



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

UPD Release Notes 1.6.16

Veterinary Medicinal Products Regulation: Union Product Database

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Version 2

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

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Changes made in revised version of release notes:

The following bugs have been resolved in the hotfix release deployed into production on Tuesday 21/02/23:

- UPD-12854 VNRA submission for variation code C.6 failed for products without existing PSMF information
 - VNRA for variation code C6 for legacy product that does not have PSMF may now be submitted. Both the PSM File Code and PSM File Location must be provided for this legacy product
 - A variation code C5 may not be submitted for a legacy product that does not have PSMF as when populating PSMF for the first time both the PSM File Code and PSM File Location must be populated. This is not possible with variation code C5.
 - Once a product has PSMF data, a subsequent VNRA for variation code C6 with PSM File Code and/or PSM File location may be submitted; or a VNRA for variation code C5.
 - Submission of variation code C6 for a product may still fail with a validation error and this will be due to some data quality issue within that product. The MAH should advise the appropriate NCA of the issue preventing submission.
- UPD-12277 VNRA submission failed where DCP/MRP/SRP procedure was included and Liechtenstein is a CMS
 - This issue had been reported in the initial release of 1.6.16, but subsequently identified there was still an issue preventing these VNRA submissions. The issue has now been resolved
- UPD-12261 Create SRP where Marketing Authorisation Number at Package Level
 - Create SRP where one or more existing RMS or a CMS has specified Marketing Authorisation number at Package level: after the Create SRP the Marketing Authorisation number at package level was deleted from the existing products
 - This issue has been resolved and Marketing Authorisation numbers are now retained in existing products

1. Overview of functionality and business value

This release is the next iterative version of the Union Product Database, v 1.6.16. The main difference with the previous version, v 1.6.13 released on 5 December 2022, is new functionality as per section 2.1 and resolution of defects as per section 2.2.

This version allows NCAs to submit/enter legacy product information, as per Article 155 of Regulation (EU) 2019/6, compliant with Chapter 4 of the July 2021 version of the [Vet EU Implementation Guide](#) (Vet EU IG); and compliant with Chapter 2 of the May 2022 version of the Vet EU IG.

Marketing Authorisation Holders (MAH) are able to view their products, submit Variations not requiring assessment, download and submit Volume of Sales, and update Marketing Authorisation Status.

This version of the UPD allows the creation of products approved under MRP procedure via the Create MRP functionality. The Reference Member State (RMS) uses their Nationally authorised product (NAP) as the basis for this creation, and adds or updates Common data. For example: add Common Product

Name, RMS and Concerned Member State(s) (CMS(s)). A new product will be created for CMS with procedure type MRP and the RMS's NAP is updated to procedure type MRP.

The approach for the load of Legacy products under DCP/MRP procedure via the Decentralised procedure may still be used. At the time of creation, the RMS will provide the RMS value 'Decentralised Procedure' for the field 'Procedure type'. According to the [Vet EU IG](#) subsequent updates will be made by the CMS as a part of the update of national data, and the procedure type for the CMS product may be updated to MRP if applicable.

In relation to the load of legacy data, for some of the products approved under DCP/MRP, it could be the case that only one RMS, and no CMS(s), is involved in the process. Given that the current implementation of the UPD does not support this scenario, the workaround for recording these products will be as follows: I/the RMS will create the DCP adding as CMS a country belonging to EEA (this country should preferably have very few CMSs and no RMS products); II/ to prevent this product from being available to the general public and to the MAH, the CMS will not update the national part of the product, and finally III/ the CMS product will be nullified by the CMS once UPD allows having these products with only one RMS.

Technical grouping:

Please note that the Technical grouping functionality for VNRA's has been recently delivered to the production environment. This functionality involves a certain complexity, but the learning curve will be less steep if we can rely on the collaboration between all of us, competent authorities (CAs) and marketing authorisation holders (MAHs). With this in mind, **we strongly recommend MAHs to only combine MRP/DCP and national VNRA's 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.

The high-level functionality provided in this release is:

- 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 product with national DCP/MRP/SRP data and documents
 - RMS can update Common data for DCP/MRP/SRP product (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 product with national DCP/MRP data (including documents)
- RMS can update Common data for DCP/MRP/SRP product (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 product (data and documents)
- Notifications for Create and Update of products and OPAD actions
- View Volume of Sales information
- View and Approve/Reject VNRA submissions
- MAH UI:
 - Search/view/export product (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 (excluding CAP products)
 - Download and Submit updates-for Availability status (excluding CAP products)
- 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 required information to register for usage of the UI or API, connect to the API or UI and to use the available functionality.

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

1.1. Functionality not included in this release

The following functionality is not included in this release. Menu items and endpoints should not be used as these are not yet fully implemented.

API:

- none

NCA UI:

- Update CAP products (by EMA or EC staff)
- Transfer Marketing Authorisation for CAP products (by EMA or EC staff)
- Transfer Marketing Authorisation for non-CAP products: Due to UPD-12726 this functionality cannot be used in this release

MAH UI:

- Submit updates for Marketing authorisation status for CAP products
- Submit updates for Availability status for CAP products

2. Changes made compared with 1.6.13

2.1. New functionality

NCA UI Create and Update Screens and Document section:

- Able to View and existing document
- Layout and buttons to manage documents now aligned to Transfer of ownership screen

API users:

- Examples in section 5.5.10 How to use Update National Data DCP/MRP/SRP product endpoint and example payload
 - The example filenames and details of the changes made in the Update payload have been corrected
 - The files and details in Release notes 1.6.12 were incorrect
 - There is **no change to the payload** to be provided in this release
 - A new zip file has been provided with this correction and this is the only change to files in the zip file

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 Vet EUIG Chapter 2 section; and then by Use Case number for those items without a specific IG reference.

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue that has been resolved
Resolved in Version 2 21/02/23:				
UC06 Submit VNRA	MAH UI	UPD-12854		VNRA submission for variation code C.6 failed for products without existing PSMF information
UC06 Submit VNRA	MAH UI	UPD-12277		VNRA submission failed where product with Liechtenstein as CMS was included
UC01 Create product	API & NCA UI	UPD-12261	5.5 Marketing authorisation number	Create SRP where one or more existing RMS or a CMS has specified Marketing Authorisation number at Package level: after the Create SRP the Marketing Authorisation number at package level was deleted from the existing products
Resolved in Version 1 30/01/23:				
UC08 Update product	API & NCA UI	UPD-13050		Update National Data DCP/MRP/SRP - Operation Outcome remained IN_PROGRESS for over 24hours and never completes (Issue seen in PROD only since 19/12/22 for some users). This issue was resolved in the 1.6.13-8 release on Wednesday 18 January 2023.

