package level there is a validation error "Unable to find matching profile for PackagedProductDefinition/" displayed and not able to submit VNRA as expected. Further investigation is required as this issue has only been observed in Production and have not been able to reproduce in UAT
UC06 Submit VNRA	NCA UI	UPD-11278		Issue affects EMA/EC users only: When VNRA is submitted, the VNeeS files is not reaching the Common Repository for some submissions
UC06 Submit VNRA	MAH UI	UPD-8440		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		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-14047		Submission on VNRA may fail with a timeout error if there are many products and/or many variation codes
UC06 Submit VNRA	MAH UI	UPD-12908		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

Use Case	Affects user	Issue reference	Vet EUIG Chapter 2 section	Known Issue Description
UC06 Submit VNRA	MAH UI	UPD-7960		Submit VNRA: No search results displayed when the 'Retrieve product' search dialog is opened a second time
UC06 Submit VNRA	MAH UI	UPD-12062		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-13953		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
UC06 Submit VNRA	MAH UI	UPD-11256		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		When View product QPPV displays as N/A even although the product does have a LOC-ID populated. This affects only some products and may be due to some Data Quality issue in the affected products
UC06 Submit VNRA UC28 View VNRA	NCA UI & MAH UI	UPD-10184		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		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		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-10288		A Product stuck in 'pending' state from a previously failed update transaction cannot be updated
UC08 Update product	API & NCA UI	UPD-12949		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		Add button in Package medicinal product section needs to have more meaningful caption

Use Case	Affects user	Issue reference	Vet EUIG Chapter 2 section	Known Issue Description
UC08 Update product	API & NCA UI	UPD-12580	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
UC08 Update product	NCA UI	UPD-13678		All procedure types: it is not possible to update an existing document and upload a document with size > 2MB
UC08 Update product	NCA UI	UPD-12726		Bulk Transfer of ownership - Incorrect validation error does now allow NCA to submit any update. This is a Regression issue from previous release.
UC08 Update product	API	UPD-4812	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	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	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
UC08 Update product	NCA UI & MAH UI	UPD-11819		For CAP products: there are examples where two products have been created and expected just one. This may occur when a new package has been added or package information has been updated. The cause of the issue will be resolved and affected products corrected
UC08 Update product	API & NCA UI	UPD-13273		For National Procedure (NAP) products that have a Data Quality issue and have been loaded without a value for Legal status of supply: when update to add value is submitted and processed, the new value for Legal status of supply has not been saved in the updated version of the product. EMA will follow-up to identify affected products and see if we can update using a Data fix. Any missing validation on Create of a product will be resolved in a separate ticket.

Use Case	Affects user	Issue reference	Vet EUIG Chapter 2 section	Known Issue Description
UC08 Update product	NCA UI	UPD-13466		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		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	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-13334		Update CAP - not able to add multiple Public Assessment Report documents. As a workaround from release 1.6.20 are able to use Bulk Upload to load multiple PuAR documents for a CAP product (as long as each document has a unique filename)
UC08 Update product	API	UPD-9709		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		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		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		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

Use Case	Affects user	Issue reference	Vet EUIG Chapter 2 section	Known Issue Description
UC08 Update product	API & NCA UI	UPD-13815		Update Common Data: Not possible to update common data when MA provided at package level for DCP RMS product-Fails with error
UC08 Update product	NCA UI	UPD-12239		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	UPD-7148	1.4 Permanent identifier	Update NAP - should reject update with validation error message if MedicinalProductDefinition.id is not populated
UC08 Update product	API	UPD-7273	1.2 Product Record Status	Update National Data - API - UPD-UC08-AC016 - Missing Validation error when update Product Status from Current to Provisional & product has been updated
UC08 Update product	NCA UI	UPD-7247		Update National Data DCP/MPR/SRP - Able to add a new Pharmaceutical Product which is a Common data; advised successful but Get OperationOutcome has Validation error
UC08 Update product	NCA UI	UPD-13486		Update National Data DCP/MRP/SRP - a CMS is able to delete a Package and this should not be possible. If they do proceed to update only the CMS product is updated but is now not aligned with RMS and other CMS products
UC08 Update product	NCA UI	UPD-13484		Update National Data DCP/MRP/SRP - if strength has a numerator of zero, there is an incorrect validation error when attempting to update the product
UC08 Update product	API & NCA UI	UPD-13959		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	API & NCA UI	UPD-13791		Update National Data DCP/MRP/SRP - not able to update National Data when Marketing Authorisation number provided at package level. There is a validation error
UC08 Update product	NCA UI	UPD-12905		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	NCA UI	UPD-13148		Update National Data for DCP/MRP/SRP where product doesn't have Pack Size populated: get validation error when populate Marketing Authorisation Number at Package Level
UC08 Update product	NCA UI	UPD-10287		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

