UPD Release Notes 1.6.1

Veterinary Medicinal Products Regulation: Union Product Database

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1. Overview of functionality and business value

This release is the next iterative version of the Union Product Database, v 1.6.1. The main difference with the previous version, v 1.5.4 released on 21 February 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 (MRP/DCP/NAP), as per Art 155 of Reg 2019/6, compliant with Chapter 4 of the July 2021 version of the Vet EU Implementation Guide (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 National Procedure product as the basis for this creation, and adds or updates Common data. For example: add Common Product Name, Reference member state and Concerned member state(s). A new product will be created for each Concerned Member State (CMS) with procedure type MRP and the RMS's NP product 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.

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 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 Nullify product
    - NCA can Bulk Upload Documents
    - 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)
- 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.

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:

- Create & Update Parallel Trade

NCA UI:

- Create & Update Parallel Trade
- Transfer Marketing Authorisation
- Update CAP products

MAH UI:

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

2. Changes made compared with 1.5.4

2.1. New functionality

- RMS can create SRP products (data and documents) (API & NCA UI)
- RMS and CMS can complement SRP product with national DCP/MRP/SRP data and documents (API & NCA UI)
- RMS can update Common data for SRP product (data and documents) (API & NCA UI)
- Create & Update Registered Homeopathic (API & NCA UI)
- Nullify product (API & NCA UI)
- Bulk Upload of Documents (NCA UI)
- UPD-BR-124 - Responsible authority (organisation) displayed as an acronym in the tables of the UPD Portal (NCA UI & MAH UI). Where an acronym exists in OMS this is now displayed instead of the organisation name.

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
Authorisation	NCA & MAH UI	UPD-8434		Authorisation: User was not able to use the UPD portal as expected when assigned to multiple roles for different organizations. The issue was not the number of organisations but the number of locations for the organisations that a user was affiliated with. This issue has been resolved.

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue that has been resolved
UC03 Search product	MAH UI	UPD-9419		MAH were not able to view CAP products where there had been a merge of Locations in OMS. This has been corrected and CAP products updated with the surviving LOC-ID
UC08 Update product	API & NCA UI	UPD-7272	1.2 Product Record Status	Update Common Data - Each CMS product was incorrectly being updated with the Product record status of the RMS product (or the product under the Product identifier selected by the RMS for the Update Common Data). This has been corrected and Product record status in CMS products are not updated.
UC08 Update product	API & NCA UI	UPD-7713	1.5 (Authorised) pharmaceu tical form	Update NAP via API or UI - every update was adding another attribute for 1.5 Authorised Pharmaceutical form in the MedicinalProductDefinition resource. When viewing or updating the product in the NCA UI or MAH UI this is not an issue. The API response to GET MedicinalProductDefinition/id/$everything showed several entries for this attribute and the duplicated entries needed to be removed when submitting an update to the API. This issue has been resolved. EMA will identify the existing products that have been affected by this issue that will need to be corrected, and facilitate a correction.
UC08 Update product	NCA UI	UPD-9079	1.9 (Pharmaco vigilance System) Master File	Update NP Legacy product - where PSM File code and Location field have been populated and update the product to remove PSMF (optional for Legacy and mandatory for Chapter 2) the submission of the update will be successful. However, the update operation fails with an error and the submitted updates are not saved. There is no notification generated. This issue will not be resolved since the majority of the legacy products have now been loaded and PSMF will be mandatory under Chapter 2 rules. Ticket has been closed.
UC01 Create product	API	UPD-6437	1.10.3 QPPV Location	There was no validation error if OMS location identifier was not populated for QPPV Location. The Post of the create bundle was accepted. However, response for GET OperationOutcome showed ERR-1002. There is now a validation error if QPPV Location is not populated correctly.

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue that has been resolved
UC18 Manage document	API	UPD-8603	1.11.1 (Attached document) identifier	EP404 Update Document - Update of a document was being treated as a create and a new DocumentReference was being added with new DocumentReference.id. This has been corrected and the existing id is being updated
UC18 Manage document	API	UPD-5143	1.11.4 (Attached document) country	Population for Attached document country was incorrectly rejected with a validation error. This attribute may now be populated and is mandatory. Refer to UPD-9748 for a new issue relating to the three EEA countries.
UC18 Manage document	API	UPD-8517	1.11.4 (Attached document) country	Attached document country is Mandatory
UC08 Update product	NCA UI	UPD-9381	1.13.1 Manufacturer	Update Common Data for DCP/MRP - the Manufacturer location for Manufacturing Business Operation may have displayed as "undefined, undefined, undefined". This did not prevent the MBO or product from being updated. This issue has been resolved.
UC08 Update product	NCA UI	UPD-8383	1.13.2 Manufacturing activity	Update NP to add another Manufacturing Activity for an existing Manufacturing Business Operation was resulting in ERR-1002. As a workaround, if the Manufacturing Business Operation was deleted and then re-added with all of the required manufacturing activities the update was successful. This issue has been resolved and the workaround is no longer required.
UC01 Create product	NCA UI	UPD-9011	2.5 Authorisation status	For National Procedure product: If value of REVOKED is selected, when view the created product it always displayed the value of VALID. This issue has been resolved and the value selected is now displayed.
UC08 Update product	NCA UI	UPD-7220	2.5 Authorisation status	UC08 Update SC2 DCP National Data - UI Only - UPD-UC08-AC015 - Authorisation status in the updated product was not the value entered on the screen and was always updated to “Valid”. This issue has been resolved and the value selected in now displayed.

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue that has been resolved
UC01 Create product UC08 Update product	API & NCA UI	UPD-8909	2.6 Date of authorisation status change	When loading legacy product with only those attributes populated that are mandatory based on Vet EUIG Chapter 4 rules, where Date of authorisation status change is 26/12/21 or later, you received a validation error with the message "PSMF is required after 28/01/2022". As a workaround for this release, populate date with latest date of 25/12/21 or populate PSMF. This issue has been resolved and the workaround is no longer required.
UC08 Update product	NCA UI	UPD-6979	4 Ingredient	Update Common Data - you were able to delete an Ingredient that is still referenced in a Manufactured item or Pharmaceutical product. When update was submitted there was a validation error. The update screen needed to be reselected from the View product screen and start edit again, or a new Ingredient added and referenced. The UI usability has been improved to prevent the deletion of an Ingredient that is still referenced from a Manufactured Item or Pharmaceutical Product
UC08 Update product	NCA UI	UPD-8773	4.3.2 Strength (quantitative composition)	If a product was updated and the Substance Strength id changed from Concentration to Presentation or Presentation to Concentration, both the old and new strength were in the updated product. The UI was always displaying the Presentation value (whether it is the old or new value supplied). In the API both attributes were populated: Ingredient.substance.strength.concentration and Ingredient.substance.strength.presentation. This issue has been resolved for any new updates. EMA will advise the NCA of existing products that have been affected by this issue that will need to be corrected.
UC05 View product	NCA UI & MAH UI	UPD-5131	5.2 Pack size	Only the numeric quantity was displayed and not the term name for Unit of presentation.

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-9418	5.2 Pack size	Pack size for a Package is optional. If no Pack size had been populated, there was a validation error when attempting to Update National Data. A workaround if MAH advised that they need to submit VNRA for product was to advise User Support of the product where CMS is blocked from populating national data. They advised what information was required in order for EMA to be able to populate the national data on CMS behalf to allow the VNRA to be submitted. This issue has been resolved and no workaround is required.
UC08 Update product	NCA UI	UPD-8933	5.6 Manufactured item (in Package)	Update NP or Update Common Data DCP/MRP/SRP - after selecting to Edit a Manufactured Item the Edit button was not enabled to allow changes for that section to be updated into the table of Manufactured items. This did not occur for all products. This issue has been resolved.
UC08 Update product	NCA UI	UPD-7002	5.6.2 Manufactured item quantity	UC08 Update SC2 NAP/ DCP National Data & SC3 Common Data - UI Only - UPD-UC08-AC035 - Manufactured Item Quantity had incorrect numeric and term code values on screen after selecting to edit product from view screen. This issue has been resolved.
UC01 Create product	API & NCA UI	UPD-9144		Create MRP - when selecting a National procedure product it was possible to select a product that has been nullified. This issue has been resolved.
UC01 Create product UC08 Update product	API & NCA UI	UPD-8970		Create MRP where NP product has two or more packages. The manufactured item quantity for the second and subsequent packages did not have the correct Manufactured item numeric quantity. Instead it showed a RMS term code. If left unchanged, the numeric quantity was incorrect in the RMS and CMS products. This issue has been resolved.
UC07 Submit Volume of Sales	MAH UI	UPD-7988		Volume of Sales: User sometimes could not see the Volume of Sales for products for which submission was successful. This issue has been resolved.
UC08 Update product	NCA UI	UPD-7507		Update SRP National Data: sometimes selecting to edit National data from the View product screen displayed the update page but was stuck with a loading animation and eventually timed out. This issue has been resolved.

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue that has been resolved
UC21 Manage Notifications	NCA UI & MAH UI	No reference		In 1.5.4 filtering by date was not working correctly. This issue has been resolved.

2.3. New 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.

There has been a change made in section 3.1. Providing Strength or Reference Strength for an Ingredient for Scenario 4. This also is not possible due to a FHIR requirement.

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue description
UC08 Update product	API & NCA UI	UPD-9448	1.11 Attached Document	Delete of a document does not work, even although receive message back to the UI that submission of the update has been successful. When product is viewed, the deleted document remains. There is no API endpoint available to delete a document. The requirements and resolution for this option are being reviewed.
UC18 Manage document	API	UPD-9748	1.11.4 (Attached document) country	There is a validation error if attempt to populate country code for any of the three EEA countries: Iceland, Liechtenstein, Norway. These three countries should be valid and should not result in a validation error.
UC01 Create	API & NCA UI	UPD-9467	1.12 Product cross-reference	Create MRP - if there is any Product Cross Reference included when Create MRP, the POST or submission of the Create is successful. However only the RMS product has been updated. GET OperationOutcome shows validation errors and the existing CMS product has not been updated; and no new products created for new CMS

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue description
UC01 Create product UC08 Update product	API	UPD-9384	1.13.2 Manufacturing activity	Create and Update Common Data DCP/MRP/SRP using Chapter 2 rules - there is a missing validation check if a manufacturer responsible for batch certification has not been provided. This should give a validation error and instead the POST is successful, and product created
UC01 Create product	API & NCA UI	UPD-9837	2.2 Authorisation/registration/ number 5.5.1 (package level)	Create MRP - if the NP product has Marketing authorisation number populated at Package level the POST is accepted. However, there is a validation error when view GET OperationOutcome. The NP product for RMS has been updated but products have not been created for CMS
UC08 Update product	API	UPD-9800	2.4 Responsible authority (organisation)	Update product via API only: when updating the LOC-ID for the Responsible authority, organisation name is not being updated if the RegulatedAuthorization.regulator.display attribute is not included in the Update bundle. This is an optional attribute that should not need to be provided. EMA will investigate if the data can be corrected in the short-term until this issue is resolved.
UC08 Update product	API	UPD-9800	2.8 Product owner (organisation)	Update product via API only: when updating the LOC-ID for the Product owner, organisation name is not being updated if the RegulatedAuthorization.holder.display attribute is not included in the Update bundle. This is an optional attribute that should not need to be provided. EMA will investigate if the data can be corrected in the short-term until this issue is resolved.
UC01 Create	API & NCA UI	UPD-9469	2.13.1 Procedure number	Create MRP - If the National procedure product did not have a Procedure number and no Procedure number is provided when submitting the Create MRP, the create should fail with a validation error. In this release the create is successful without a procedure number.