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue that has been resolved
UC01 Create product	NCA UI	UPD-12284	1.11 Attached Document	Create DCP and Create MRP, the RMS was able to successfully attach National documents during the DCP/MRP product creation and they were saved on the RMS and CMS products. Any national documents should be ignored or Create rejected
UC08 Update product	NCA UI	UPD-12141	1.11 Attached Document	Update National Data DCP/MRP/SRP: User was able to delete a Common Data document from their product (common document is not removed from other products under that Product Identifier). The delete button is now disabled for common documents.
UC01 Create product	NCA UI	UPD-10714	1.13 Manufacturing Business Operation	Create Homeopathic - Manufacturing business operation - the "Add" button was always enabled even if no Manufacturer and Activity had been entered
UC03 Search product	MAH UI	UPD-9253	2.8 Product Owner (organisation)	MAH was not able to search and view product where they are the Product Owner if the OMS Location selected by the NCA is the non-surviving location as a result of a merge in OMS
All UC	NCA UI & MAH UI	UPD-12055		Retrieve Product dialog: enter search criteria and Submit. Sometimes the dialog hung and remained showing the progress control. No error message was returned to the user. The only workaround was to refresh the screen which refreshed the screen where were attempting to retrieve a product. Therefore any data that had been input in that calling screen was lost. For example issue has been observed for MAH Submit VNRA; and for NCA in Create MRP when retrieving the NAP product. This was an intermittent issue.

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue that has been resolved
UC01 Create product UC03 Search product UC05 View product UC08 Update product	NCA UI	UPD-11879		The preferred name is now displayed for a Substance
UC01 Create product UC08 Update product	API & NCA UI	UPD-10716		All procedure types: ATC Vet code fields are conditional. Either an ATC Vet code or ATC Vet code pending flag should be populated when create or update a product. There should be a validation error if neither is populated. No longer able to create/update without providing either value.
UC01 Create product UC08 Update product	NCA UI	UPD-9857		Parallel Trade product: the Authorised pharmaceutical form had been implemented as single drop-down list and not two like Create/Update screens for other procedures. This has now been split into two drop-down lists so that all create/update screens are the same.
UC01 Create product UC08 Update product	API	UPD-10145		Create or Update Registered Homeopathic product via API - POST was rejected with validation error if any attributes that are not applicable for this procedure type are populated. Instead the post should be accepted without validation error and all of the not applicable attributes should be silently ignored and data values not output into the product. This issue has been resolved.
UC01 Create product	API & NCA UI	UPD-12890		Create SRP: If RMS product had a National document a product was not created for the new CMS. An update was made to existing RMS/CMS to add new CMS to list of CMS, thus leaving existing products with CMS listed but no actual product. This issue has been resolved. The existing datafix to resolve DCP/MRP/SRP where RMS/CMS products are not in sync with the list of CMS in the RMS product will also resolve any procedures that had been affected by this issue.

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue that has been resolved
UC05 View product	NCA UI	UPD-11474		When viewing product with procedure type SRP, sometime the "Edit National data" button was not displayed
UC06 Submit VNRA	MAH UI	UPD-12246		<p>If MAH is affiliated with many Organisations, when they Submit a VNRA the Notifications for MAH were generated based on affiliations that the logged on MAH has and should have been based on Products in the Submission. This means MAH user only affiliated to some of the organisations may have seen a Notification but they will not be able to view the Submission and will not be able to view any products where they are not the MAH for all products in that submission.</p> <p>This issue has been resolved.</p> <p>Please note that the resolution only applies for new VNRA Submissions and existing notifications that were incorrectly generated remain.</p>
UC06 Submit VNRA	MAH UI	UPD-12277		VNRA submission failed where product with Liechtenstein as CMS was included
UC07 Submit Volume of Sales	MAH UI	UPD-7992		Volume of Sales: Error was incorrectly triggered by the system in the error file after the submission of VoS
UC07 Submit Volume of Sales	MAH UI	UPD-11489		<p>Download list of packages - example from Create DCP where one of the new products is not included in the csv file. The MAH is able to search and view all products under that Product Identifier. This does not happen in all cases and believe is when the create DCP transaction did not complete successfully.</p> <p>This issue has been resolved and all products MAH is able to view in UPD are included in downloaded file.</p>
UC07 Submit Volume of Sales	MAH UI	UPD-11603		UC07 Submission of Volume of Sales – Was not possible to submit for Non-EEA country

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue that has been resolved
UC08 Update product	NCA UI	UPD-12096		Bulk Transfer of Ownership screen: were not able to update existing document. Now able to update existing documents.
UC08 Update product	NCA UI	UPD-11559		On View product screen, the edit product buttons were not correctly enabled or disabled. An NCA was able to edit a product that they shouldn't have been able to; and in some cases may not have had edit button enabled when it should be
UC08 Update product	NCA UI	UPD-10894		Registered Homeopathic product couldn't be updated as there were a number of unexpected validation errors (regression issue). This issue has been resolved and now able to update product.
UC08 Update product	API & NCA UI	UPD-6961		UC08 - Update DCP SC2 National data UPD-UC08-AC041 – Were able to delete Manufactured item from package and submit update without a validation error
UC08 Update product	NCA UI	UPD-12260		When updating product and managing document: the Size of existing documents was not displayed; and when add new document the Country and Language was not displayed in documents grid. However, the update of the product and documents was successful. This was a display issue in the edit screen and has been resolved.
UC08 Update product	NCA UI	UPD-12408		When updating a product, NCA was now able to View a product document from the edit screen. This issue has been resolved.

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue that has been resolved
UC09 Approve/Reject VNRA	NCA UI	UPD-12464		Products under DCP/MRP/SRP should be grouped by Product Identifier. In previous release they were not listed by sub-group within the Variation code and instead each product was listed under its own Product Identifier heading. This meant that selecting Approve or Reject check-box for one product under a Product Identifier was not selecting the same checkbox for all of the other products under that Product Identifier
UC09 Approve/Reject VNRA	NCA UI	UPD-12231		Submission and variation level checkboxes were not enabled as expected when submission contains products for many NCA
UC19 Nullify product	API & NCA UI	UPD-12048		A product with a Data Quality issue was not able to be nullified
UC19 Nullify product	API	UPD-10115		Nullify Parallel Trade product via API was giving an error with response code of 500 Internal server error
UC21 Manage Notifications	NCA UI & MAH UI	UPD-11200		When approving VNRA for product under DCP/MRP/SRP, duplicate notification records were generated for some CMS products
UC21 Manage Notifications	NCA UI & MAH UI	UPD-12091		When select to view notifications from the Menu, the search results and total count showed only those notifications for the past month. If user searched again the total count then displayed the correct total of all notifications. When user selects from the menu the total is now for all notifications.
UC25 Update Availability status	MAH UI	UPD-11251		Download of product data file for Availability status: sometimes received error message "ERROR Resource(s) not found for User Id: Y and Organisation Id: X". This issue has been resolved

