UPD Release Notes 1.5.2-0

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 1.5.2-0. The main difference with the previous version, v 1.5.1 released on 13 December 2021, 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).

The current version of the UPD allows the creation of products approved under DCP/MRP procedure via the Decentralised procedure. 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.

The high-level functionality provided in this release is:

- API:
    - RMS can create DCP products (data and documents)
    - RMS and CMS can complement DCP/MRP product with national DCP/MRP data and documents
    - NCA can create and update NAP products (data and documents)
    - Search/view product (data and documents)
- NCA UI:
    - RMS can create DCP products (data and documents)
    - RMS and CMS can complement DCP/MRP product with national DCP/MRP data (including documents)
    - NCA can create NAP products (data and documents)
    - NCA can update NAP products (data and documents)
    - Search/view/export product (data and documents)
    - Notifications for Create and Update of products
    - View Volume of Sales information (only in scope for use in UAT and not in PROD)
    - View and Approve/Reject VNRA submissions (only in scope for use in UAT and not in PROD)
- MAH UI (only in scope for use in UAT and not in PROD):
    - Search/view/export product (data and documents)
    - Notifications for Create and Update of products
    - Download, Submit and View Volume of Sales information
    - Submit VNRA and View VNRA submissions
- 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
- Additional functionality for the components of the UPD that were delivered in release 01.02, i.e. the core UPD Repository, Application Programming Interface (API), the NCA User interface and the document management functionality.

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

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.

2. Changes made compared with 1.5.1-0

2.1. New functionality

API:

- none

NCA UI:

- when RMS and CMS complement DCP/MRP product with national DCP/MRP data, documents can now be added or existing document updated
- when NCA update NAP products, documents can now be added or existing document updated

MAH UI (only in scope for use in UAT and not in PROD):

- none

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.

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-6999	1.10.3 QPPV Location 2.8 Product owner (organisation)	UC08 Update SC2 NAP/DCP National data & SC2 DCP Common data - UI only - UPD-UC08-AC035 QPPV Location and MAH Holder were swapped around on screen after selecting to edit product from view screen. This no longer happens and the correct values are displayed in the edit screen.
UC08 Update product	NCA UI	UPD-6962	1.11 Attached Document	UC08 - Update SC2 DCP National data – New national documents were not saved when updating product to add National data, even although you received successful update message. Updates to national data were saved. New documents are now saved.
UC01 Create product	NCA UI	UPD-5126	1.11.4 (Attached document) country	Attached document country value was not populated into table of attached documents, and this value was not saved when product created and the documents saved. Therefore, when view product the document country value was not displayed. This issue has been resolved.

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	NCA UI	UPD-7308	1.11.6 (Attached document) language	NCA was not able to add a document with language of Norwegian when creating or updating a product. Norwegian is now in the list of languages.
UC01 Create product UC08 Update product	API & NCA UI	UPD-7658	1.11.6 (Attached document) language	When creating or updating a product for any procedure type, you were not able to add a document with the language of Icelandic. This is now an available language.
UC01 Create product	NCA UI	UPD-3319	1.12 Product cross-reference	It was not possible to save any product cross-reference. When you searched for and selected a product as the cross-reference this was not displayed on the create screen and was not saved when the product is created. This has been resolved and you can now add a product cross-reference.
UC05 View product	NCA UI & MAH UI	UPD-4262	1.12 Product cross-reference	Cross-referenced products were not displayed. This issue has been resolved and any cross-referenced product is now displayed.
UC01 Create product	NCA UI	UPD-6998	1.12.1 Product cross-reference type	After retrieving the cross reference product, the cross reference type showed as "undefined". This issue has been resolved and the type is 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	NCA UI	UPD-7966	2.1 Authorisation/registration/entitlement type	Any procedure type: 2.1 Authorisation/registration/entitlement type should not have been an enterable field on the screen and the system should populate this attribute. This issue has been resolved and field is no longer included on the screen.
UC01 Create product UC08 Update product	NCA UI	UPD-5676	2.2 Authorisation/registration/entitlement number 5.5.1 Marketing authorisation number (package level)	UC01 Create & UC08 Update - all procedure types - tool tips for 2.2 5.5.1 Authorisation number were out-of-date and not aligned with IG. The tool-tips have been updated.
UC03 Search product	NCA UI & MAH UI	UPD-4758	2.5 Authorisation status	Authorisation status value was N/A in extended details. The correct value is now displayed.
UC05 View product	NCA UI & MAH UI	UPD-4758	2.5 Authorisation status	Authorisation status value was N/A. The correct value is now displayed.
UC08 Update product	NCA UI	UPD-7003	2.6 Date of authorisation status change 2.7 Marketing authorisation date	UC08 Update SC2 NAP UPD-UC08-AC035 - Marketing authorisation date and Date of authorisation status change were swapped around on screen after selecting to edit product from view screen. This issue has been resolved and no workaround is now required.