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue description
UC08 Update product	NCA UI	UPD-9849	5.4 Legal status for the supply (package level)	Update National Data DCP/MRP/SRP - Legal status of Supply at Package level is not being saved. If it is populated at Product level it is saved correctly.
UC05 View product	NCA UI & MAH UI	UPD-9502	5.6.1 Unit of presentation	On View product screen within each Package, the Unit of presentation for a Manufactured item is not being displayed. This should be shown before the manufactured item quantity.
UC03 Search product	NCA UI & MAH UI	UPD-9471	5.7.2 Availability status	The product information card on the Search product screen is not displaying the Availability Status. Instead it is displaying the Product Status.
UC01 Create product	API	UPD-9731		Create DCP - duplicate products are being created for some CMS. This is an intermittent issue and we do not have any indication at this time how frequently this is occurring. Analysis is ongoing to identify the root cause and also to identify existing procedures that have been affected by this issue
UC01 Create product UC08 Update product	NCA UI	UPD-9802		Create DCP/MRP/SRP or Update Common Data DCP/MRP/SRP - not able to add more than one package. This was possible in the previous release and will be resolved in the next release
UC01 Create product UC08 Update product	API	UPD-9771		Create or Update via API: the request remains in status QUEUED for an abnormally long time. There has been an error during the processing of the request but this is not displayed when reviewing status with Get OperationOutcome and the status always remains as QUEUED.
UC05 View product	NCA UI & MAH UI	UPD-8518		If more than 20 updates have been made to a product, only the first 2 are being displayed when that product is viewed. If an attempt is made to update that product there will be a validation error that the product version number does not match the current version

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue description
UC06 Submit VNRA	MAH UI	UPD-9758		MAH submits VNRA and receives message that VNRA has been submitted. However when go to View Submissions page the new submission is not listed, even after waiting for some period of time. At this time this is an issue only observed in the Production environment and investigations are ongoing to establish if submission has been saved and what the issue is when displaying.
UC06 Submit VNRA	MAH UI	UPD-9429		When submitting VNRA, not able to select more than one National Procedure product. This is a regression issue in this release and will be corrected in the next release.
UC06 Submit VNRA	MAH UI	UPD-9465		When submitting VNRA, the Responsible authority is not populated with the organisation name and instead is showing "Object, Object"
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-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.
UC09 Approve/Reject VNRA	NCA UI	UPD-9494		UC28 View VNRA submissions and UC09 Approve/Reject: cannot download VneeS file. This is an intermittent failure and sometimes download will be successful. This issue affects both the MAH who submitted the VNRA and NCA
UC09 Approve/Reject VNRA	NCA UI	UPD-9853		VNRA for a CAP product: Any NCA is able to Approve/Reject a VNRA for a CAP product and should only be able to View

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue description
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
UC21 Manage Notifications	NCA UI & MAH UI	UPD-9815		The date in datagrid (search results) for VNRA Approved/Rejected should be the date the VNRA was approved or rejected (the Action date) and not the Decision date
UC21 Manage Notifications	NCA UI & MAH UI	UPD-9466		The drop-down list to filter by Action does not contain all of the possible values
UC21 Manage Notifications	NCA UI & MAH UI	UPD-9878		Notifications are not displayed in descending date order when select from menu. There is one entry with all values as N/A. This issue only occurs in the Production environment
UC27 View Volume of Sales	MAH UI	UPD-9741		When select to view submissions of Volume of Sales the progress control remains on the screen and the view submission page is not loaded
UC28 View VNRA	NCA UI & MAH UI	UPD-9494		UC28 View VNRA submissions and UC09 Approve/Reject: cannot download VneeS file. This is an intermittent failure and sometimes download will be successful. This issue affects both MAH who submitted the VNRA and NCA.
UC28 View VNRA	NCA UI & MAH UI	UPD-9383		When viewing a VNRA for a National Procedure product, the Responsible authority is not correctly displayed and as the name of the Product owner

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
UC08 Update product	NCA UI	UPD-8246	1.3 Product identifier	Update SRP National data - The Product identifier is displaying [object Object], [object Object]
UC01 Create product	API	UPD-8281	2.12 Concerned member states	Create SRP - should receive a validation error if add new CMS for country not in EEA
UC01 Create product	API	UPD-9411	2.2 Authorisation/registration/ number 5.5.1 (package level)	Registered Homeopathic product based on Chapter 2 validation rules: there should be a validation error if submit without any value for Marketing Authorisation Number at either Product or Package level. In this release it is possible to create without populating. This should be populated to comply with the Vet EUIG.
UC01 Create product	API & NCA UI	UPD-9335	2.2 Authorisation/registration/entitlement number 5.5.1 Marketing authorisation number (package level)	Registered Homeopathic product based on Chapter 4 Legacy validation rules: there should be a validation error if submit without any value for Marketing Authorisation Number at either Product or Package level. In this release it is possible to create without populating. This should be populated to comply with the Vet EUIG.
UC01 Create product	NCA UI	UPD-5908	3 Pharmaceutical Product	Create SRP - Pharmaceutical products section - Labels for 'Edit' and 'Delete' are missing in the table after adding a Pharmaceutical Product
UC08 Update product	NCA UI	UPD-7506	5 Packaged medicinal product	Update Common Data for SRP - on some occasions Package information is missing when select to 'Edit common data'. This prevents an update as the Submit button will remain disabled
UC01 Create product	NCA UI	UPD-7504	5.1.1 Language	Create SRP - the package language should display the RMS language name and not the term code after adding/editing package description

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue description
UC01 Create product	NCA UI	UPD-7511	5.6 Manufactured item (in Package)	Create SRP - when click on button to 'Edit Manufactured Item', the manufactured item is deleted. If update is required to Manufactured item this should be completed in two steps: first Create SRP; and then Update Common Data
UC01 Create product	NCA UI	UPD-8621	5.6 Manufactured item (in Package)	Registered Homeopathic product: Manufactured item at Package level should not be mandatory
UC08 Update product	NCA UI	UPD-9505	5.7 Availability status	Registered Homeopathic product: any updates to Availability status are not saved in the updated product
UC01 Create product	API & NCA UI	UPD-9760		Create SRP: Creating SRP based on product under SRP fails
UC19 Nullify product	API & NCA UI	UPD-9432		Nullify product: Action in notification should be **Nullify** and not "**UPDATE, Upload Document**"
UC34 Bulk Upload for Documents	NCA UI	UPD-9412		Bulk Upload of Documents Notification: There is a spelling error in Action value and it has Bul instead of Bulk
UC34 Bulk Upload for Documents	NCA UI	UPD-7440		Bulk Upload of Documents: There is a spelling error in the static text on the screen related to the file size exeed vs. exceed
UC34 Bulk Upload for Documents	NCA UI & MAH Ui	UPD-9412		The Action value has a typo in the name for notifications where document has been added/updated by the NCA using UC34 Bulk Upload functionality

3. Implementation based on the version of the Veterinary EU Implementation Guide revised in July 2021

This UPD release is based on the July 2021 version of the Vet EU IG.

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 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 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 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" were 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.

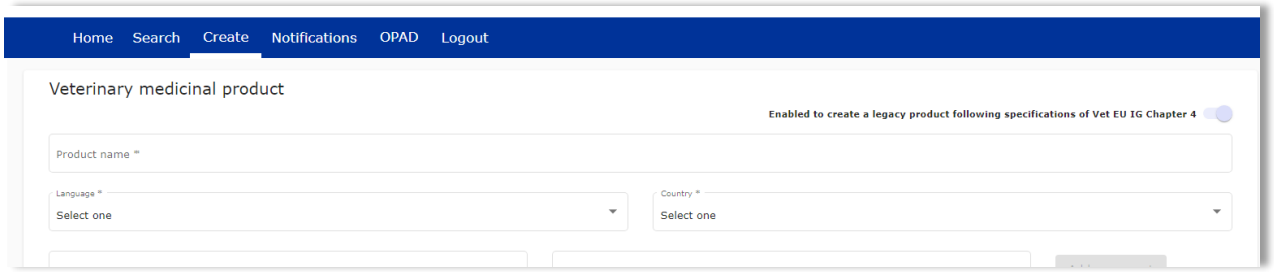
Supported browsers for the NCA UI are Chrome and Edge.

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 *Manage My Access* Reference guide: https://register-test.ema.europa.eu/identityiq/help/requestaccess.html
    - use "UPD" as a search option to filter available roles
    - select appropriate role:
        - **UPD CA Super User** **(reminder**: **attach document** as evidence of your authority to manage users for your organisation)
        - **UPD CA Edit Search View**
        - **UPD CA Search View**
    - Some UPD-specific screenshots can be found in Annex 1.
    - The request for the first "UPD CA Super User" for your organisation will be approved by EMA. Access is only being granted to NCA staff.
    - The approved "UPD CA Super User" will manage all other access requests for your organisation.
    - Once registered, the UI in UAT can be found at:

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

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

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

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

- Participated (viewed recording) in the training/demo on how to submit legacy data in UPD of 4 August 2021
- Carried out some testing in the UAT environment compliant with the latest version of the EU Implementation Guide.

To request access:

- If you do not already have an EMA account in the Production environment:
    - EAM Production can be found at: https://register.ema.europa.eu/identityiq/login.jsf
    - *Create a new EMA account* Reference guide: https://register.ema.europa.eu/identityiq/help/selfregister.html
- Log into EAM Production once registration is complete to Request Access to one of the UPD NCA UI roles
    - select *Manage My Access* Reference guide: https://register.ema.europa.eu/identityiq/help/requestaccess.html
    - use "UPD" as a search option to filter available roles
    - select appropriate role:
        - **UPD CA Super User (reminder**: **attach** Nomination **document** as evidence of your authority to manage users for your organisation)
        - **UPD CA Edit Search View**
        - **UPD CA Search View**
    - Some UPD-specific screenshots can be found in Annex 1.
    - The request for the first "UPD CA Super User" for your organisation will be approved by EMA. Access is only being granted to NCA staff.
    - The approved "UPD CA Super User" will manage all other access requests for your organisation.
- Once registered, the UI in PROD can be found at:

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

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

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

5.2. UPD API supported Product Service endpoints

EP302 Search Product Part and EP305 Get Product Part endpoints are no longer available.