Use Case	Affects user	Issue reference	Vet EUIG Chapter 2 section	Known Issue Description
UC08 Update product	API & NCA UI	UPD-13296		Update of product fails leaving product in Pending state and this blocks and subsequent update
UC08 Update product	API & NCA UI	UPD-12385		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	NCA UI	UPD-13430		Update package where pack size has not been populated: an incorrect validation error related to pack size is being displayed and therefore this prevents 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		Update Parallel Trade : It is not possible to add new documents
UC08 Update product	API	UPD-12286		Update Parallel Trade via API fails with validation error messages relating to RMS and CMS (regression issue from previous release)
UC08 Update product	API & NCA UI	UPD-12396		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	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	API & NCA UI	81576		Update Registered Homeopathic based on Chapter 4/Legacy validation rules: validation errors are received if PSMF is not populated. This should be optional under Chapter 4 rules. If PSMF is populated the update will be successful.
UC08 Update product	NCA UI	UPD-8246	1.3 Product identifier	Update SRP National data - The Product identifier is displaying [object Object], [object Object]
UC08 Update product	API	UPD-5192	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.
UC09 Approve/Reject VNRA	NCA UI	84163		For product under DCP/MRP/SRP, a CMS user has Approve/Reject checkboxes enabled and they shouldn't. If they do attempt to select Accept/Reject the Submit button does still remains disabled

Use Case	Affects user	Issue reference	Vet EUIG Chapter 2 section	Known Issue Description
UC09 Approve/Reject VNRA	NCA UI	UPD-9866		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		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		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		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		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	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-12249		Create or Update of Document via API - infrequently the POST fails with response code 500 Internal server error. This is an intermittent issue as POST of the same payload is subsequently successful. This is an issue only observed in PROD environment
UC18 Manage document	API	UPD-11460		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	Vet EUIG Chapter 2 section	Known Issue Description
UC19 Nullify product	API	UPD-13659		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		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		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		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		When you nullify a product, the confirmation message does not include the Permanent Identifier
UC21 Manage Notifications	NCA UI & MAH UI	UPD-10184		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	UPD-13049		Date format inconsistent between different actions
UC21 Manage Notifications	NCA UI	UPD-8340		For an update National Data for DCP/MRP/SRP UPD-UC08-AC018, the CMS should only see notifications for their own product. At present they also see notifications for RMS & other CMS products
UC21 Manage Notifications	MAH UI	UPD-13984		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		Not able to search notifications using Procedure number

Use Case	Affects user	Issue reference	Vet EUIG Chapter 2 section	Known Issue Description
UC21 Manage Notifications	NCA UI & MAH UI	UPD-13820		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		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		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		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-12334		The Notification for Update NAP without document shows action as "Update, Upload Document" and should be "Update"
UC21 Manage Notifications	NCA UI & MAH UI	UPD-12591		VNRA Submitted action: the notification card has incorrect labels. Decision Comment should be Submission Comment. Date of Decision should be Date of Submission. Date of Implementation is not displayed. The correct values of the submission date and submission comment are displayed.
UC21 Manage Notifications	NCA UI & MAH UI	UPD-13135		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		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		Sorting of the product search results table by any column does not work
UC24 Marketing authorisation status	MAH UI	UPD-12092		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.

Use Case	Affects user	Issue reference	Vet EUIG Chapter 2 section	Known Issue Description
UC25 Update Availability status	MAH UI	UPD-13491		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-12934		Availability Status Date format of YYYY-MM is not accepted though Chapter 7 states it should
UC25 Update Availability status	MAH UI	UPD-13766		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-13487		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		Format of value for Availability status date column is not as expected in download file; and validation not being applied as expected to this value in submission file
UC25 Update Availability status	MAH UI	UPD-10637		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-7980		Not able to select all products to download in the one csv file if product search results are over two or more pages
UC25 Update Availability status	MAH UI	UPD-13467		Submission of Availability Status - validation is missing for ERR.02 (product status is Current or Provisional)
UC25 Update Availability status	MAH UI	UPD-13458		Submission of Availability status for CMS product under DCP/MRP/SRP is incorrectly updating the RMS product with the new availability status and not the CMS product specified in the csv file. Therefore we recommend not to submit any updates for Availability status in this release although updates for NAP is not affected by this issue. This issue is expected to be resolved in 1.6.22
UC25 Update Availability status	MAH UI	85589		The day within availability status date in submitted file is being ignored and first day of the month always used instead when updating the product