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue that has been resolved
UC28 View VNRA	NCA UI & MAH UI	UPD-12464		Products under DCP/MRP/SRP should be grouped by Product Identifier. In previous release they were not listed by sub-group within the Variation code and instead each product was listed under its own Product Identifier heading
UC28 View VNRA	NCA UI & MAH UI	UPD-11633		UPD-BR-066 VNRA Submission PDF: date format was yyyy-mm-dd and is now dd-mm-yyyy
UC28 View VNRA	NCA UI & MAH UI	UPD-11890		VNRA submission for CAP products is present in Notifications but is not listed as pending submission on View VNRA Submissions screen. This issue has been resolved.
UC28 View VNRA	NCA UI & MAH UI	UPD-11936		When selecting to view a VNRA Submission, on the view submission screen it displayed "System error: Try again in few seconds". This usually only occurred for the first submission you selected after logging on. The workaround was to refresh the screen using the F5 function button. The selected VNRA submission was then displayed.
UC28 View VNRA	NCA UI & MAH UI	UPD-12539		UC28 - VNRA PDF file showed Null field on C.5 automated code
UC34 Bulk Upload for Documents	NCA UI	UPD-12223		Advised submission of files was successful but there was no Notification and document was not added to product
UC34 Bulk Upload for Documents	NCA UI	UPD-11885		Bulk upload: sometimes the file was not uploaded to product(s). Potentially this issue was when filename contains characters other than lower case characters a-z, digits 0-9 or a hyphen. This is the guidance in Vet EU IG Chapter 2 Annex 2 and there is now validation to enforce this.
UC34 Bulk Upload for Documents	NCA UI	UPD-12226		Not all documents added in one submit were loaded to the product

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue that has been resolved
UC34 Bulk Upload for Documents	NCA UI	UPD-12218		Trying to update an existing document sometimes resulted in an addition of a duplicate document for combination of country/document type/language

2.3. New known issues for functionality in previous release

This table is ordered by Vet EUIG Chapter 2 section; and then by Use Case number for those items without a specific IG reference. 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	Issue description
UC08 Update product	API	UPD-12747	1.9 (Pharmacovigilance System) Master File	API user only: Update National Data DCP/MRP/SRP where product has been loaded using Chapter 4/Legacy rules without PSMF: if the Update National Data payload has incorrectly included PSMF information the update remains IN_PROGRESS. Since PSMF is Common Data, if PSMF is added as part of National Data update the values should be silently ignored and the update should complete successfully
UC08 Update product	NCA UI	UPD-12734	5.6.4 Ingredient (in Manufactured item)	If a product has more than one Ingredient referenced within a Manufactured Item, when product is edited there are no Ingredients listed in the summary table for that Manufactured item. If that Manufactured Item is edited only one of the Ingredients is listed.
UC01 Create product	API	UPD-12923		API user only - Create DCP with XML payload - if there is a comment before an extension attribute there will be a validation error "Unknown element 'fhir_comments' found during parse" (Regression)
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

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue description
UC01 Create product	NCA UI	UPD-13291		Create SRP: if update an existing Common document with a new file, the new version is updated on the existing RMS & CMS products; but the new CMS product has the old version of that document. As a work-around: do not update any existing Common Documents as part of a Create SRP; and instead update using an Update Common Data.
UC01 Create product	NCA UI	UPD-13162		Create Parallel Trade product: the list of Ingredients is incorrect when the Product retrieved as Source Member State has more than one Ingredient. The Substance code from one of the Ingredients is being output for all of the Ingredients in the new Parallel Trade product.
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
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 UC08 Update product	API & NCA UI	UPD-12932		UPD is missing terms from SPOR (RMS) - Units of measurement list
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

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue description
UC01 Create product UC08 Update product	NCA UI	UPD-12914		When creating or updating a product and receive some validation error, the package description and language have disappeared and after correcting the first error will then receive a validation error that there is no package description. The only workaround is to either Edit each package and re-add a package description; or to refresh the screen and reapply the updates taking into account the first validation error that had been received. For updates this issue affects Update NAP and Update Common Data DCP/MRP/SRP; but is not an issue for Update National Data DCP/MRP/SRP.
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	NCA UI & MAH UI	UPD-13149		For DCP/MRP/SRP products, the product card on the search results page doesn't contain "Reference Member State" and "Concerned Member State" fields. This information is available on the View product screen
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
UC06 Submit VNRA		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
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
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

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue description
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	NCA UI	UPD-12911		Impacts only EMA staff on Update CAP - incorrectly get Validation error as wrong list ID has been used for Country for Product Name
UC08 Update product		UPD-12907		Update Common Data DCP/MRP/SRP - fails with DQ-Error-001 displayed incorrectly or a timeout and Update Common Data is blocked. This does not occur for all products and believe is only those where there are many CMS, or where there have been many previous updates that has resulted in more than 50 Notifications for the Product Identifier
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-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 contains the notes and they cannot be removed
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 & API	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.
UC08 Update product		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 has been corrupted. The Ingredient that had been removed still exists in the product but does not contain reference to the Pharmaceutical product.

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue description
UC09 Approve/Reject VNRA	NCA UI	UPD-12930		If approving an automated variation code for product that has been loaded using Chapter 4/Legacy rules there is a validation error displayed and the VNRA can't be approved. This is because Chapter 2 validation rules are being applied instead of Chapter 4 validation rules.
UC21 Manage Notifications	NCA UI & MAH UI	UPD-13049		Date format inconsistent between different actions
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-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"
UC21 Manage Notifications	NCA UI & MAH UI	UPD-13137		When submission of Bulk Upload has failed: the Notification card does not match the definition documented in "UPD - Notifications in processes"
UC24 Marketing authorisation status	MAH UI	UPD-12888		Sorting of the product search results table by any column does not work
UC25 Update Availability status	MAH UI	UPD-12934		Availability Status Date format of YYYY-MM is not accepted though Chapter 7 states it should
UC27 View Volume of Sales	MAH UI	UPD-13292		UC27 View Volume of Sales (MAH users only) MAH products with submitted values for Volume of Sales are not being displayed as expected and need to paginate through search results to see list of all products that have had sales data loaded
UC27 View Volume of Sales	NCA UI & MAH UI	UPD-13294		UC27 View Volume of Sales - changing search results from default of 20 products per page doesn't always change number of products in Search results table; and may also affect navigation through search result page
UC28 View VNRA	NCA UI & MAH UI	UPD-12885		MAH has submitted VNRA for variation code "A4 Change in ATCVet code" for two or more products, where the products do not have the same existing ATC Vet Codes. When NCA or MAH view the VNRA submission the field "A4-ATC-VetCodeCurrent" for each product does not display the correct data. The existing values from one of the products is being displayed for all products.

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue description
UC28 View VNRA	NCA UI	UPD-12942		NCA BVL in Germany only affected: Some VNRA submitted prior to HF 1.6.13-8 release - BVL still don't see all expected submissions
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.
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)."

2.4. Known issues for new functionality in this release

This table is ordered by Vet EUIG Chapter 2 section; and then by Use Case number for those items without a specific IG reference.

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue description
n/a				

3. Veterinary EU Implementation Guide versions for this Release

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

- Chapter 2 May 2022
- Chapter 4 July 2021
- Chapter 6 (Examples for the submission of Legacy data) December 2021
- Chapter 7 (Submission of OPAD data) May 2022
- All other chapters based on 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 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

Other menu items or options should not be used as these are not in scope for this release and are not fully implemented.