SPOR API Specification v2	API Manager
EP301 Search Product	GET MedicinalProductDefinition - Search for a MedicinalProductDefinition resource or resources
EP303 Get Product	GET MedicinalProductDefinition - Get a MedicinalProductDefinition ID
EP304 Get Product Full	GET Everything Current - Get $everything for a MedicinalProductDefinition ID
EP306 Get Product Version	GET MedicinalProductDefinition Version - Get version of MedicinalProductDefinition ID
EP306a Get Product Version Full	GET Everything Versioned - Get $everything for a version of MedicinalProductDefinition ID
EP307 Get Product Versions	GET MedicinalProductDefinition - Get history of MedicinalProductDefinition ID

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

5.3. API Manager product subscription

Any new API users should register a user and subscribe to the product Authorised - UPD API - Milestone 3 (UPD 1.03) in API Manager.

The credentials for this new product can be used for all supported endpoints as listed in section 5.2. UPD API supported Product Service endpoints

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

5.4. Apply Chapter 4 Legacy or Chapter 2 Validation rules

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

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

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

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

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

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

Request Header: Key	Values	Purpose
Content-type	application/fhir+xml application/fhir+json	Specifies the format of the request body that is being submitted
Accept	application/fhir+xml application/fhir+json	Specifies the format for the response body of the POST if there are any validation or other errors

5.5.2. Create and Update endpoints

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

- Create MRP is an update to an existing NP product. The Bundle should be based on all national data in that product, with the additional Common data added, and the procedure type updated to MRP
- Create SRP is an update to an existing DCP/MRP/SRP product. The Bundle should be based on all national data in that product, with the additional Common data added
- Please refer to the example bundles and recommended approach sections

Type and Procedure	POST Endpoint	Request header Key for validation rules	Additional Request header
Create NP	/pms/api/v2	chapter4	
Update NP	/pms/api/v2	chapter4	is_update = true
Create DCP	/upd/api/v1/dcp-bundle/	chapter4	
Update Common Data DCP/MRP/SRP	/upd/api/v1/common-data-bundle/	chapter4	is_update = true
Update National Data DCP/MRP/SRP	/upd/api/v1/national-data-bundle/	chapter4	is_update = true
Create MRP	/upd/api/v1/mrp-data-bundle/	chapter4	
Create SRP	/upd/api/v1/srp-data-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
To Validate any Create or Update bundle	/pms/api/v2/$Validate	Use appropriate request header to apply validation rules based on the procedure type	Use is_update = true when validating the following bundles: • Update NP • Update Registered Homeopathic

Type and Procedure	POST Endpoint	Request header Key for validation rules	Additional Request header
			• 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	{
	"permanentId": "*Permanent Identifier*"
	}

	For example:
	{
	"permanentId": "600011984989"
	}

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 transactionnfirm the update has
- 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

POST	Content Location example showing post-operation and format of the operation-outcome-id
Create SRP	srp-operation-outcome/cf7af9a9-b34d-4db9-a551-89d40c077306-SRP

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
	No changes are required for this release
5.2 Pack size	The example files for mandatory attributes have been corrected (file name *_C2_Mandatory_*). Pack size is optional and the previous example files contained this attribute. PackagedProductDefinition.extension with url="http://ema.europa.eu/fhir/extension/containedItemQuantity”

5.5.7. API EP309 Create NP and DCP 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_1.6.1-4_DCP_Chpt2_C2_Mandatory_VetIG.JSON UPD_1.6.1-4_DCP_Chpt2_C2_Mandatory_VetIG.XML UPD_1.5.1-0_DCP_Chpt2_C110_VetEUIG_AllData.JSON

Procedure type	Validation rules	Example file
		UPD_1.5.1-0_DCP_Chpt2_C110_VetEUIG_AllData.XML
DCP	Chapter 4 Legacy	UPD_1.6.1-4_DCP_Legacy_C2_Mandatory_VetIG.JSON UPD_1.6.1-4_DCP_Legacy_C2_Mandatory_VetIG.XML UPD_1.5.1-0_DCP_Legacy_C110_VetEUIG_AllData.JSON UPD_1.5.1-0_DCP_Legacy_C110_VetEUIG_AllData.XML
NAP	Chapter 2	2.2 Authorisation/registration/entitlement number is specified at Product level UPD_1.6.1-4_NAP_Chpt2_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel.JSON UPD_1.6.1-4_NAP_Chpt2_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel.XML UPD_1.5.1-0_NAP_Chpt2_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel.JSON UPD_1.5.1-0_NAP_Chpt2_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel.XML --- 5.5 Marketing authorisation (package level) UPD_1.5.1-0_NAP_Chpt2_C111_VetEUIG_AllData_MANumber_AtPackageLevel.JSON This example contains 2 packages. There are 3 RegulatedAuthorization resources: • One with subject reference = MedicinalProductDefinition resource; populated with attributes from Section 2 (Vet EUIG Chapter 2), excluding the marketing authorisation number • One with subject reference = 1st PackagedProductDefinition resource; populated with the Marketing authorisation number for Package 1 • One with subject reference = 2nd PackagedProductDefinition resource; populate with the Marketing authorisation number for Package 2

Procedure type	Validation rules	Example file
NAP	Chapter 4 Legacy	UPD_1.6.1-4_NAP_Legacy_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel.JSON UPD_1.6.1-4_NAP_Legacy_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel.XML UPD_1.5.1-0_NAP_Legacy_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel.JSON UPD_1.5.1-0_NAP_Legacy_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel.XML
NAP	Chapter 4 Legacy	UPD_1.5.1-0_NAP_Legacy_Cx_ManyAttributesAndResources_MANumberAtMedicinalProductLevel.XML This example contains: • 2 or more values for those attributes that are repeatable. For example Product name, ATC Vet Code, Manufacturing Business Operation • 2 Packages (PackagedProductDefinition) • 2 Manufactured Items (ManufacturedItemDefinition) • 3 Ingredients (Ingredient)
NAP	Chapter 2	UPD_1.5.1-0_NAP_Chpt2_ExampleForStrengthAsPresentationOrConcentration.XML This example contains Ingredient resources that illustrate how to specify Substance and Reference Strength as either Presentation or Concentration.
Registered Homeopathic	Chapter 2	UPD_1.6.1-4_HOM_Chpt2_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel.JSON UPD_1.6.1-4_HOM_Chpt2_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel.JSON

5.5.8. Recommended approach to prepare update request bundle

The recommended approach for preparing a request bundle to update a product (any procedure type) is:

- Use the response from EP304 GET MedicinalProductDefinition/{permanent identifier}/$everything as a starting point
- Add Bundle.entry.request for each resource and update Bundle.type

Attribute	Change
Bundle.type	Must be "transaction"
For every Bundle.entry	Bundle.entry.request must also be populated. Bundle.entry.request.method should be: • PUT to update an existing resource • POST to add a new resource Bundle.entry.request.url should be: • Same value as Bundle.entry.fullUrl

For example:

```
<?xml version="1.0" encoding="utf-8"?>
<Bundle xmlns="http://hl7.org/fhir">
    <id value="600000022531" />
    <meta>
        <versionId value="1" />
        <lastUpdated value="2021-07-07T08:52:51.607+00:00" />
    </meta>
    <type value="transaction" />
    <entry>
        <fullUrl value="MedicinalProductDefinition/600000022531" />
        <resource>
            <MedicinalProductDefinition>
        </resource>
        <request>
            <method value="PUT" />
            <url value="MedicinalProductDefinition/600000022531" />
        </request>
    </entry>
    <entry>
        <fullUrl value="PackagedProductDefinition/170427" />
        <resource>
            <PackagedProductDefinition>
        </resource>
        <request>
            <method value="PUT" />
            <url value="PackagedProductDefinition/170427" />
        </request>
    </entry>
```

- DO NOT edit or remove the IDs for each resource and in-line within each resource in the EP304 Get $everything response

5.5.9. How to use Update NP product endpoint and example bundle

Create product via API	POST Bundle	Sample XML bundle used: UPD_1.5.1-0_NAP_Legacy_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel.XML
Check operation outcome	MSG_CREATED message expected containing Permanent identifier	
EP304 Get Product Full	Prepare update bundle based on the response by updating Bundle.type to transaction and adding Bundle.entry.request.method for each resource. Edit the response e.g. - modify product name - add another ATC Vet code - add another ManufacturedItemDefinition including this into the existing PackagedProductDefinition	Sample XML of Get Everything response used as a starting point: UPD_1.5.1-0_EP311_UpdateProduct_GetEverything_version1.XML Update bundle prepared: UPD_1.5.1-0_EP311_UpdateProduct_RequestBundle.XML
Update product via API	POST Bundle with request headers to /pms/api/v2 • "is_update=true" • "chapter4" = true or false for the validation rules to apply	
Check operation outcome	MSG_CREATED message expected containing Permanent identifier	
EP304 Get Product Full	Check the response for modifications	Sample XML of GET everything after update: UPD_1.5.1-0_EP311_UpdateProduct_GetEverything_version2.XML

5.5.10. How to use Update National Data DCP/MRP/SRP product endpoint and example bundle

Create product via API	POST Bundle	Sample XML bundle used: UPD_1.5.1-0_NAP_Legacy_C110_VetEUIG_AllDa

		ta_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 response e.g. - modify product name - add another ATC Vet code - add another ManufacturedItemDefinition including this into the existing PackagedProductDefinition	Sample XML of Get Everything response used as a starting point: UPD_1.5.1-0_EP311_UpdateProduct_GetEverything_version1.XML Update bundle prepared: UPD_1.5.1-0_EP311_UpdateProduct_RequestBundle.XML
Update product via API	POST Bundle with request headers to /upd/api/v1/national-data-bundle/ • "is_update=true" • "chapter4" = true or false for the validation rules to apply	
Check operation outcome	MSG_CREATED message expected containing Permanent identifier	
EP304 Get Product Full	Check the response for modifications	Sample XML of GET everything after update: UPD_1.5.1-0_EP311_UpdateProduct_GetEverything_version2.XML

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

EP304 Get Product Full	Prepare update bundle based on the response by updating Bundle.type to transaction and adding Bundle.entry.request.method for each resource. Edit the response e.g. - modify common product name - add another ATC Vet code Important: any national data that has been populated should be also included in the update bundle.	Sample XML of Get Everything response used as a starting point: UPD_1.5.3-4_DCP_UpdateCommonData_Product_600000149642_GetEverything_Version1.XML Update bundle prepared: UPD_1.5.3-4_DCP_UpdateCommonData_Product_600000149642_UpdateBundleBasedOnVersion1.XML

Update product via API	POST Bundle with request headers to /upd/api/v1/common-data-bundle/ • "is_update=true" • "chapter4" = true or false for the validation rules to apply	
Check operation outcome	MSG_CREATED message expected containing Permanent identifiers	
EP304 Get Product Full	Only the Common data in the RMS and CMS products under that Product Identifier will be updated	Please refer to Known issues section for any outstanding issues where national data submitted when updating common data is not being ignored.