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-7219	2.6 Date of authorisation status change 2.7 Marketing authorisation date	UC08 Update SC2 DCP Update National Data - UI Only - UPD-UC08-AC015 – **First update to add National data only:** Marketing authorisation date and Date of authorisation status change were swapped in updated product. This issue has been resolved and no workaround is now required.
UC08 Update product	NCA UI	UPD-7006	3.3 Target Species 3.4 Withdrawal period	UC08 Update SC2 NAP UPD-UC08-AC035 - It was not possible to edit Target Species or Withdrawal Period on screen after selecting to edit product from view screen. This issue has been resolved.
UC08 Update product	NCA UI	UPD-7005	3.4 Withdrawal period	UC08 Update SC2 NAP UPD-UC08-AC035 - Withdrawal period values were incorrect on screen after selecting to edit product from view screen. This issue has been resolved and the correct values are now displayed.
UC08 Update product	API	UPD-5187	4 Ingredient	When adding an Ingredient, the update post was successful. However the new ingredient had not been saved and therefore not included when you retrieved the updated product. This issue has been resolved.
UC08 Update product	NCA UI	UPD-7285	5 Packaged medicinal product	UC08 Update SC2 NAP - Adding a new package failed because of empty package identifier field. This issue has been resolved and now able to add another package.

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-7000	5.2 Pack size	UC08 Update SC2 NAP/DCP National data & SC3 Common data - UI only - UPD-UC08-AC035 Pack size quantity was an incorrect value on the screen after selecting to edit product from view screen. This issue has been resolved and the correct pack size quantity is displayed.
UC01 Create product UC08 Update product	API & NCA UI	UPD-2235 UPD-5708	5.5.1 Marketing authorisation number (package level)	NAP Create – implementation for Marketing authorisation at package level was incomplete. This has been completed and Marketing authorisation number can be populated at package level. Authorisation country at Package level should be optional but was mandatory. This issue has been resolved.
UC01 Create product	NCA UI	UPD-5128	5.6 Manufactured item (in Package)	If there are two or more Manufactured Items with the same Ingredient(s), and no Unit of Presentation: it was not possible to identify which manufactured item to select as the manufactured dose form was not shown. This issue has been resolved.
UC05 View product	NCA UI & MAH UI	UPD-5129	5.6 Manufactured item (in Package)	Where a package has more than one manufactured item these were not all listed and only values for one was displayed. This issue has been resolved and all manufactured items in a package are now shown.

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue that has been resolved
UC01 Create Product	NCA UI	UPD-4344		When creating a product, sometimes the list of Manufactured Items when adding a Package would be empty and therefore not able to add package or create product. Issue also existed when selecting Ingredient for a Manufactured Item. This issue has been resolved.
UC01 Create product	NCA UI	UPD-6217		You were advised Create DCP was successful. On a search of products using the product name the results will confirm that products have been created for the RMS and each CMS. However, when viewing the Product card for each CMS Common Documents may not have been loaded for that CMS product. In addition a notification was not created for that CMS product. This issue may have affected all or some of the CMS products. This issue has been resolved.
UC01 Create product	API	UPD-6615	5.5.1 Marketing authorisation number (package level)	Incorrectly getting Validation error when specify Marketing authorisation number at Package level (regression issue as this worked in the previous release). (As a workaround the Marketing authorisation number could have been specified at the product level). This issue has been resolved.