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 \(upd-portal-uat.azurewebsites.net\)](https://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 \(upd-portal-prod.azurewebsites.net\)](https://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

SPOR API Specification v2	API Manager
EP307 Get Product Versions	GET MedicinalProductDefinition - Get history of MedicinalProductDefinition ID
EP309 Create Product	<p>NAP: POST Bundle - Create/Update resources in the bundle</p> <p>DCP: POST dcp-bundle - Submit a Create DCP payload</p> <p>MRP: POST mrp_bundle - Submit a Create MRP payload</p> <p>SRP: POST srp_bundle - Submit a Create SRP payload</p> <p>Refer to 5.5.2. Create and Update endpoints</p>
EP309 Create Product EP311 Update Product for use with any Create or Update	<p>GET OperationOutcome - Get a resource by ID</p> <p>Note: use this to query the outcome of Create or Update when response to Post is "202 Accepted"</p>
EP311 Update Product	<p>NAP: POST Bundle - Create/Update resources in the bundle</p> <p>Update National Data: POST /upd/api/v1/national-data-bundle/ - Submit an Update National Data payload for DCP/MRP/SRP products</p> <p>Update Common Data: POST /upd/api/v1/common-data-bundle/ - Submit an Update Common Data payload for DCP/MRP/SRP products</p>
EP318 Validate Product	<p>POST Validate Bundle - To validate a bundle and the resources in the bundle</p> <p>Used for all procedure types; for both chapter 2 or legacy validation rules; and for both Create & Update</p>
EP UC19 Nullify Product	POST /upd/api/v1/vmp-nullification/
EP401 Search document	<p>GET DocumentReference - Search for DocumentReference</p> <p>No</p>
EP402 Get/Retrieve document by Id	<p>GET DocumentReference - Get a DocumentReference by Id</p> <p>Note</p>
EP403 Create document	POST DocumentReference - Create a DocumentReference
EP404 Update document by Id	<p>PUT DocumentReference - Update a DocumentReference</p> <p>Please note: API Manager method shows as PUT however please use POST with request header is_update=true.</p>

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
<i>Request header not included</i>	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	Use is_update = true when

Type and Procedure	POST Endpoint	Request header Key for validation rules	Additional Request header
		validation rules based on the procedure type	validating the following bundles: <ul style="list-style-type: none"> • Update NP • 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/	For NP, DCP, MRP, SRP products: chapter4=true	

Content-Type	Request body
JSON	<pre>{ "permanentId": "Permanent Identifier" }</pre> <hr/> <p>For example:</p> <pre>{ "permanentId": "600011984989" }</pre>

Content-Type	Request body
XML	Not supported in this release

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."

In this release the following issues are outstanding UPD-9773:

- Validation that is relevant when updating a product is being applied using the default value of Chapter 2 rules. Therefore, for legacy products that don't comply with Chapter 2 rules there will be validation errors. If nullification is always submitted with Request header of chapter4=true to apply Legacy validation rules this will workaround this issue
- there is no Content Location with OperationOutcome ID. In a future release this will be changed so that this is provided when POST response is 202 Accepted, and GET OperationOutcome can be used to review the status of the transaction to confirm the update has been successful
- some of the validation errors are not in the format specified in the request Accept header and instead are listed as plain text
- POST in XML format is not supported

5.5.4. Response to POST for Create or Update and use of Get OperationOutcome

When POST for Create or Update 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 or update 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 it is the second part with operation-outcome-id that is used for Get OperationOutcome.

POST	Content Location example showing post-operation and format of the operation-outcome-id
Create NP	OperationOutcome/baab996e-8e58-4825-89d1-90a8f30458db
Update NP	OperationOutcome/c2e2275c-141c-4631-a42e-045726d95adb
Create DCP	dcp-operation-outcome/ddb9f96b-10f5-4428-9503-170feb5c58db-DCP
Update Common Data DCP/MRP/SRP	common-data-operation-outcome/f4d76850-358a-48f1-a9bb-3fb4b1615bdb-CD
Update National Data DCP/MRP/SRP	national-data-operation-outcome/b371f2db-dd29-4c60-b6ab-63b0abf95bdb-ND
Create MRP	mrp-operation-outcome/2f89089c-3ad7-4427-9311-7ea491395ddb-MRP
Create SRP	srp-operation-outcome/cf7af9a9-b34d-4db9-a551-89d40c077306-SRP
Create & Update Registered Homeopathic	OperationOutcome/a588416b-7a0b-40b1-8d03-a88ea4668f8f
Create & Update Parallel Trade	OperationOutcome/04b5bc00-16f4-4ea0-b33e-1a95029d8f8f-PTP

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

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

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

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

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

Attribute	Change
none	

5.5.7. API EP309 Create product example request bundles

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

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

Procedure type	Validation rules	Example file
DCP	Chapter 2	UPD_1.6.5-6_DCP_Chpt2_C2_Mandatory_VetIG.JSON UPD_1.6.5-6_DCP_Chpt2_C2_Mandatory_VetIG.XML 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	<p>2.2 Authorisation/registration/entitlement number is specified at Product level</p> <p>UPD_1.6.1-4_NAP_Chpt2_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel.JSON</p> <p>UPD_1.6.1-4_NAP_Chpt2_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel.XML</p> <p>UPD_1.5.1-0_NAP_Chpt2_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel.JSON</p> <p>UPD_1.5.1-0_NAP_Chpt2_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel.XML</p> <hr/> <p>5.5 Marketing authorisation (package level)</p> <p>UPD_1.5.1-0_NAP_Chpt2_C111_VetEUIG_AllData_MANumber_AtPackageLevel.JSON</p> <p>This example contains 2 packages.</p> <p>There are 3 RegulatedAuthorization resources:</p> <ul style="list-style-type: none"> One with subject reference = MedicinalProductDefinition resource; populated with attributes from Section 2 (Vet EUIG Chapter 2), excluding the marketing authorisation number One with subject reference = 1st PackagedProductDefinition resource; populated with the Marketing authorisation number for Package 1

Procedure type	Validation rules	Example file
		<ul style="list-style-type: none"> One with subject reference = 2nd PackagedProductDefinition resource; populate with the Marketing authorisation number for Package 2
NAP	Chapter 4 Legacy	<p>UPD_1.6.1-4_NAP_Legacy_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel.JSON</p> <p>UPD_1.6.1-4_NAP_Legacy_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel.XML</p> <p>UPD_1.5.1-0_NAP_Legacy_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel.JSON</p> <p>UPD_1.5.1-0_NAP_Legacy_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel.XML</p>
NAP	Chapter 4 Legacy	<p>UPD_1.5.1-0_NAP_Legacy_Cx_ManyAttributesAndResources_MANumberAtMedicinalProductLevel.XML</p> <p>This example contains:</p> <ul style="list-style-type: none"> 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	<p>UPD_1.5.1-0_NAP_Chpt2_ExampleForStrengthAsPresentationOrConcentration.XML</p> <p>This example contains Ingredient resources that illustrate how to specify Substance and Reference Strength as either Presentation or Concentration.</p>
Registered Homeopathic	Chapter 2	<p>UPD_1.6.1-4_HOM_Chpt2_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel.JSON</p> <p>UPD_1.6.1-4_HOM_Chpt2_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel.JSON</p>
Parallel Trade	Chapter 2	UPD_1.6.8-4_PAT_Chpt2_C2_Mandatory_VetIG.JSON