5.5.12. How to use Create MRP product endpoint and example bundle

EP304 Get Product Full	Prepare update bundle based on the response by updating Bundle.type to transaction and adding Bundle.entry.request.method for each resource.	Sample XML of Get Everything response used as a starting point: UPD_1.5.3-4_CreateMRP_NP_600000184179_GetEverything_version1.XML
Prepare Create MRP Bundle	• Change procedure type from NP to MRP • Add Common Name with Country = EU and Language = English • Add Reference member state and Concerned member state • Add Common package description in English (if doesn't exist)	Create MRP bundle prepared: UPD_1.5.3-4_CreateMRP_BasedOn_NP_version1.XML
Create MRP via API	POST Bundle with request headers to /upd/api/v1/mrp-data-bundle/ • "chapter4" = true or false for the validation rules to apply	
Check operation outcome	MSG_CREATED message expected containing Permanent identifiers for RMS NP product and products created for each CMS	
EP304 Get Product Full	RMS: • Contains the Common data that was added CMS: • Each new product is only populated with Common data, with status of Provisional	

5.5.13. How to use Create SRP product endpoint and example bundle

EP304 Get Product Full	Prepare update bundle based on the response by updating Bundle.type to transaction and adding Bundle.entry.request.method for each resource.	Sample XML of Get Everything response used as a starting point: UPD_1.6.1-4_CreateSRP_RMSProduct_GetEverything_version1.XML
Prepare Create SRP Bundle	• Add new Concerned member state(s) • Update common data as required	Create SRP bundle prepared: UPD_1.6.1-4_CreateSRP_BasedOnRMSProduct_version1.XML
Create SRP via API	POST Bundle with request headers to /upd/api/v1/srp-data-bundle/ • "chapter4" = true or false for the validation rules to apply	
Check operation outcome	MSG_CREATED message expected containing Permanent identifiers for existing RMS & CMS products and products created for each new CMS	
EP304 Get Product Full	RMS & existing CMS: • Contains the new CMS • Procedure type remains unchanged • Contains the Common data that was updated New CMS: • Each new product is only populated with Common data, with status of Provisional, and procedure type of SRP	

5.6. API Manage document

5.6.1. EP403 Create document

Resource Information

Endpoint	POST /v {version}/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/upd/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 /v{version}/DocumentReference?{ param}={value}[&{param}={value}]
Request	
Accept	application/fhir+xml application/fhir+json
Body	n/a
Content-Type	n/a
Response	
Body	Bundle of <DocumentReference>(s) e.g. Bundle Total value=N [entry {DocumentReference Resource Type}] *

Path Parameters

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

Query Parameters

Name	Description
related	Permanent identifier of the product the document is related to
type	Type of document
_summary	Boolean set to true or false. If set to true, the contents of the document is not populated in the response in DocumentReference.content.atttachement,data. There is a url provided but it is not intended that you can use this to retrieve the document.

Example request

GET /v2/DocumentReference?related=MedicinalProductDefinition/600000216133

GET /v2/DocumentReference?type=100000155538

GET /v2/DocumentReference?related=MedicinalProductDefinition/600000216133&_summary=true

5.6.3. EP402 Get/retrieve document

Resource Information

Endpoint	GET /v{version}/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 /v {version}/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/upd/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

As advised in the release notes for 1.5.4, the resolution of two bugs in 1.6.1 requires a change in the payload for EP403 Create document and EP404 Update document.

Country code must now be populated when Create or Update a Document via API. If country code is not populated there will be a validation error.

The two defects are:

UC18 Manage document	API	UPD-8517	1.11.4 (Attached document) country	Attached document country should be Mandatory and give a Validation error if it is not populated. This ticket to be resolved at same time or after UPD-5143
UC18 Manage document	API	UPD-5143	1.11.4 (Attached document) country	Population for Attached document country incorrectly is rejected with a validation error

Example of how to populate:

```
<DocumentReference xmlns = "http://hl7.org/fhir" >
    <status value = "current" />
```

```
    <type>
        <coding>
            <system value = "http://spor.ema.europa.eu/v1/lists/100000155531" />
            <code value = "100000155532" />
        </coding>
    </type>
    <category>
        <coding>
            <system value="http://spor.ema.europa.eu/v1/lists/100000000002" />
            <code value="100000000529" />
        </coding>
    </category>

...
```

The example files have been updated.

5.7. Change required to payload in upcoming release

- None

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
- Submit updates for Marketing authorisation status

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 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 EMA-Test once registration is complete to Request Access to one of the UPD MAH UI roles
  - select *Manage My Access* Reference guide: https://register-test.ema.europa.eu/identityiq/help/requestaccess.html
  - 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 UAT can be found at:

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

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

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6.3. 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 *Manage My Access* Reference guide: https://register.ema.europa.eu/identityiq/help/requestaccess.html
  - use "UPD" as a search option to filter available roles
  - select the appropriate role:

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

- Some UPD-specific screenshots can be found in Annex 1.
- The request for the first "UPD Industry Super User" for your organisation will be approved by EMA.
- The approved "UPD Industry Super User" will manage all other access requests for your organisation.
- Once registered, the UI in the production environment can be found at:

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

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

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7. Known issues

Please refer to Annex II.

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.

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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

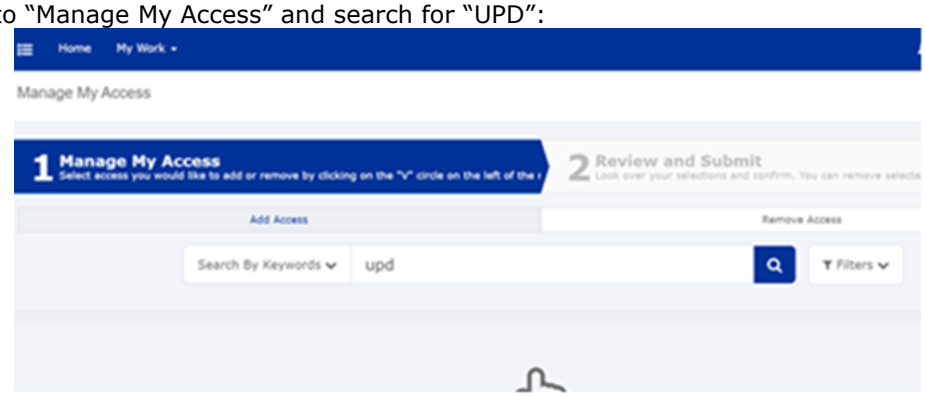
1. UPD 01.03 Registration Process for UPD API in Production (PDF document)
2. UPD 01.03 Registration Process for UPD API in UAT (PDF document)

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_1.6.1_ReleaseNotes_ExampleFilesForAPI (zip file)
10. Nomination letter for EAM CA Super user role

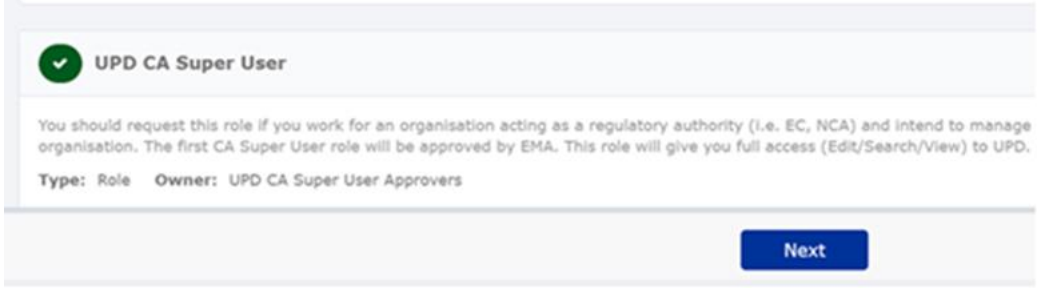
Annex 1: UPD-Specific Screenshots for Registration for an Account for the UI

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 "Manage My Access" and search for "UPD":

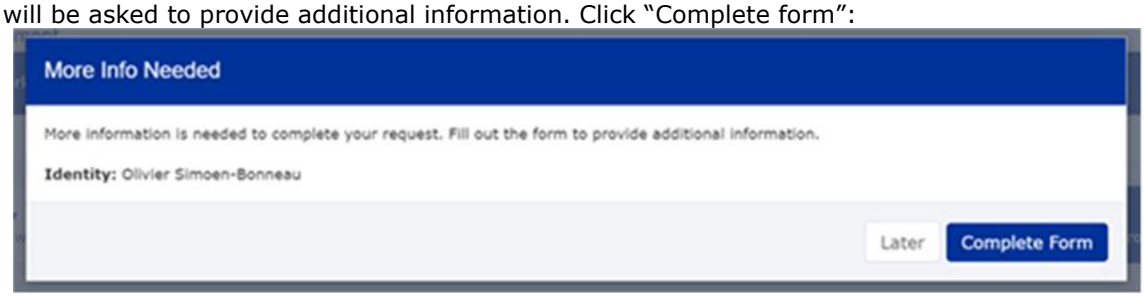


3. Select "UPD Super User"

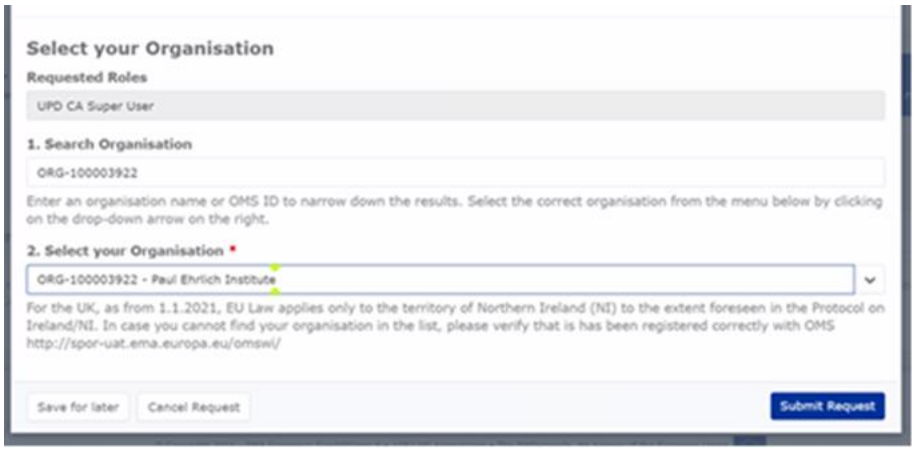


4.Upload a document (see paperclip button to the right) to show your affiliation to your organisation. For now, just upload any document (We'll need the formal document later and will also need this for production)