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-7231	5.7.3 Availability status date	UC08 - Update SC2 DCP National data - Availability status date format was incorrect in the UI after selecting a value. This issue has been resolved.
UC03 Search product	NCA UI & MAH UI	UPD-5144		Search by Marketing authorisation holder now works.
UC05 View product	NCA UI	UPD-6621		Selected to Edit NAP product and get error message advising there is a problem and try again later. However, even if you tried later still received the same error message, and were not able to update that particular NAP product via the UI. This issue has been resolved.
UC08 Update product	NCA UI	UPD-7951		When you selected to edit from the View product screen, there was an error displayed "there is a problem please try again later". This was an intermittent issue and did not occur for all products. This issue has been resolved.
UC21 Manage Notifications	NCA UI & MAH UI	UPD-8029		The action name type should display full word and was only displaying the first letter (C instead of Create etc). This issue has been resolved for new notifications for creates and updates made in 1.5.2-0 onwards. Filtering of notifications by Action will still include those that display single letter or the full word.

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	UPD-8038		Notifications: Complete product name was not displayed in search result table. It was only displaying the first word. This issue has been resolved.
UC06 Submit VNRA	MAH UI	UPD-7650		After successfully submitting a VNRA, a message is displayed on the submission screen. You were not able to leave the submission screen by selecting an option from the Menu. This issue has been resolved.
UC28 View VNRA	NCA UI & MAH UI	UPD-7664		Notifications for Submission of a VNRA have been implemented.
UC28 View VNRA	NCA UI & MAH UI	UPD-7230		Submitted VNRA were not being displayed in the list of Submissions. This issue has been resolved.
UC07 Submit Volume of Sales	MAH UI	UPD-6514		UC07 - Volume of Sales - Submission of VoS - Species column is accepting incorrect values as it is validating against the wrong RMS list. Instead of validating against Species it was using the Target Species list. This issue has been resolved and it now validates against the correct Species list.
UC07 Submit Volume of Sales	MAH UI	UPD-5566		UC07 - Volume of Sales - Submission of VoS – Notifications are now generated upon successful submission
UC07 Submit Volume of Sales	MAH UI	UPD-7236		UC07 Submit VoS - function execution takes more than 30 minutes for some files and may time out. Some improvements have been made in this release.

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue that has been resolved
UC27 View Volume of Sales	NCA UI & MAH UI	UPD-7216		UC27 - Volume of Sales - View - Not always able to download Sales for a user affiliated with multiple organisations. This issue has been resolved.
UC07 Submit Volume of Sales	MAH UI	UPD-7990		Volume of Sales: Download file of packages was missing values of Country and Country identifier (affects some products and packages but not all). This issue has been resolved.

2.3. New issues

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue description
UC08 Update product	NCA UI	UPD-8376	1.8 Veterinary medicinal product name	When updating a product (any procedure type) you will receive a validation error regarding the List ID for Country of the Product Name. The system has incorrectly changed the ID from the value for the Country list to that of the Country Grouping List. Error message will be similar to: "Unknown code 'http://spor.ema.europa.eu/v1/lists/100000000003#100000000395' for 'http://spor.ema.europa.eu/v1/lists/100000000003#100000000395'" Workaround: select "Edit" for name, and then "Save changes". No actual change needs to be made to the product name text or dropdown values selected for country or language.