Procedure type	Validation rules	Example file
		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	<p>Bundle.entry.request must also be populated.</p> <p>Bundle.entry.request.method should be:</p> <ul style="list-style-type: none"> • PUT to update an existing resource • POST to add a new resource <p>Bundle.entry.request.url should be:</p> <ul style="list-style-type: none"> • 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>

```

```

      </MedicinalProductDefinition>
    </resource>
    <request>
      <method value="PUT" />
      <url value="MedicinalProductDefinition/600000022531" />
    </request>
  </entry>
  <entry>
    <fullUrl value="PackagedProductDefinition/170427" />
    <resource>
      <PackagedProductDefinition>

```

```

      </PackagedProductDefinition>
    </resource>
    <request>
      <method value="PUT" />
      <url value="PackagedProductDefinition/170427" />
    </request>
  </entry>
</Bundle>

```

- 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. <ul style="list-style-type: none"> - 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 <ul style="list-style-type: none"> • "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.	Create DCP using this example file: UPD_1.6.16-5_CreateDCPForUpdateNationalData.XML Product Identifier: d0f4414c-cd65-478b-921e-f107c66f7a85
------------------------	--	--

	<ul style="list-style-type: none"> - Product name - Legal status of supply (product level) - Package description - Marketing authorisation number (product level) - Marketing authorisation status & dates - Responsible authority 	<p>CMS for Italy Permanent identifier: 600000251886</p> <p>Sample XML of Get Everything response used as a starting point: UPD_1.6.16_DCP_UpdateNationalData_600000251886_GetEverything_v1.XML</p> <p>Update bundle prepared: UPD_1.6.16_DCP_UpdateNationalData_600000251886_BasedOn_v1.XML</p>
Update product via API	<p>POST Bundle with request headers to /upd/api/v1/national-data-bundle/</p> <ul style="list-style-type: none"> • "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	<p>Sample XML of GET everything after update:</p> <p>UPD_1.6.16_DCP_UpdateNationalData_600000251886_GetEverything_v2.XML</p>

5.5.11. How to use Update Common Data DCP/MRP/SRP product endpoint and example bundle

EP304 Get Product Full	<p>Prepare update bundle based on the response by updating Bundle.type to transaction and adding Bundle.entry.request.method for each resource.</p> <p>Edit the payload e.g.</p> <ul style="list-style-type: none"> - modify common product name - add another ATC Vet code <p>Important: any national data that has been populated should be also included in the update bundle.</p>	<p>Sample XML of Get Everything response used as a starting point:</p> <p>UPD_1.5.3-4_DCP_UpdateCommonData_Product_600000149642_GetEverything_Version1.XML</p> <p>Update bundle prepared:</p> <p>UPD_1.5.3-4_DCP_UpdateCommonData_Product_600000149642_UpdateBundleBasedOnVersion1.XML</p>
Update product via API	<p>POST Bundle with request headers to /upd/api/v1/common-data-bundle/</p> <ul style="list-style-type: none"> • "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	<ul style="list-style-type: none"> • 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/ <ul style="list-style-type: none"> • "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: <ul style="list-style-type: none"> • Contains the Common data that was added CMS: <ul style="list-style-type: none"> • 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_RMSPProduct_GetEverything_version1.XML
Prepare Create SRP Bundle	<ul style="list-style-type: none">• Add new Concerned member state(s)• Update common data as required	Create SRP bundle prepared: UPD_1.6.1-4_CreateSRP_BasedOnRMSPProduct_version1.XML
Create SRP via API	POST Bundle with request headers to /upd/api/v1/srp-bundle/ <ul style="list-style-type: none">• "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: <ul style="list-style-type: none">• Contains the new CMS• Procedure type remains unchanged• Contains the Common data that was updated New CMS: <ul style="list-style-type: none">• 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.attachement,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 (excluding CAP products)
- UC25 Download and Submit updates-for Availability status (excluding CAP products)
- Other menu items should not be used as these are not in scope for this release and are not fully implemented.

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 \(upd-portal.azurewebsites.net\)](https://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 **Search** bar can be used to filter results on organisations, users or roles.

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

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

<input type="checkbox"/>	Name	Display Name	Email	Role	Organisation	Application
<input type="checkbox"/>	account_c	Carlo Account	carlo.account@company.email.com	IRIS Industry User Admin (ORG-100119598 - Test Medicines Company)	ORG-100119598	IRIS
<input type="checkbox"/>	account_c	Carlo Account	carlo.account@company.email.com	SPOR Unaffiliated User		
<input type="checkbox"/>	account_c	Carlo Account	carlo.account@company.email.com	IRIS Industry Manager (ORG-100032441 - Achilles - testcompany)	ORG-100032441	IRIS
<input type="checkbox"/>	account_c	Carlo Account	carlo.account@company.email.com	Azure Birthrights External		
<input type="checkbox"/>	account_c	Carlo Account	carlo.account@company.email.com	IRIS Industry Contributor (ORG-100119598 - Test Medicines Company)	ORG-100119598	IRIS
<input type="checkbox"/>	account_c	Carlo Account	carlo.account@company.email.com	IRIS Individual User		
<input type="checkbox"/>	account_c	Carlo Account	carlo.account@company.email.com	IRIS Industry User Admin (ORG-100032441 - Achilles - testcompany)	ORG-100032441	IRIS
<input type="checkbox"/>	account_c	Carlo Account	carlo.account@company.email.com	IRIS Industry User Admin (ORG-100119572 - Sab_Test2IAM)	ORG-100119572	IRIS
<input type="checkbox"/>	account_j	John Account	emauser2022@gmail.com	IRIS Industry Manager (ORG-100119598 - Test Medicines Company)	ORG-100119598	IRIS
<input type="checkbox"/>	demo_c	Carlo DEMO	carlo.demo@randomcompany.com	IRIS Industry Contributor (ORG-100119572 - Sab_Test2IAM)	ORG-100119572	IRIS

Showing 1 to 10 of 12 results

Previous 1 2 Next

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:

01 Search Criteria

02 Search Organisations

03 Select Roles

04 Additional Info

05 Request Submitted

Search Criteria

Provide the search criteria to look for the desired organisations:

- Select one or more country by typing in the Country field, selected countries will appear under the field
- Provide one of the other search criteria like the organisation name
- By default searches are performed in English (EN)

Need more help? Have a look at the [step by step documentation](#).

Country Required

Select Value +

Other Criteria

Organisation ID

Organisation Name

Location ID

City

Postal code

Address

Language Required

EN

Reset Next

3. Select “UPD” to find the roles:

✓ Select Organisations

03 Select Roles

04 Additional Info

05 Submit Request

Roles

14 results

Search

UPD |

?

Name	Description	Language Required?

4. Choose the UPD CA Super User role:

☐ **UPD CA Super User**

You should request this role if you work for an organisation acting as a regulatory authority (i.e. EC, NCA) and intend to manage (approve/reject/revoke) access to UPD for colleagues of your organisation. The first CA Super User role will be approved by EMA. This role will give you full access (Edit/Search/View) to UPD.

No

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)

About

You have selected one or more user administrators roles. The first user administrator of an organisation is validated by the EMA based on provided documentation, please compile and attach the related affiliation template, more information about user administrator roles can be found [here](#).The affiliation template should be signed by a different person from the one submitting the request.

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:

The screenshot shows the '01 Search Criteria' step of a five-step process. The left sidebar contains instructions: 'Provide the search criteria to look for the desired organisations:', 'Select one or more country by typing in the Country field, selected countries will appear under the field', 'Provide one of the other search criteria like the organisation name', and 'By default searches are performed in English (EN)'. It also includes a link to 'step by step documentation'. The main form area has a 'Country' field with a dropdown menu showing 'Select Value' and a '+' icon, marked as 'Required'. Below this is a section for 'Other Criteria' with fields for 'Organisation ID', 'Organisation Name', 'Location ID', 'City', 'Postal code', 'Address', and 'Language' (with 'EN' selected and marked as 'Required'). 'Reset' and 'Next' buttons are at the bottom right.

3. Select "UPD" to find the roles:

The screenshot shows the '03 Select Roles' step. The left sidebar is titled 'Roles' and shows '14 results'. A search bar contains the text 'UPD |'. Below the search bar is a table with columns 'Name', 'Description', and 'Language Required?'. The '01 Select Organisations' step is marked as completed with a checkmark.

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:

01 Search Criteria 02 Search Organisations 03 Select Roles 04 Additional Info 05 Request Submitted

Search Criteria

Provide the search criteria to look for the desired organisations:

- Select one or more country by typing in the Country field, selected countries will appear under the field
- Provide one of the other search criteria like the organisation name
- By default searches are performed in English (EN)

Need more help? Have a look at the [step by step documentation](#).

Country Required
 +

Other Criteria

Organisation ID

Organisation Name

Location ID

City

Postal code

Address

Language Required

Reset Next

3. Select "UPD" to find the roles:

✓ Select Organisations 03 Select Roles 04 Additional Info 05 Submit Request

Roles

14 results

Search ?

Name	Description	Language Required?
UPD CA Super User	You should request this role if you work for an organisation acting as a regulatory authority (i.e. EC, NCA) and intend to manage (approve/reject/revoke) access to UPD for colleagues of your organisation. The first CA Super User role will be approved by EMA. This role will give you full access (Edit/Search/View) to UPD.	No
UPD Industry Super User	You should request this role if you intend to manage (approve/reject/revoke) access to UPD for colleagues of your organisation. The first Industry Super User will be approved by EMA and you will need to attach a completed and signed copy of the "Affiliation Template Letter", as proof of authority to represent the organisation. This role will give you full access (Edit/Search/View) to UPD.	No

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

<input type="checkbox"/>	UPD CA Super User	You should request this role if you work for an organisation acting as a regulatory authority (i.e. EC, NCA) and intend to manage (approve/reject/revoke) access to UPD for colleagues of your organisation. The first CA Super User role will be approved by EMA. This role will give you full access (Edit/Search/View) to UPD.	No
<input type="checkbox"/>	UPD Industry Super User	You should request this role if you intend to manage (approve/reject/revoke) access to UPD for colleagues of your organisation. The first Industry Super User will be approved by EMA and you will need to attach a completed and signed copy of the "Affiliation Template Letter", as proof of authority to represent the organisation. This role will give you full access (Edit/Search/View) to UPD.	No

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

About

You have selected one or more user administrators roles. The first user administrator of an organisation is validated by the EMA based on provided documentation, please compile and attach the related affiliation template, more information about user administrator roles can be found [here](#). The affiliation template should be signed by a different person from the one submitting the request.

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 Vet EUIG Chapter 2 section; and then by Use Case number for those items without a specific IG reference.

Use Case	Affects user	Issue reference	Vet EUIG Chapter 2 section	Issue Description
UC08 Update product	API	UPD-7273	1.2 Product Record Status	UC08 Update SC2 Update National - API - UPD-UC08-AC016 - Missing Validation error when update Product Status from Current to Provisional & product has been updated
UC08 Update product	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-7148	1.4 Permanent identifier	UC08 Update SC2 NAP - should reject update with validation error message if MedicinalProductDefinition.id is not populated
UC08 Update product	API	UPD-9031	1.6 Legal status of supply 5.4 Legal status of supply	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 : the updated product still has the previous value at Package as well as the new value at Product level
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.
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 be a validation error. Instead the update is accepted and product is updated
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 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

Use Case	Affects user	Issue reference	Vet EUIG Chapter 2 section	Issue Description
UC08 Update product	API	UPD-12747	1.9 (Pharmacovigilance System) Master File	API user only: Update National Data DCP/MRP/SRP where product has been loaded using Chapter 4/Legacy rules without PSMF: if the Update National Data payload has incorrectly included PSMF information the update remains IN_PROGRESS. Since PSMF is Common Data, if PSMF is added as part of National Data update the values should be silently ignored and the update should complete successfully
UC01 Create product	NCA UI	UPD-10750	1.11 Attached Document	Create DCP UPD-UC01-AC202 - Only Common Documents where country is European Union (EU) and language is English should be output to the created products and any other documents should be ignored
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.
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
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
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)
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	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

Use Case	Affects user	Issue reference	Vet EUIG Chapter 2 section	Issue Description
UC08 Update product	API & NCA UI	UPD-6927	2.5 Authorisation status	Update Common Data - when a CMS is removed from the list the Acceptance criteria has been updated and there should no longer be any update of the authorisation status in the removed CMS product
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 getting validation error based on Legacy/Chapter 4 rules. It should be optional for Legacy
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
UC01 Create product	API	UPD-12240	2.12 Concerned member states	Create NAP/MRP/SRP via API - able to create product with old country code 100000000556 (United Kingdom of Great Britain and Northern Ireland) as CMS and this should reject with validation error
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	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	UPD-4734	4.2 Manufacturer	Change of manufacturer in an Ingredient results in no manufacturer being populated in the updated product for that Ingredient
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
UC08 Update product	API	UPD-5384	5.1 Package description	New Package description added to product is output in main package description attribute and not as a translation as expected
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

Use Case	Affects user	Issue reference	Vet EUIG Chapter 2 section	Issue Description
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	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.
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.
UC08 Update product	NCA UI	UPD-12734	5.6.4 Ingredient (in Manufactured item)	If a product has more than one Ingredient referenced within a Manufactured Item, when product is edited there are no Ingredients listed in the summary table for that Manufactured item. If that Manufactured Item is edited only one of the Ingredients is listed.
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-9862		All search result tables/grids - sorting search results should apply the sort across all entries matching the search criteria and not just sort the current page of search results
All UC	NCA UI & MAH UI	UPD-12400		Search and View product screens and others: the Country term code sometimes displays the expected short name and sometimes the full term name (e.g. Spain vs. Kingdom of Spain)
All UC	NCA UI & MAH UI	UPD-12084		There should be consistent display of the Marketing Authorisation Holder information across UPD screens with all address details displayed (street address, city, postcode, country). Some screens only display the organisation name or organisation name and street address
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

Use Case	Affects user	Issue reference	Vet EUIG Chapter 2 section	Issue Description
UC01 Create product	API	UPD-12923		API user only - Create DCP with XML payload - if there is a comment before an extension attribute there will be a validation error "Unknown element 'fhir_comments' found during parse" (Regression)
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	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	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-13291		Create SRP: if update an existing Common document with a new file, the new version is updated on the existing RMS & CMS products; but the new CMS product has the old version of that document. As a work-around: do not update any existing Common Documents as part of a Create SRP; and instead update using an Update Common Data.