5. Click "Next"
4. Click "Submit"
5. You will be asked to provide additional information. Click "Complete form":



6. Search and Select your organisation:

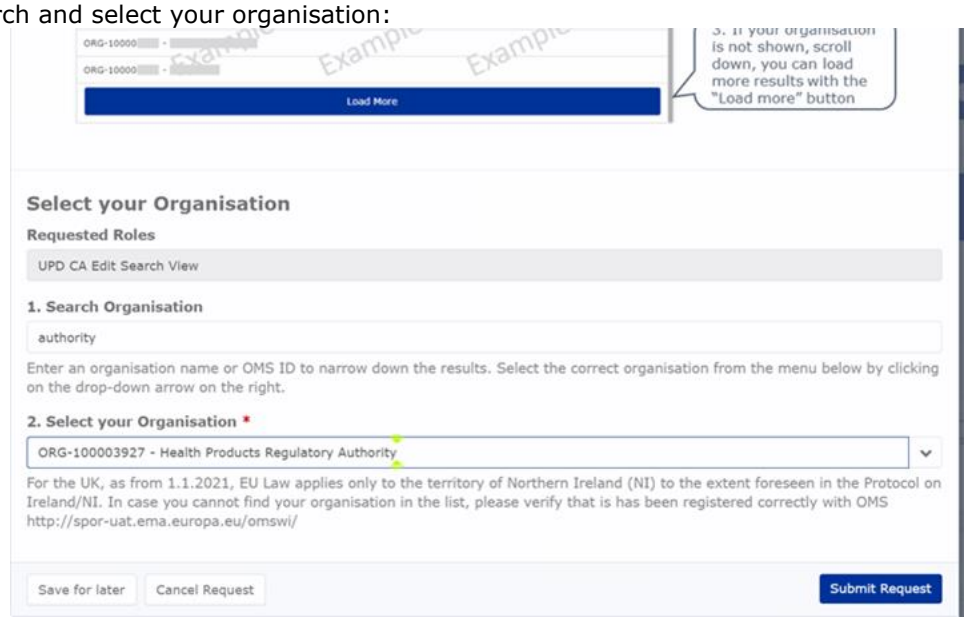


7. "Submit Request"

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 "Manage My Access" and search for "UPD"
3. Select "UPD CA Edit Search View" (read/write) or "UPD CA Search View" (read-only)

3. On the next screen, click "Submit"
4. On the next screen, click "Complete Form"
5. Search and select your organisation:



6. Click "Submit Request"
7. The super user of your organisation will then get a request to approve this.

3. Request the NCA 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 "Manage My Access" and search for "UPD":

3. Select "UPD CA Super User"

4.Upload the Nomination Letter (see paperclip button to the right). You can find the template below.

5. Click "Next"

4. Click "Submit"

5. You will be asked to provide additional information. Click "Complete form":

6. Search and Select your organisation. Contact @UPD-Registration if in doubt on which the correct organisation ID is for your organisation.

7. "Submit Request"

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

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 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 II: 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 API and/or UI user	Issue reference	Vet EUIG Chapter 2 section	Issue Description
UC01 Create product	API	UPD-9005	1.2 Product Record Status	Create DCP - If RMS has Product status of Current when they Create DCP via API, the created products for RMS and CMS will incorrectly have status of Current and not Provisional. This will result in products being published in the Public Portal without national data populated. When this issue is resolved, the status provided by the RMS will be ignored and all products created with the correct status of Provisional
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-8377	1.3 Product identifier	The Product Identifier is not correctly populated on some update screens and shows as [object Object],[object Object]. The product is able to be updated
UC08 Update product	NCA UI	UPD-8377	1.3 Product identifier	Update National Data - Product Identifier is not correctly populated on the update screen and shows as [object Object],[object Object]
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-4810	1.5 (Authorised) pharmaceutical form	Change to Authorised pharmaceutical form results in both old and new value in updated product if existing inline attribute id is not included in the request body
UC01 Create product	API & NCA UI	UPD-9148	1.6 Legal status of supply 5.4 Legal status of supply	UC01 Create product & Update Product SC2 -1.6 & 5.4 Legal status for the supply - term can specify at product level should give validation error if use at package level

UC08 Update product				
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.
UC01 Create product	API	UPD-4747	1.8 Veterinary medicinal product name	DCP create is not ignoring any national product names include in the request. If country is not EU these should be silently ignored. Instead they are being output in the products created for the RMS and each CMS.
UC03 Search product	NCA UI & MAH UI	UPD-8611	1.8 Veterinary medicinal product name	If a product has been updated more than 10 times and has product version 11 or more, the product name in the search results doesn't show the product name from the latest version. It shows the product name from version 10. Using a search criteria of the current name does find the product, and the current name is displayed on the View product screen.
UC08 Update product	API & NCA UI	UPD-8599	1.8 Veterinary medicinal product name	For products under DCP/MRP/SRP when submitting an Update for National data you are not able to delete existing National name leaving only the Common name.
UC08 Update product	NCA UI	UPD-8966	1.8 Veterinary medicinal product name	Update MRP Common data - when editing the common product name the national name for the RMS is displayed instead. Country will not be populated and Language will not be populated unless english has been used for that national name. As a workaround you can copy/paste the correct common name from the name table and make the required update; populate Country & Language with EU & English; and Save changes. The table of names will now include 2 entries. When Update Common is submitted, the RMS & CMS products are updated with the changed name.
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	NCA UI	UPD-6096	1.8.1 Veterinary medicinal product name	One of consecutive embedded spaces within a product name are being removed when displayed in UI. Therefore, if you copy/paste the name from the search screen for example to use when retrieving reference product, no product will be found.
UC03 Search product	NCA UI & MAH UI	UPD-6096	1.8.1 Veterinary medicinal product name	One of consecutive embedded spaces within a product name are being removed when displayed in UI
UC05 View product	NCA UI & MAH UI	UPD-6096	1.8.1 Veterinary medicinal product name	One of consecutive embedded spaces within a product name are being removed when displayed in UI
UC01 Create product UC08 Update product	API & NCA UI	UPD-5531	1.8.2.1 Name type	Do not select term of "Full name" when entering a name part. It is not an option that should be included as an available option. If used, the created/updated product will have an additional full name rather than the intended name part
UC01 Create product	API & NCA UI	UPD-8372	1.8.3 Country / Language	Create MRP/SRP - there should be a validation error if there is not a Common product name when the RMS submits the Create MRP/SRP
UC01 Create product UC08 Update product	API	UPD-8764	1.8.3 Country / Language	It is possible to create a DCP without a Common Name of English/EU, if have a name with Country as EU and some other language, and a name that has Language as English and some other country. If there is no common name with County = EU and Language = English there should be a validation error.
UC01 Create product UC08 Update product	MAH UI	UPD-8759	1.8.3.1 Country	For a CAP Product with country set to EEA, the list term code is set to that of Country instead of Country Grouping. This prevents this product being updated when MAH updates Availability status or Marketing authorisation status
UC08 Update product	API	UPD-4796	1.10.1 QPPV Name	Change to QPPV name is not saved if existing inline attribute id is not included in the request body
UC01 Create product	API	UPD-5975	1.10.3 QPPV Location	There is no validation error if OMS location identifier is not populated for QPPV Location. The Post of the create bundle is accepted. However, response for GET OperationOutcome will show ERR-1002
UC08 Update product	API	UPD-4732	1.10.3 QPPV Location	Change to QPPV File location is not saved (whether existing inline attribute id is included or not in the request body)
UC08 Update product	API & NCA UI	UPD-7246	1.10.3 QPPV Location	Update Common Data - updates to QPPV Location is not saved in the updated version of the product and the old value remains
UC03 Search product	NCA UI & MAH UI	UPD-9428	1.11 Attached Document	There is an error if attempt to view a document using the link on the Search notification card. Documents may be viewed from the View product screen.

UC08 Update product	API & NCA UI	UPD-9448	1.11 Attached Document	Delete of a document does not work, even although receive message back to the UI that submission of the update has been successful. When product is viewed, the deleted document remains. There is no API endpoint available to delete a document. The requirements and resolution for this option are being reviewed.
UC18 Manage document	API	UPD-9748	1.11.4 (Attached document) country	There is a validation error if attempt to populate country code for any of the three EEA countries: Iceland, Liechtenstein, Norway. These three countries should be valid and should not result in a validation 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
UC01 Create product UC08 Update product	NCA UI	UPD-7654	1.11.8 (Attached document) title	UC01 Create MRP/SRP and UC08 Update for any procedure type: the document name for existing documents is displayed as HTML code. In this release you are not able to Update any documents. Submission of the update with the document name displayed like this is successful.
UC01 Create	API & NCA UI	UPD-9467	1.12 Product cross-reference	Create MRP - if there is any Product Cross Reference included when Create MRP, the POST or submission of the Create is successful. However only the RMS product has been updated. GET OperationOutcome shows validation errors and the existing CMS product has not been updated; and no new products created for new CMS
UC01 Create product UC08 Update product	API	UPD-7160	1.12.2 Reference product identifier	There is no validation error if the provided product reference is an alphanumeric value that contains an embedded space. The create/update is accepted but fails with ERR-1001 when view result using GET OperationOutcome. When referencing one of the dummy products available to use the Permanent Identifier of the corresponding product should be specified. For example in UAT env for “VMP data not provided”: <crossReference> <productReference> <reference value="MedicinalProductDefinition/600000004496" /> Please note that the Permanent Identifier values for these dummy products are not the same in UAT env as in PROD env.
UC01 Create product	API	UPD-9384	1.13.2 Manufacturing activity	Create and Update Common Data DCP/MRP/SRP using Chapter 2 rules - there is a missing validation check if a manufacturer responsible for batch

UC08 Update product				certification has not been provided. This should give a validation error and instead the POST is successful and product created
UC01 Create product UC08 Update product	API	UPD-7159	1.13.2 Manufacturing activity	UC01 Create & UC08 Update - Any procedure type - Validation is missing if manufacturingBusinessOperation.type.code is missing or has no value
UC08 Update product	API	UPD-4733	1.9.4 (PSM) File location	Change to PSMF File location is not saved if existing inline attribute id is not included in the request body
UC08 Update product	API & NCA UI	UPD-7246	1.9.4 (PSM) File location	Update Common Data - updates to PSMF Location is not saved in the updated version of the product and the old value remains
UC01 Create product UC08 Update product	NCA UI	UPD-6910	1.9.4 (PSM) File location 1.10.3 QPPV Location	The Validate button doesn't highlight PSMF or QPPV Location as missing mandatory fields if the code/contact value s populated but no location selected (PSMF for Chapter 2 only)
UC01 Create product	API	UPD-8281	2.12 Concerned member states	Create SRP - should receive a validation error if add new CMS for country not in EEA
UC01 Create product	API	UPD-9411	2.2 Authorisation/registration/entitlement number 5.5.1 Marketing authorisation number (package level)	Registered Homeopathic product based on Chapter 2 validation rules: there should be a validation error if submit without any value for Marketing Authorisation Number at either Product or Package level. In this release it is possible to create without populating. This should be populated to comply with the Vet EUIG.
UC01 Create product	API & NCA UI	UPD-9335	2.2 Authorisation/registration/entitlement number 5.5.1 Marketing authorisation number (package level)	Registered Homeopathic product based on Chapter 4 Legacy validation rules: there should be a validation error if submit without any value for Marketing Authorisation Number at either Product or Package level. In this release it is possible to create without populating. This should be populated to comply with the Vet EUIG.
UC01 Create product	API & NCA UI	UPD-9837	2.2 Authorisation/registration/entitlement number 5.5.1 Marketing authorisation number (package level)	Create MRP - if the NP product has Marketing authorisation number populated at Package level the POST is accepted. However there is a validation error when view GET OperationOutcome. The NP product for RMS has been updated but products have not been created for CMS
UC08 Update product	API & NCA UI	UPD-8956	2.2 Authorisation/registration/entitlement number 5.5.1 Marketing	Update National Data DCP/MRP/SRP - there should be a validation error if Marketing Authorisation Number is not populated at any level; or if specified