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue description
UC18 Manage document	API	UPD-8603	1.11.1 (Attached document) identifier	EP404 Update Document - Update of a document is being treated as a create and a new DocumentReference is being added with new DocumentReference.id
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
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 results in ERR-1002. As a workaround, if the Manufacturing Business Operation is deleted and then readded with all of the required manufacturing activities the update is successful
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	NCA UI	UPD-8399	3.1 Ingredient	Update product that has more then one Pharmaceutical product. There will be a validation error when update is submitted if one of the Pharmaceutical Product has no linked Ingredients. Workaround is to ensure at least one Ingredient is linked for each Pharmaceutical Product
UC08 Update product	API & NCA UI	UPD-8289	5.1 Package description	Update National Data for DCP/MRP/SRP - the national Package description added by RMS or CMS are not being saved even although advised update has been successful
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
UC01 Create product UC08 Update product	NCA UI	UPD-7983	5.6.2 Manufactured item quantity	Millilitre(s) has to be typed in full in order to select from Unit of Measurement drop down list for Manufactured item quantity within Package section

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue description
Authorisation	NCA & MAH UI	UPD-8434		Authorisation : User is not able to use the UPD portal as expected when assigned to multiple roles for different organizations
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-8500		Ingredient denominator unit value is not populated when Ingredient is displayed in Pharmaceutical product, Manufactured Item or Package sections
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	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.
UC03 Search product	NCA & MAH UI	UPD-8435		Number of search results may differ for two users with same roles for same organization
UC06 Submit VNRA	MAH UI	UPD-8439		UC06 Submit VNRA UPD-UC06-AC027 Adding more products to the list of VNRA replaces already existing products and instead should have added to the existing products
UC06 Submit VNRA	MAH UI	UPD-8440		Overall Date of submission shows red outline if it had been populated, then value removed and individual values added for each variation for each product

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue description
UC06 Submit VNRA	MAH UI	UPD-8441		Removing variation from one product removed variations of other product as well
UC06 Submit VNRA	MAH UI	UPD-8466		Date of implementation is changed to a common date after submitting the variation if different dates have been input for each combination of variation and product
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-8380		Update National Data DCP/MRP/SRP - many Common Data attributes are editable and should be read only
UC09 Approve/Reject VNRA	NCA UI	UPD-8056		UC09 Approve/Reject VNRA - no message if submission was successful or failed; & first 2-3 times Submit Approval/Rejection get an error message and on 2nd-3rd attempt it is Accepted
UC09 Approve/Reject VNRA	NCA UI	UPD-8202 UPD-8438		Date of decision that is saved is not the value entered by NCA. It appears to be the Date of implementation + 1 month
UC09 Approve/Reject VNRA	NCA UI	UPD-8436		Decision comment still shown in variation summary even after removing it (after entering and deleting before submitting the approval or rejection)
UC21 Manage Notifications	NCA & MAH UI	UPD-8037		Search by authorization country is not functioning.
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

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue description
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
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
UC28 View VNRA	NCA & MAH UI	UPD-8201		Responsible Authority now shows label in field of "Responsible authority (organisation)" and need to hover over to view name

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

UPD version 1.4.4-0 is based on the July 2021 version of the Vet EU IG.

Note that two aspects of that version of the IG are not yet implemented but will be in next versions of UPD:

3.1. Presentation strength

Chapter 2 sections 4.3.2.1.1 - Strength (presentation single value) and 4.3.3.1.2. Reference strength

- The denominator should be expressed by a numeric value and a unit (e.g. tablet) where the unit is a **unit of presentation**. Reference to unit of measurement has been deleted
- A product created with denominator using Unit of Measurement will be accepted and doesn't give a validation error. This will be corrected in a future release.
- For this release only use a term from Unit of Presentation so that created products will comply with the revised rules and avoid the need to correct the products in the future.
- This applies to products created using the NCA *UI or API*.

3.2. Date of authorisation status change for Legacy products

For **Date of authorisation status change,** section 2.6 Chapter 2:

- The January 2021 Vet EU IG specified that this attribute is mandatory for legacy products.
- The July 2021 Vet EUIG has changed this and it is no longer mandatory.
- The validation rules will be updated in a future release.

- For this release, a value will still need to be provided (if unknown, suggested to use current date).

3.3. 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.

"x" within each scenario is used to indicate what was expected to be valid scenario.