Use Case	Affects user	Issue reference	Vet EUIG Chapter 2 section	Known Issue Description
UC25 Update Availability status	MAH UI	UPD-13988		When searching products to download file for Availability status, the Permanent identifier number incorrectly has type of search icon. This should not be included as not able to search using starts with or contains options
UC25 Update Availability status	MAH UI	UPD-13481		When select to download file the search products grid has an incorrect column heading for "Marketing authorisation status". Column heading is currently "Marketing status"
UC27 View Volume of Sales	NCA UI & MAH UI	UPD-13650		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	UPD-13814		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	84524		Some MAH users: when select to download Volume of Sales there is an error "server encountered an error" and user is not able to download existing VoS that had been loaded prior to release or new submission made in this release. Some MAH users and NCA users are able to successfully download VoS
UC27 View Volume of Sales	MAH UI	UPD-13321		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		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"

Use Case	Affects user	Issue reference	Vet EUIG Chapter 2 section	Known Issue Description
UC28 View VNRA	NCA UI & MAH UI	UPD-14043		For a submission with many products & variation codes, there may be a timeout error downloading PDF or when viewing submission
UC28 View VNRA	NCA UI	UPD-13717		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		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		NCA Germany only for DCP/MRP/SRP where National Data has been populated with Responsible Authority of either PEI or BVL. Where VNRA Submission made for product: Both PEI and BVL can view and approve the submission and they should only be able to view those submissions where they are the Responsible authority. Only where National Data has not been populated and Responsible Authority is the default value of EMA both PEI and BVL should be able to view a VNRA submission.
UC28 View VNRA	NCA UI & MAH UI	UPD-13673		New search criteria of date displays the date in the wrong format. Displays as mm-dd-yyyy instead of dd-mm-yyyy. The value specified is correctly applied when searching and the search results do match the selected date(s)
UC28 View VNRA	NCA UI & MAH UI	UPD-13814		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

Use Case	Affects user	Issue reference	Vet EUIG Chapter 2 section	Known Issue Description
UC28 View VNRA	NCA UI & MAH UI	UPD-11574		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		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		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-13850		VNRA PDF file - information on variation codes count differs from UI and is not correct if the same variation code has been included more than once
UC28 View VNRA	NCA UI & MAH UI	UPD-13854		When view an old VNRA submission that contains more than one variation code, only one variation code as header is displayed and counted. This means that NCA is not able to partially approve/reject combinations for product/variation code. The correct variation code and product details are listed in each product card
UC28 View VNRA	NCA UI & MAH UI	UPD-13805		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 is displayed and not the page the user had been viewing. If any search criteria had been entered these are retained and the search results displayed are based on that criteria
UC34 Bulk Upload for Documents	NCA UI	UPD-13677		Bulk Upload is not accepting file for document type pllab
UC34 Bulk Upload for Documents	NCA UI	UPD-12937		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		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	Vet EUIG Chapter 2 section	Known Issue Description
UC34 Bulk Upload for Documents	NCA UI	UPD-13298		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-10699		For CAP products - EPAR document type is not available and it should be possible to add multiple EPAR documents for a CAP product
UC34 Bulk Upload for Documents	NCA UI	UPD-11376		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	UPD-13906		Loading of Public Assessment Report documents for CAP products sometimes results in duplicate documents added in UPD
UC34 Bulk Upload for Documents	NCA UI	UPD-12182		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	UPD-13641		Validation is 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
UC34 Bulk Upload for Documents	NCA UI	UPD-13855		When submit a new file that should update an existing document: user advised submission of documents was successful but the documents have not been updated and there is no Notification of failure (issue only occurs in Production)

Annex 3: Release Schedule

	Environment	From	To	Description
3	UAT (TBC)	31/03/23	31/03/23	Upgrade of UPD to 1.6.22
4	PROD (TBC)	13/04/23	17/04/23	Upgrade of UPD to 1.6.22
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