			authorisation number (package level)	in only one of several packages. At present product can be updated with this data quality issue
UC01 Create product UC08 Update product	API & NCA UI	UPD-5764	2.2 Authorisation/registration/entitlement number 5.5.1 Marketing authorisation number (package level)	UC01 Create UC08 Update - should reject if Marketing Authorisation Number is populated at both Product and Package Level
UC08 Update product	API	UPD-9800	2.4 Responsible authority (organisation)	Update product via API only: when updating the LOC-ID for the Responsible authority, organisation name is not being updated if the RegulatedAuthorization.regulator.display attribute is not included in the Update bundle. This is an optional attribute that should not need to be provided. EMA will investigate if the data can be corrected in the short-term until this issue is resolved.
UC08 Update product	API	UPD-4811	2.4 Responsible authority (organisation) 2.8 Product Owner (organisation)	Change to Responsible authority or Product Owner is not saved if existing inline attribute id is not included in the request body
UC08 Update product	NCA UI	UPD-8651	2.5 Authorisation status	For products under DCP/MRP when submitting an Update for National data the Authorisation status value selected in the UI is ignored and the system always sets to Valid
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-8044	2.5 Authorisation status 2.6 Date of authorisation status change 2.7 Marketing authorisation date	Update National Data - there is missing validation if the following mandatory attributes are not populated when updating national Data for DCP/MRP/SRP procedure product 2.5 Authorisation status 2.6 Date of authorisation status change 2.7 Marketing authorisation date
UC01 Create product	API	UPD-5974	2.7 Marketing authorisation date	Mismatch between Vet EUIG Chapter 2 and implementation for value in RegulatedAuthorization.relatedDate.type.system.value. Guide specifies “http://ema.europa.eu/fhir/authorisationDateType” and implementation is

				using “http://ema.europa.eu/fhir/code-systems/authorisation-date-type”. The example files provided are aligned with the implementation
UC01 Create product UC08 Update product	API	UPD-7714	2.8 Product Owner (organisation)	When Creating/Updating a product via the API there is a missing validation error if LOC-ID not populated for the Marketing Authorisation Holder. The response to the POST will be 202 accepted but the GET OperationOutcome will show ERR-1002. Attribute affected is RegulatedAuthorization.holder.reference and should be populated as per this example (where inline attribute id of 1270116 is only included for an update): <holder id="1270116"> <reference value="http://spor.ema.europa.eu/v1/locations/LOC-100002852" /> <display value="Pfizer Manufacturing Deutschland GmbH" /> </holder>
UC03 Search product	MAH UI	UPD-9253	2.8 Product Owner (organisation)	MAH is 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
UC03 Search product	NCA UI & MAH UI	UPD-8778	2.8 Product Owner (organisation)	Search of products by Product owner is not working. All products are being displayed, filtered by any other criteria that has been specified (that does not also have an issue).
UC08 Update product	API	UPD-9800	2.8 Product owner (organisation)	Update product via API only: when updating the LOC-ID for the Product owner, organisation name is not being updated if the RegulatedAuthorization.holder.display attribute is not included in the Update bundle. This is an optional attribute that should not need to be provided. EMA will investigate if the data can be corrected in the short-term until this issue is resolved.
UC01 Create product	NCA UI	UPD-6911	2.11 Reference member state 2.12 Concerned Member States	Create DCP/MRP: The Validate button does not highlight Reference Member State or Concerned Member States if not populated
UC08 Update product	API & NCA UI	UPD-7278	2.11 Reference member state	Update Common Data - Role cannot be switched from RMS to an existing CMS
UC08 Update product	API & NCA UI	UPD-7147	2.11 Reference member state	Update Common Data - the validation error when attempt to switch CMS of United Kingdom (Northern Ireland) to be the RMS is not clear enough that this is the issue

UC08 Update product	API & NCA UI	UPD-6986	2.11 Reference member state	Update Common Data - United Kingdom (Northern Ireland) is able to be the RMS. This should result in a validation error
UC01 Create product	API	UPD-6561	2.12 Concerned member states	UPD-UC01-AC047 Validation missing as able to select non-EU/EEA country as CMS
UC08 Update product	API & NCA UI	UPD-6982	2.12 Concerned member states	Update Common Data - updates are applied to the product for a CMS that has been removed from the list of CMS and they shouldn't be as no longer a current CMS
UC01 Create	API & NCA UI	UPD-9469	2.13.1 Procedure number	Create MRP - If the National procedure product did not have a Procedure number and no Procedure number is provided when submitting the Create MRP, the create should fail with a validation error. In this release the create is successful without a procedure number.
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-7250	2.13.1 Procedure number	UC08 - Update DCP SC2 National data - Able to successfully edit Procedure number which is Common data so should be non-editable
UC08 Update product	API	UPD-9085	2.13.2 Procedure type	Update DCP by CMS when populating National Data and change procedure type from DCP to MRP fails with validation error related to no Ingredient for Manufactured Item
UC01 Create product	NCA UI	UPD-5908	3 Pharmaceutical Product	Create SRP - Pharmaceutical products section - Labels for 'Edit' and 'Delete' are missing in the table after adding a Pharmaceutical Product
UC05 View product	NCA & MAH UI	UPD-8374	3 Pharmaceutical Product	Pharmaceutical section should list all Ingredients and at present it isn't
UC08 Update product	API & NCA UI	UPD-8582	3 Pharmaceutical Product	Update Common Data - there are validation errors if update common data for a product that has two or more Pharmaceutical products
UC08 Update product	API & NCA UI	UPD-9068	3 Pharmaceutical Product	Update NP - Addition of multiple pharmaceutical products corrupts the product data and referenced Ingredient is not populated in the new Pharmaceutical product. This results in a validation error when attempt to submit a subsequent update
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
UC01 Create product	API	UPD-8062	3.4.1 Tissue 3.4.2 Period	There should be a validation error if Tissue and Period (numeric value and units) in Withdrawal period are not populated when populating a value for

UC08 Update product				the note. If Tissue and Period are not populated but Note is, the create/update POST will pass validation and result in a 202 Accepted response. GET OperationOutcome/id will show that the create/update failed with ERR-1002.
UC01 Create product UC08 Update product	NCA UI	UPD-7863	3.4.3 Note	When creating and updating a product, include a tooltip for cases where withdrawal note is populated but no withdrawal period has been entered.
UC01 Create product	NCA UI	UPD-6432	4.2 Manufacturer	Create MRP - existing Manufacturer of an Ingredient is not being retained when create is submitted. Manufacturer is no longer populated in the RMS product and is not populated in the new products for the CMS
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 & MAH UI	UPD-2940	4.3.1 Substance 4.3.3.1 Reference (active) substance	The preferred name for the Substance or Reference Substance within an Ingredient should be displayed. When searching or viewing a Substance to select for an Ingredient, the preferred name should be displayed. In this release any one of the names for that Substance will be displayed and it may be the preferred name or one of the alternate names. It may appear that Substance search results are including substances that are not applicable to the input search criteria. However, at least one of the substance names will meet the search criteria.
UC03 Search product	API & NCA UI & MAH UI	UPD-2940	4.3.1 Substance 4.3.3.1 Reference (active) substance	The preferred name for the Substance or Reference Substance within an Ingredient should be displayed
UC05 View product	API & NCA UI & MAH UI	UPD-2940	4.3.1 Substance 4.3.3.1 Reference (active) substance	The preferred name for the Substance or Reference Substance within an Ingredient should be displayed
UC01 Create product UC08 Update product	API & NCA UI	UPD-8646	4.3.2 Strength (quantitative composition)	Strength or Reference Strength is only required in an Ingredient if the Substance role is Active. At present the Strength must be specified for all Ingredients irrespective of the role.
UC01 Create product	API & NCA UI	UPD-9109	4.3.2 Strength (quantitative composition) & Reference Substance Strength	When ingredient strength is zero for numerator or denominator there should be a validation error. Numeric value for strength should be greater than zero.

UC08 Update product				
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	NCA UI	UPD-7492	4.3.3.2 Reference strength (concentration)	Update DCP/MRP/SRP National data: if one of the Ingredients in the product has a Reference Strength as concentration, with denominator from the Units of Measurement list, there will be a validation error when update is submitted. Since this is Common data it can't be updated to correct the issue and there submit an update for that product.
UC08 Update product	NCA UI	UPD-7506	5 Packaged medicinal product	Update Common Data for SRP - on some occasions Package information is missing when select to 'Edit common data'. This prevents an update as the Submit button will remain disabled
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	API	UPD-7245	5.1 Package description	UC08 Update SC2 Update DCP National - API - UPD-UC08-AC015 - National package description is not saved in updated product (similar issue to UPD-8289)
UC01 Create product	NCA UI	UPD-7504	5.1.1 Language	Create SRP - the package language should display the RMS language name and not the term code after adding/editing package description
UC08 Update product	NCA UI	UPD-7001	5.1.1 Language	UC08 Update SC2 NAP UPD-UC08-AC035 - Package description has term code ID and not term name after selecting to edit product from view screen
UC01 Create product UC08 Update product	API & NCA UI	UPD-9112	5.1.1 Package description	Create or Update Common data DCP/MRP/SRP - there should be a validation error if the RMS has not input a Common Package Description with language of English
UC08 Update product	API	UPD-7198	5.3 Package identifier	UC08 Update SC2 NAP - API only - should reject update with valid error message if Package Identifier in PackageProductDefinition.identifier is missing
UC08 Update product	NCA UI	UPD-9849	5.4 Legal status for the supply (package level)	Update National Data DCP/MRP/SRP - Legal status of Supply at Package level is not being saved. If it is populated at Product level it is saved correctly.