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	x Amoxicillin 3H2O	x 300 mg/tablet			Amoxicillin 3H2O 300 mg/tablet	Yes	
2	Amoxicillin	500 mg/tablet	x	x	Amoxicillin 500 mg/tablet	No and not fixable as this is a FHIR requirement to always have substance specified.	Report as substance
3	X Amoxicillin	500 mg/tablet	X empty	X empty	Amoxicillin 3H2O expressed as amoxicillin 500 mg/tablet	No – bug to fix UPD-7228	Recommendation: Report the reference substance as substance.
4	X Amoxicillin 3H2O	X 300 mg/tablet	X		Amoxicillin 3H2O 300 mg/tablet expressed as amoxicillin	No – bug to fix UPD-7228	Recommentation: just report the substance + strength and do not report Ref Substance
5	X Amoxicillin 3H2O	X 300 mg/tablet	X Amoxicillin	X 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 – CAP/NAP/National Registered products – Manual Key In
  - Scenario 2 Create Product – Decentralised Procedure – Manual Key In
  - Scenario 5 Cancel Create Product
  - Able to Create NAP or DCP 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 NAP and National data for DC/MR procedures (data only)
  - Scenario 5 Cancel Update 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-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 (only in scope for use in UAT and not in PROD)
- UC09 Approve/Reject Variation Not Requiring Assessment via UI (only in scope for use in UAT and not in PROD)

Other menu items or the edit option to update common data for a DCP/MRP/SRP product should not be used as these are not in scope for this release and are not fully implemented.

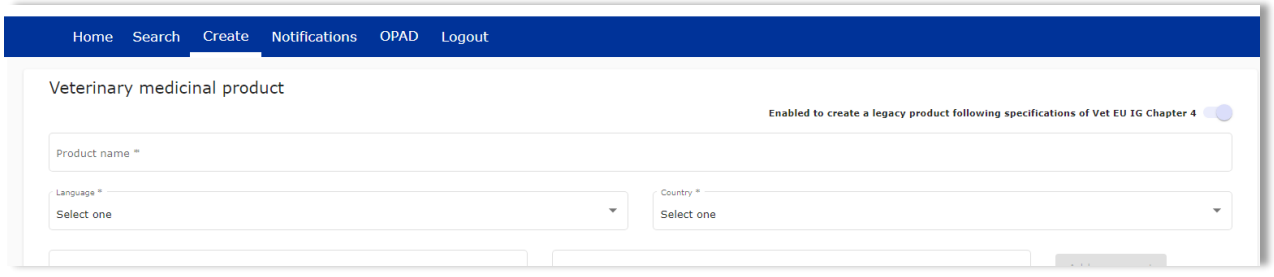
Authorisation has not been implemented in this release to control menu items based on the users role.

Supported browsers for the NCA UI are Chrome and Edge.

4.2. Apply Chapter 4 Legacy or Chapter 2 Validation rules

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

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



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.
UPD-5771	4.3.2.1.1 Strength (presentation single value)	May 21 Vet EUIG specified that the denominator may be a term from the Unit of Presentation or the Unit of Measurement list. July 21 Vet EUIG has updated this and the denominator may only be a term from the Unit of Presentation list. When entering strength for an ingredient and selecting a Unit of Measurement term for the denominator (for Per), please only select "Concentration single value". The Create screens will be updated to implement this change in a future release.

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. Send an email requesting access to the NCA UI in the UAT environment to UPD-Registration@ema.europa.eu. Please send the request from your NCA email address so that EMA can verify it. 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, email UPD-Registration@ema.europa.eu.

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 to submit your legacy product data manually, 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, email UPD-Registration@ema.europa.eu.

5. UPD API

5.1. 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
EP309 Create Product	NAP: POST Bundle - Create/Update resources in the bundle DCP: POST dcp-bundle - Submit a DCP payload Refer to **5.5.1. Endpoint for NAP and DCP**
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

SPOR API Specification v2	API Manager
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
EP401 Search document	GET DocumentReference - Search for DocumentReference Note: previous release referred to EP51 and now changed to the correct EP number of EP401.
EP402 Get/Retrieve document by Id	GET DocumentReference - Get a DocumentReference by Id Note: previous release referred to EP51 and now changed to the correct EP number of EP402.
EP403 Create document	POST DocumentReference - Create a DocumentReference Note: previous release referred to EP51 and now changed to the correct EP number of EP403.
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. Note: previous release referred to EP51 and now changed to the correct EP number of EP404.