UC01 Create product	API & NCA UI	UPD-10475		Create SRP based on selecting one of the existing CMS products should not be possible. The RMS should select their own product as a basis for the Create SRP
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)

Use Case	Affects user	Issue reference	Vet EUIG Chapter 2 section	Issue Description
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	API	UPD-10136		POST Create bundle for DCP where URI starts with https and not http - this should be rejected with a validation error. Instead the post is accepted and product is created
UC01 Create product	API	UPD-10673		Post to the EP318 Validate end point for Create DCP displays an incorrect validation error relating to Marketing Authorisation Number "Marketing Authorisation Number must be provided either on product level or for all packages.". If this is the only validation error, the POST of the create to the EP309 Endpoint will be successful
UC01 Create product	API & NCA UI	UPD-11798		Products are created even though the transaction has failed and Operation Outcome shows there has been a timeout error. No Notification will have been created. This is expected to be an infrequent occurrence
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-13162		Create Parallel Trade product: the list of Ingredients is incorrect when the Product retrieved as Source Member State has more than one Ingredient. The Substance code from one of the Ingredients is being output for all of the Ingredients in the new Parallel Trade product.
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
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

Use Case	Affects user	Issue reference	Vet EUIG Chapter 2 section	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	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
UC01 Create product UC08 Update product	API	UPD-10133		POST Create or Update bundle for NP where URI starts with https and not http - this should be rejected with a validation error. Instead the post is accepted and product is created
UC01 Create product UC08 Update product	API & NCA UI	UPD-12932		UPD is missing terms from SPOR (RMS) - Units of measurement list
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

Use Case	Affects user	Issue reference	Vet EUIG Chapter 2 section	Issue Description
UC01 Create product UC08 Update product	NCA UI	UPD-12914		When creating or updating a product and receive some validation error, the package description and language have disappeared and after correcting the first error will then receive a validation error that there is no package description. The only workaround is to either Edit each package and re-add a package description; or to refresh the screen and reapply the updates taking into account the first validation error that had been received. For updates this issue affects Update NAP and Update Common Data DCP/MRP/SRP; but is not an issue for Update National Data DCP/MRP/SRP.
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-12586		Document of type "Public Assessment Report" is not saved in the created or updated product
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

Use Case	Affects user	Issue reference	Vet EUIG Chapter 2 section	Issue Description
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-12278		Active substance and strength column in Search table shows N/a instead of zero for products having substance strength or reference strength values as zero
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	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 is always displaying 100 products
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	API & NCA UI & MAH UI	UPD-1024		Search should be accent insensitive when using the exact modifier and it is not
UC03 Search product	NCA UI & MAH UI	UPD-11115		Sort of search results by alphabetical order of the product name does not work
UC03 Search product	API & NCA UI & MAH UI	UPD-140		Sort of search results does not work
UC03 Search product	NCA UI & MAH UI	UPD-10666		When searching for products may receive an error message "There has been a glitch". In most cases a resubmission of the search will be successful and return products matching the submitted criteria.
UC03 Search product	NCA UI & MAH UI	UPD-13149		For DCP/MRP/SRP products, the product card on the search results page doesn't contain "Reference Member State" and "Concerned Member State" fields. This information is available on the View product screen

Use Case	Affects user	Issue reference	Vet EUIG Chapter 2 section	Issue Description
UC04 Export	NCA UI & MAH UI	UPD-9861		The downloaded csv file should contain all products matching the search criteria. The file only contains those displayed on the current page
UC05 View product	NCA UI & MAH UI	UPD-12758		On the view product screen, documents with language of Norwegian or Icelandic display language as N/A
UC05 View product	NCA UI & MAH UI	UPD-12585		Reference Strength is not being displayed when viewing a product
UC05 View product	NCA UI & MAH UI	UPD-10956		The strength information is not displayed next to the Substance within an Ingredient
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-12753		When viewing a product, the hyperlinks in the left hand menu to sections within the product data do not work
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
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-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
UC06 Submit VNRA	MAH UI	UPD-11596		If Submission Comment exceeds limit of 4000 a meaningful error message is displayed. Instead it displays an error of "undefined" in the banner (with red background).
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	NCA UI	UPD-11278		Issue affects EMA/EC users only: When VNRA is submitted, the VNeS 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

Use Case	Affects user	Issue reference	Vet EUIG Chapter 2 section	Issue Description
UC06 Submit VNRA		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
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-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-12755		Submission of Volume of Sales - if any product name or package description contains an embedded quotation mark the submission fails with a validation error "invalid char between encapsulated token and delimiter"
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	Issue Description
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	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	NCA UI	UPD-9483		For product under DCP/MRP/SRP procedure, an NCA who is not the RMS or CMS is able to select to edit a product under the procedure. Only the RMS should be able to Update Common Data or Update National Data; and only CMS should be able to update National Data for their product
UC08 Update product	API	UPD-4714		<p>If there are duplicate inline attribute IDs within a resource, the request will be rejected.</p> <p>The validation message will say that the resource is not included and is mandatory, with no other validation errors in the response.</p> <p>As a workaround, remove the existing inline ID from one attribute so there is no longer duplicate values.</p> <p>This may occur and most frequently affects:</p> <ul style="list-style-type: none"> - MedicinalProductDefinition.contact - MedicinalProductDefinition.masterFile - AdministrableProductDefinition.routeOfAdministration - AdministrableProductDefinition.routeOfAdministration.targetSpecies - AdministrableProductDefinition.routeOfAdministration.targetSpecies.withdrawalPeriod
UC08 Update product	NCA UI	UPD-12911		Impacts only EMA staff on Update CAP - incorrectly get Validation error as wrong list ID has been used for Country for Product Name
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-7247		UC08 - Update DCP SC2 National data - Able to add a new Pharmaceutical Product which is a Common data; advised successful but Get OperationOutcome has Validation error
UC08 Update product	API	UPD-6882		UC08 Update SC2 Update National Data for DCP/MRP/SRP. The Content location in the response is in the format: national-data-operation-outcome/e915f652-d3b9-4cca-8c4d-23f0aae5a19a-ND. The id value should be used with a GET OperationOutcome/id.

Use Case	Affects user	Issue reference	Vet EUIG Chapter 2 section	Issue Description
UC08 Update product	NCA UI	UPD-11218		Update National data and after entering what is believed to be all national data, the Update button is not enabled (Package data is not displayed which is likely to be the underlying issue) (intermittent issue)
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		UPD-12907		Update Common Data DCP/MRP/SRP - fails with DQ-Error-001 displayed incorrectly or a timeout and Update Common Data is blocked. This does not occur for all products and believe is only those where there are many CMS, or where there have been many previous updates that has resulted in more than 50 Notifications for the Product Identifier