UC01 Create product	API	UPD-6078	5.5.1 Marketing authorisation number (package level)	When Marketing authorisation number is populated at the package level, the created product incorrectly has RegulatedAuthorization.basis and RegulatedAuthorization.case populated in the resource(s) at package level.
UC08 Update product	API & NCA UI	UPD-8887	5.5.1 Marketing authorisation number (package level)	Update DCP/MRP National Data to edit Marketing Authorization number at Package level fails to update the product. Submission is successful but there is an error when viewing OperationOutcome result
UC08 Update product	API	UPD-9030	5.5.1 Marketing authorisation number (package level)	Updating National data for DCP and specifying Marketing authorisation number at Package Level - the update post is successful with no validation error. When checking status of update using OperationOutcome/ID there are many errors related to RegulatedAuthorization resource
UC08 Update product	API	UPD-5729	5.5.1 Marketing authorisation number (package level)	When Marketing authorisation number is populated at the package level, the created product incorrectly has RegulatedAuthorization.basis and RegulatedAuthorization.case populated in the resource(s) at package level. This prevents this product from being updated and there will be a validation error if an update is attempted.
UC01 Create product	NCA UI	UPD-7511	5.6 Manufactured item (in Package)	Create SRP - when click on button to 'Edit Manufactured Item', the manufactured item is deleted. If update is required to Manufactured item this should be completed in two steps: first Create SRP; and then Update Common Data
UC01 Create product	NCA UI	UPD-8621	5.6 Manufactured item (in Package)	Registered Homeopathic product: Manufactured item at Package level should not be mandatory
UC01 Create product	API	UPD-7015	5.6 Manufactured item (in Package)	UC01 Create - doesn't reject Create payload if there is no ManufacturedItemDefinition resource
UC08 Update product	NCA UI	UPD-9023	5.6 Manufactured item (in Package)	The quantity and units of presentation are not shown in package table for Manufactured Item. The values are displayed if the package is edited. This is only issue with display of information on the UI and no data has been lost from the product
UC08 Update product	NCA UI	UPD-8400	5.6 Manufactured item (in Package)	UPD-UC08-AC041 User should not be able to remove a Manufactured Item used in a package
UC05 View product	NCA UI & MAH UI	UPD-9502	5.6.1 Unit of presentation	On View product screen within each Package, the Unit of presentation for a Manufactured item is not being displayed. This should be shown before the manufactured item quantity.

UC01 Create product UC08 Update product	API & NCA UI	UPD-9338	5.6.2 Manufactured item quantity	The Manufactured Item Quantity will be truncated to 2 decimal places. It should be possible to enter greater precision if required of up to 8 decimal places.
UC01 Create product UC08 Update product	NCA UI	UPD-7395	5.6.2 Manufactured item quantity	Create or Update product for all procedure types: the Manufactured item quantity list for "Unit of measurement" does not show all available options
UC08 Update product	API	UPD-3313	5.6.2 Manufactured item quantity	Validation that Term code is from the specified List ID is missing for Manufactured item quantity
UC01 Create product	API	UPD-7014	5.6.4	UC01 Create NAP Legacy - rejects without Ingredient for Manufactured Item but this is not Mandatory in Chapter 4
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.
UC05 View product	NCA UI & MAH UI	UPD-9004	5.7 Availability status	The Package section shows NA without any title field and is displaying the Availability status
UC08 Update product	NCA UI	UPD-9505	5.7 Availability status	Registered Homeopathic product: any updates to Availability status are not saved in the updated product
UC08 Update product	NCA UI	UPD-7237	5.7 Availability status	Update DCP/MRP/SRP National data - it is not possible to add or update the Availability status or Availability status date for each package. The update will be successful without this populated.
UC03 Search product	NCA UI & MAH UI	UPD-9471	5.7.2 Availability status	The product information card on the Search product screen is not displaying the Availability Status. Instead it is displaying the Product Status.
Authorisation	NCA UI & MAH UI	UPD-7967		User Access request for an EAM role for a second organization overrides the previous access for the first organization
UC01 Create product	API	UPD-9731		Create DCP - duplicate products are being created for some CMS. This is an intermittent issue and we do not have any indication at this time how

			frequently this is occurring. Analysis is ongoing to identify the root cause and also to identify existing procedures that have been affected by this issue
UC01 Create product	NCA UI	UPD-5479	Create MRP - the Reset button does not clear the search results table in the Retrieve Reference Product search dialog
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	API	UPD-8275	Create MRP should give a validation error if the existing product being used is not a NP. There is no validation error if the existing product already has procedure type of MRP
UC01 Create product	API & NCA UI	UPD-9760	Create SRP: Creating SRP based on product under SRP fails
UC01 Create product	API	UPD-4723	PackagedProductDefinition.package.quantity is not an attribute to be populated for a create. When you retrieve the product you will find this attribute has been populated with a value of zero. This will be corrected in a future release.
UC01 Create product	NCA UI	UPD-1663	Search for cross-reference product by marketing authorisation number does not work
UC01 Create product	API	UPD-4279	Submit of a request bundle for DCP procedure with national data populated to the Endpoint for NAP procedure is not rejected
UC01 Create product	NCA UI	UPD-6932	UC01 Create DCP - Products are created but a token error was generated when submitting the request (intermittent issue)
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	API & NCA UI	UPD-8889	When create MRP there should be a Validation error immediately if submit without a Common Package description with language of English. In this release the create is successful but there is a validation error when reviewing the OperationOutcome result when attempting to create product for CMS. Only the RMS product has been updated.

UC01 Create product UC08 Update product	NCA UI	UPD-9802	Create DCP/MRP/SRP or Update Common Data DCP/MRP/SRP - not able to add more than one package. This was possible in the previous release and will be resolved in the next release
UC01 Create product UC08 Update product	API	UPD-9771	Create or Update via API: the request remains in status QUEUED for an abnormally long time. There has been an error during the processing of the request but this is not displayed when reviewing status with Get OperationOutcome and the status always remains as QUEUED.
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	NCA UI	UPD-8500	Ingredient denominator unit value is not populated when Ingredient is displayed in Pharmaceutical product, Manufactured Item or Package sections
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
UC03 Search product	NCA & MAH UI	UPD-8339	Inconsistencies found in Search functionality when paging through search results. This may only be an issue if Export option has been used and then select to navigate to the next page.
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-7998	Search Product : Search should be possible by any product name. Example where were not able to search using National name
UC03 Search product	NCA UI & MAH UI	UPD-7984	Search product works intermittently. Relogging in with same credentials works. This is related to unexpected expiration of the authorisation token.

			Duplicate ticket to UPD-8432. Both retained until resolved so issue can be tracked under either reference
UC03 Search product	NCA UI & MAH UI	UPD-8001	Search product: Search results displays Common name for some products and National name for some products
UC03 Search product	NCA & MAH UI	UPD-8432	Search Products has issue for several users - fails intermittently and shows no search results, even although you know that products do exist that match the search criteria. After logging out and logging in again it works and able to search products. This is related to unexpected expiration of the authorisation token. Duplicate ticket to UPD-7984. Both retained until resolved so issue can be tracked under either reference
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	API & NCA UI & MAH UI	UPD-140	Sort of search results does not work
UC03 Search product	NCA UI & MAH UI	UPD-4275	UC03 Search - Search criteria missing on search screen when click on "Back to search results" option on View product screen
UC03 Search product	NCA UI & MAH UI	UPD-7970	User unable to Search products though after clearing cache it worked again (intermittent issue)
UC05 View product	NCA UI & MAH UI	UPD-5138	Active substances where manufacturer has been populated are not listed in the Manufacturing business operation section.
UC05 View product	NCA UI & MAH UI	UPD-8518	If more than 20 updates have been made to a product, only the first 2 are being displayed when that product is viewed. If an attempt is made to update that product there will be a validation error that the product version number does not match the current version
UC05 View product	NCA UI & MAH UI	UPD-2169	Marketing authorisation number may not always display the correct value
UC05 View product	NCA UI & MAH UI	UPD-3765	Package section of the View screen is only displaying one Ingredient when the linked Manufactured Item contains two or more 2 Ingredients. They should all be listed
UC05 View product	NCA UI & MAH UI	UPD-8061	Under the Manufacturer business operations section, the manufacturer for the active substances detail is missing

UC06 Submit VNRA	MAH UI	UPD-9076	CAP products may not have Authorisation County populated with value of EEA, and may display "European Union" or blank
UC06 Submit VNRA	MAH UI	UPD-8572	Change request: When submitting a VNRA, the conformance will be changed from Mandatory to Optional for the Vnees zip file. As a workaround for a VNRA that has no impact on UPD data or documents, the MAH may attach a zip file does not contain any document with a filename of empty.zip. The NCA will ignore any VNees of this name when approving/rejecting the VNRA.
UC06 Submit VNRA	MAH UI	UPD-8775	In the Submit VNRA screen when retrieving products, the search by Authorisation Country is not working. All products the MAH is responsible for are being displayed, filtered by any other criteria that has been specified (that does not also have an issue).
UC06 Submit VNRA	MAH UI	UPD-8776	In the Submit VNRA screen when retrieving products, the search by Authorisation Status is not working. All products the MAH is responsible for are being displayed, filtered by any other criteria that has been specified (that does not also have an issue).
UC06 Submit VNRA	MAH UI	UPD-8777	In the Submit VNRA screen when retrieving products, the search by Product owner is not working. All products the MAH is responsible for are being displayed, filtered by any other criteria that has been specified (that does not also have an issue).
UC06 Submit VNRA	MAH UI	UPD-9758	MAH submits VNRA and receives message that VNRA has been submitted. However when go to View Submissions page the new submission is not listed, even after waiting for some period of time. At this time this is an issue only observed in the Production environment and investigations are ongoing to establish if submission has been saved and issue is when displaying.
UC06 Submit VNRA	MAH UI	UPD-8440	Overall Date of submission shows red outline if it had been populated, then value removed and individual values added for each variation for each product
UC06 Submit VNRA	MAH UI	UPD-8959	Submission should not fail if Vnees zip file is more than 10 MB
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-9077	The MAH field is being populated with the manufacturer from the Manufacturing Business Operation. This is a display issue in the UI only for

			this screen and the correct value is displayed when use the main search and view products screen. The submission of the VNRA will be successful.
UC06 Submit VNRA	MAH UI	UPD-8774	The retrieve product dialog search options of Starts with and Contains are not valid options for Marketing Authorisation Number and will be removed. You are only able to search using the full number
UC06 Submit VNRA	MAH UI	UPD-9091	When submitting a VNRA, it is not possible to remove the last product remaining in the list of Products by Variation. As a workaround, search and select the required product; and then delete
UC06 Submit VNRA	MAH UI	UPD-9429	When submitting VNRA, not able to select more than one National Procedure product. This is a regression issue in this release and will be corrected in the next release.
UC06 Submit VNRA	MAH UI	UPD-9465	When submitting VNRA, the Responsible authority is not populated with the organisation name and instead is showing "Object, Object"
UC07 Submit Volume of Sales	MAH UI	UPD-8881	CAP products: the download file does not include CAP products. The file should contain one row for each Package Identifier for each country in EEA for CAP products.
UC07 Submit Volume of Sales	MAH UI	UPD-7465	Volume of Sales - Download - Few fields in the downloaded file have 'Not available' as the text even though value is present in product
UC07 Submit Volume of Sales	MAH UI	UPD-7986	Volume of Sales: Validation on submitted volume of sales file need to be reviewed as some columns are being validated that should not be
UC07 Submit Volume of Sales	MAH UI	UPD-7968	Volume of Sales: Column name for the date of the period for which the volume of sales provide is Month/Year and the format to provide date in is YYYY-MM (for example 2022-01). Column name to be changed to match format to be provided
UC07 Submit Volume of Sales	MAH UI	UPD-7992	Volume of Sales: Error incorrectly triggered by the system in the error file after the submission of VoS
UC07 Submit Volume of Sales	MAH UI	UPD-7994	Volume of Sales: System validates the creation date of product from the downloaded file while submitting even when the field is not mandatory