UC08 Update product	API	UPD-12224		Update Common Data DCP/MRP/SRP where RMS product does not have National data populated: POST has response code of 500 Internal server error. If Authorisation status and Date of Authorisation status change date attributes are populated the POST is successful. This is a regression issue and update common data should not require these attributes to be populated if RMS has not populated national data for their product.
UC08 Update product	NCA UI	UPD-12393		Update Common Data MRP/DCP/SRP - Delete Common Document only deletes the document from RMS product and does not delete from CMS products
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	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-11292		Update National Data DCP/MRP/SRP: User cannot edit or delete an existing or new national name before submitting the update
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
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)

Use Case	Affects user	Issue reference	Vet EUIG Chapter 2 section	Issue Description
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-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 contains the notes and they cannot be removed
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 & API	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.
UC08 Update product		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 has been corrupted. The Ingredient that had been removed still exists in the product but does not contain reference to the Pharmaceutical product.
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-12930		If approving an automated variation code for product that has been loaded using Chapter 4/Legacy rules there is a validation error displayed and the VNRA can't be approved. This is because Chapter 2 validation rules are being applied instead of Chapter 4 validation rules.
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
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	Issue Description
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-9773		Implementation of endpoint to nullify a product is not as expected: didn't expect to have to specify which Validation rules to apply; there is no Content Location with OperationOutcome ID; format of errors when POST are not in the format specified in request Accept header; does not support request in XML format
UC19 Nullify product	NCA UI	UPD-10910		Nullify Registered Homeopathic - not able to nullify as get error when submit "there was an error when trying to nullificate the product" (regression)
UC19 Nullify product	API	UPD-11204		Response when submit POST to nullify a product is to be reviewed: there is no message returned in response body; consider aligning the nullify endpoint with other create/update endpoints and provide an OperationOutcome ID that can be used to query outcome
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 & 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	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

Use Case	Affects user	Issue reference	Vet EUIG Chapter 2 section	Issue Description
UC21 Manage notifications	NCA UI & MAH UI	UPD-11827		Not able to search notifications using Procedure number
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-12405		Returning to search results in the notifications screen displays the previously selected search criteria. But the notifications displayed are the default to display when first selecting notifications from the menu and has not applied the selected search criteria. As a workaround need to Search again.
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"
UC21 Manage Notifications	NCA UI & MAH UI	UPD-13137		When submission of Bulk Upload has failed: the Notification card does not match the definition documented in "UPD - Notifications in processes"
UC24 Marketing authorisation status	MAH UI	UPD-10751		Availability status is not updated to "Not marketed" when Authorisation status updated to Suspended or Revoked
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	Issue Description
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-12751		Download fails with a validation error if any product that has been selected to download has Authorisation status of Suspended, Revoked, Surrendered or Expired
UC25 Update Availability status	MAH UI	UPD-11130		If there are errors when submitting file for Availability status updates, the Error report file has incorrect values for "Pack size_Unit of presentation identifier" and Marketing Authorisation Number
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-12755		Submission of Availability Status - if any product name or package description contains an embedded quotation mark the submission fails with a validation error "invalid char between encapsulated token and delimiter"
UC25 Update Availability status	MAH UI	UPD-12752		Submission of Availability status file: there are validations being applied for some columns of the submission file that shouldn't happen and cause the submission to fail
UC25 Update Availability status	MAH UI	UPD-11420		When submit Availability status and the logged on MAH is not affiliated to the Product owner of the product, an incorrect error message is being displayed. "ERR.05 Package identifier provided doesn't belong to the country selected" is being displayed and it should be "ERR.01: Package Identifier provided doesn't belong to a product under the User's responsibility".
UC27 View Volume of Sales	MAH UI	UPD-12423		View Volume of Sales for a Product that has had Volume of sales successfully submitted. After selecting product and sales period and submit this fails with an error 499 (issue in PROD env only)
UC27 View Volume of Sales	MAH UI	UPD-13292		UC27 View Volume of Sales (MAH users only) MAH products with submitted values for Volume of Sales are not being displayed as expected and need to paginate through search results to see list of all products that have had sales data loaded

Use Case	Affects user	Issue reference	Vet EUIG Chapter 2 section	Issue Description
UC27 View Volume of Sales	NCA UI & MAH UI	UPD-13294		UC27 View Volume of Sales - changing search results from default of 20 products per page doesn't always change number of products in Search results table; and may also affect navigation through search result page
UC28 View VNRA	NCA UI	UPD-12208		Datafix for existing VNRA. Following the resolution of the root-cause under UPD-11604 in release 1.6.10, a datafix was required for existing VNRA submitted prior to that release so that NCA able to view. This datafix has now been applied. Therefore, NCA should now be able to view VNRA submissions as expected
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 & MAH UI	UPD-12885		MAH has submitted VNRA for variation code "A4 Change in ATCVet code" for two or more products, where the products do not have the same existing ATC Vet Codes. When NCA or MAH view the VNRA submission the field "A4-ATC-VetCodeCurrent" for each product does not display the correct data. The existing values from one of the products is being displayed for all products.
UC28 View VNRA	NCA UI	UPD-12942		NCA BVL in Germany only affected: Some VNRA submitted prior to HF 1.6.13-8 release - BVL still don't see all expected submissions
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-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	NCA UI & MAH UI	UPD-12522		The PDF for VNRA for variation Code A4 ATC Vet code is currently displaying the RMS Term code for the current and proposed ATC Vet codes. It should be displaying the RMS Term as displayed on the View VNRA Submission page.
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

Use Case	Affects user	Issue reference	Vet EUIG Chapter 2 section	Issue Description
UC28 View VNRA	NCA UI & MAH UI	UPD-11888		View VNRA submission: Empty VneeS file viewing submission when MAH has attached a zip file that contains file(s) while submitting the VNRA. This infrequently occurs.
UC28 View VNRA	NCA UI & MAH UI	UPD-12047		VNRA PDF: the existing MAH is listed as for all variation codes and data value is only printed for A.1.a; Current and proposed values for MAH should only be printed for A.1.a
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' are not populated in Notification card when viewing Notification
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-11418		Document uploaded with Type = "epar" is being wrongly saved as "puar"
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-12182		Notifications are not all generated after uploading multiple documents using the bulk upload functionality (files have been added to the product)

Annex 3: Release Schedule

#	Environment	Date From	Date Till	Description
37	PROD	12 Jan 23	13 Jan 23	Upgrade of UPD to 1.6.16 This deployment cancelled
38	UAT (TBC)	19 Jan 23	20 Jan 23	Upgrade of UPD to 1.6.17 Deployment cancelled
39	PROD	26 Jan 23	27 Jan 23	Upgrade of UPD to 1.6.16

#	Environment	Date From	Date Till	Description
40	UAT (TBC)	16 Feb 23	17 Feb 23	Upgrade of UPD to 1.6.19 Deployment cancelled
41	UAT (TBC)	24 Feb 23	24 Feb 23	Upgrade of UPD to 1.6.20
42	PROD (TBC)	02 Mar 23	02 Mar 23	Upgrade of UPD to 1.6.20
43	UAT (TBC)	10 Mar 23	10 Mar 23	Upgrade of UPD to 1.6.21
44	PROD (TBC)	16 Mar 23	16 Mar 23	Upgrade of UPD to 1.6.21