UC07 Submit Volume of Sales	MAH UI	UPD-7991	Volume of Sales: The error file generated by the system didn't contained any rows with information or error messages
UC07 Submit Volume of Sales	MAH UI	UPD-7993	Volume of Sales: When submission file is prepared with Excel and saved using the CSV UTF-8 format, this fails submission and displays error messages which indicate the issue to be with the content of the submission file. If file is saved from Excel with CSV format it can be successfully uploaded.
UC07 Submit Volume of Sales	MAH UI	UPD-8000	Volume of Sales: When user downloads file of packages, receives a warning that download file may be corrupt or unsafe; this doesn't occur for other files
UC07 Submit Volume of Sales	MAH UI	UPD-7985	Volume of Sales: Zero or negative dose factor value does not throw a validation error when submitting the Volume of Sales
UC08 Update product	NCA UI	UPD-7996	Add button in Package medicinal product section needs to have more meaningful caption
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	If there are duplicate inline attribute IDs within a resource, the request will be rejected. The validation message will say that the resource is not included and is mandatory, with no other validation errors in the response. As a workaround, remove the existing inline ID from one attribute so there is no longer duplicate values. This may occur and most frequently affects: - MedicinalProductDefinition.contact - MedicinalProductDefinition.masterFile - AdministrableProductDefinition.routeOfAdministration - AdministrableProductDefinition.routeOfAdministration.targetSpecies - AdministrableProductDefinition.routeOfAdministration.targetSpecies .withdrawalPeriod

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	NCA UI	UPD-7233	UC08 - Update DCP SC2 National data - Refreshing edit page using browser refresh option changes the URL and takes back to search screen
UC08 Update product	API & NCA UI	UPD-6961	UC08 - Update DCP SC2 National data UPD-UC08-AC041 - Able to delete Manufactured item from package and submit update and should get validation error
UC08 Update product	API	UPD-6985	UC08 Update SC2 NAP - API only - Should reject update for NAP using common-data-bundle endpoint
UC08 Update product	NCA UI	UPD-7013	UC08 Update SC2 NAP UPD-UC08-AC015 - Update of NAP from UI is failing with ERR-1001 error for products created via API
UC08 Update product	NCA UI	UPD-7011	UC08 Update SC2 SC3 SC5 - pop-up dialogs to confirm Update or to confirm Cancellation refer to "create" and not "update"
UC08 Update product	API	UPD-7244	UC08 Update SC2 Update DCP National - API - UPD-UC08-AC036 - Updates by CMS to 3 Common Data fields should have been ignored but are updated in their product - product name, pkg desc, procedure number
UC08 Update product	API	UPD-7286	UC08 Update SC2 Update National - API - UPD-UC08-AC016 - Missing Validation if not all Mandatory attributes populated when Update National
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.
UC08 Update product	NCA UI	UPD-7242	UC08 Update SC2 Update National DCP – advised that submission of update from UI was successful and review OperationOutcome. View product and updates have not been applied. Failed with ERR-1002 (intermittent issue related to data in the product)
UC08 Update product	NCA UI	UPD-7008	UC08 Update SC2 UPD-UC08-AC035 - Permanent Identifier, Product Identifier and Product Status are not on screen after selecting to edit product from view screen
UC08 Update product	API	UPD-9709	Update Common Data - the response to Get OperationOutcome in some circumstances does not contain the status of the POST and instead has "Failed to parse JSON encoded FHIR content: Content does not appear to be FHIR JSON, first non-whitespace character was: '<' (must be '{')". This issue

			only arises for some instances where there has been a failure processing the update. It is not expected that this will occur frequently.
UC08 Update product	NCA UI	UPD-8476	Update Common Data: a CMS should not be able to select to Update Common Data for any product under DCP/MRP/SRP procedure. On the View Product screen they should only have the option to select to Edit national data. Authorisation is still to be fully implemented for which products an NCA can update
UC08 Update product	API	UPD-8768 UPD-8769	Update DCP/MRP Common data where payload format is XML may give Get OperationOutcome response of "com.ctc.wstx.exc.WstxUnexpectedCharException: Unexpected character '{' ". This will only occur if there is some issue in the environment and one of the components is not responding within the specified timeout period. The likelihood of this occurring is low.
UC08 Update product	NCA UI	UPD-8979	Update MRP Common data - if a new Ingredient is added, the list of Ingredients in the Manufactured item section does not include the new Ingredient
UC08 Update product	NCA UI	UPD-8380	Update National Data DCP/MRP/SRP - many Common Data attributes are editable and should be read only
UC08 Update product	API & NCA UI	UPD-7387	When a product is updated the version number should be incremented by one. For some updates the version number is incrementing by two and two updates can be seen when viewing the version history for that product. Both versions contain the updates there were made to the product.

UC08 Update product	API	UPD-7424	When updating a product via the API, the update bundle must include the current version number of the product in the attribute MedicinalProductDefinition.version.
			This attribute is not listed in Vet EUIG Chapter 2. You will see that it is populated in response to EP304 Get Product Full GET /MedicinalProductDefinition/id/$everything
			If this attribute is not populated you will get a validation error. From the error message it is not clear what is missing. Validation error is:
			{
			"resourceType": "OperationOutcome",
			"issue": [{
			"severity": "error",

			"code": "business-rule", "diagnostics": "Not able to validate product: MedicinalProductDefinition/600000073934", "location": ["MedicinalProductDefinition"] }] }
UC09 Approve/Reject VNRA	NCA UI	UPD-9494	UC28 View VNRA submissions and UC09 Approve/Reject: cannot download VneeS file. This is an intermittent failure and sometimes download will be successful. This issue affects both the MAH who submitted the VNRA and NCA
UC09 Approve/Reject VNRA	NCA UI	UPD-9853	VNRA for a CAP product: Any NCA is able to Approve/Reject a VNRA for a CAP product and should only be able to View
UC09 Approve/Reject VNRA	NCA UI	UPD-8771	When a VNRA has been submitted for a product under DCP/MRP/SRP, the CMS for a product in the submission should not be able to Approve/Reject the VNRA. Only the RMS should be able to Approve/Reject
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	API & NCA UI	UPD-9432	Nullify product: Action in notification should be **Nullify** and not "**UPDATE, Upload Document**"
UC21 Manage Notifications	NCA UI	UPD-8340	For an update National Data for DCP/MRP/SRP UPD-UC08-AC018, the CMS should only see notifications for their own product. At present they also see notifications for RMS & other CMS products
UC21 Manage Notifications	NCA & MAH UI	UPD-8604	If select to view a product from Notifications screen, when return to search results it listing the default list when select from menu and not previous search results
UC21 Manage Notifications	NCA UI & MAH UI	UPD-8002	Notifications : Product hyperlink (Name and Permanent Identifier) in notifications tab works very slowly (intermittent)

UC21 Manage Notifications	NCA & MAH UI	UPD-8037	Search by authorization country is not functioning.
UC21 Manage Notifications	NCA UI & MAH UI	UPD-8069	Search of notifications is not working for Action options of VNRA Submitted, Approved or Rejected). Selecting any of the VNRA action types will return no search results, even if notifications do exist for the selected Action (and any other search criteria). Filter by Create will also include the VNRA and VoS related notifications.
UC21 Manage Notifications	NCA UI & MAH UI	UPD-9815	The date in DataGrid (search results) for VNRA Approved/Rejected should be the date the VNRA was approved or rejected (the Action date) and not the Decision date
UC21 Manage Notifications	NCA UI & MAH UI	UPD-9466	The drop-down list to filter by Action does not contain all of the possible values
UC21 Manage Notifications	NCA UI & MAH UI	UPD-9878	Notifications are not displayed in descending date order when select from menu. There is one entry with all values as N/A. This issue only occurs in the Production environment
UC24 Marketing authorisation status	MAH UI	UPD-9093	The Action for an Update of Marketing Authorisation Status is displayed as "UPDATE, Upload Document" instead of "Update MA Status"
UC24 Marketing authorisation status	MAH UI	UPD-9459	The total number of products matching the search criteria may not be correct. Products that match the search criteria where the product status is not Current or authorisation status is not Valid or Suspended are being counted which is not correct. These products are not being listed in the search results (which is the expected result).
UC24 Marketing authorisation status	MAH UI	UPD-8997	When MAH is updating marketing authorisation status, after selecting a date using the date picker, the month and day of the selected date are shown the wrong way around in the UI. The correct date that was selected in the date picker is updated in the product
UC27 View Submission Volume of Sales	MAH UI	UPD-6559	UC27 - Volume of Sales - UPD-UC27-AC021 Not able to view submissions that are in progress

UC27 View Volume of Sales	NCA & MAH UI	UPD-7989	Messages displayed by the system on the View Volume of sales screen should be more business orientated
UC27 View Volume of Sales	NCA UI & MAH UI	UPD-9123	There is an error message when navigate to the last page of the search results, and it is not possible to view the last page
UC27 View Volume of Sales	NCA UI & MAH UI	UPD-6056	UC27 - Volume of Sales - View values as MAH/NCA - system defaulting Volume of Sales to 0 has not been implemented
UC27 View Volume of Sales	MAH UI	UPD-9393	When MAH views Submissions for Volume of Sales, there is a hyperlink on the submission filename. This hyperlink should not exist and it should not be possible to download the file that was submitted.
UC27 View Volume of Sales	MAH UI	UPD-9741	When select to view submissions of Volume of Sales the progress control remains on the screen and the view submission page is not loaded
UC28 View VNRA	NCA UI	UPD-8043	UC28 View VNRA NCA is able to view Submissions for products that are not under their responsibility
UC28 View VNRA	NCA UI & MAH UI	UPD-9494	UC28 View VNRA submissions and UC09 Approve/Reject: cannot download VneeS file. This is an intermittent failure and sometimes download will be successful. This issue affects both MAH who submitted the VNRA and NCA.
UC28 View VNRA	NCA UI & MAH UI	UPD-7486	View VNRA: The date formatting is wrong in the "view VNRA submissions" Page
UC28 View VNRA	NCA UI & MAH UI	UPD-9383	When viewing a VNRA for a National Procedure product, the Responsible authority is not correctly displayed and as the name of the Product owner
UC34 Bulk Upload for Documents	NCA UI	UPD-9412	Bulk Upload of Documents Notification: There is a spelling error in Action value and it has Bul instead of Bulk
UC34 Bulk Upload for Documents	NCA UI	UPD-7440	Bulk Upload of Documents: There is a spelling error in the static text on the screen related to the file size exeed vs. exceed
UC34 Bulk Upload for Documents	NCA UI & MAH Ui	UPD-9412	The Action value has a typo in the name for notifications where document has been added/updated by the NCA using UC34 Bulk Upload functionality