5.2. 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 5.1. 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.

5.3. Apply Chapter 4 Legacy or Chapter 2 Validation rules

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

Request Header: Key	Value	Validation rules applied
chapter4	*Request header not included*	Vet EUIG Chapter 2
chapter4	false	Vet EUIG Chapter 2
chapter4	true	Vet EUIG Chapter 4 Legacy

5.4. Scope of this release for API

- Create DCP based on Chapter 4 Legacy or Chapter 2 rules
- Create NAP based on Chapter 4 Legacy or Chapter 2 rules
- Update single product based on Chapter 4 Legacy or Chapter 2 rules
    - For DCP and changes to Common data by the RMS: the same change will need to be made to each product
    - 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
    - Nullifications were not in scope for this release
- RMS and CMS can complement DCP/MRP product with national DCP/MRP data and documents
- Search and retrieve products
- Upload, search, retrieve, and update Documents

5.5. API EP309 Create product

5.5.1. Endpoint for NAP and DCP

There are two endpoints for EP309 Create Product depending on the procedure type.

5.5.1.1. Nationally authorised procedure product (NAP)

- As specified in SPOR API v2 Specification section 6.4.12
- POST /v{version} {root of server for this version}
- UAT for example is: POST https://spor-uat.azure-api.net/pms/api/v2

5.5.1.2. Decentralised procedure product (DCP)

Endpoint	POST /upd/api/v1/dcp-bundle/
Request	
Accept	application/fhir+xml application/fhir+json
Body	<Bundle (type=transaction) of MedicinalProductDefinition and other types

	e.g. Bundle type=transaction entry MedicinalProductDefinition request method value=POST [entry fullUrl value="AuthorizationUuid" RegulatedAuthorization request method value=POST] * [entry fullUrl value=TempUuid (another temporary local id) {other Medicinal Product type resources (not MedicinalProductDefinition itself) } request method value=POST] *
Content-type	application/fhir+xml application/fhir+json
Response	
Body	<Bundle (type=transaction-response)> e.g. Bundle type value="transaction-response entry response (states id of created resource) [entry response (for other linked child resources)] *

Query Parameters

None

Example Request

For UAT environment: POST https://spor-uat.azure-api.net/upd/api/v1/dcp-bundle

5.5.2. Creating of products for DCP 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.

5.5.3. Key changes in valid request bundle for create

Attribute	Change
	No changes are required for this release

5.5.4. API EP309 Create product example request bundles

Examples for EP309 Create Product. 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_1.5.1-0_DCP_Chpt2_C2_Mandatory_VetIG.JSON UPD_1.5.1-0_DCP_Chpt2_C2_Mandatory_VetIG.XML UPD_1.5.1-0_DCP_Chpt2_C110_VetEUIG_AllData.JSON UPD_1.5.1-0_DCP_Chpt2_C110_VetEUIG_AllData.XML
DCP	Chapter 4 Legacy	UPD_1.5.1-0_DCP_Legacy_C2_Mandatory_VetIG.JSON UPD_1.5.1-0_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_1.5.1-0_NAP_Chpt2_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel.JSON UPD_1.5.1-0_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)

Procedure type	Validation rules	Example file
		UPD_1.5.1-0_NAP_Chpt2_C111_VetEUIG_AllData_MANumber_AtPackageLevel.JSON Note: due to known issue UPD-6615, specifying at package level will fail. 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 • Please note: due to issue UPD-6615, this example fails validation. However, example remains included in this release to illustrate the expected values to be populated. In a future release it will be possible to create/update a product with marketing authorisation at the package level.
NAP	Chapter 4 Legacy	UPD_1.5.1-0_NAP_Legacy_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel.JSON UPD_1.5.1-0_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)

Procedure type	Validation rules	Example file
		• 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.

5.6. API EP311 Update product

5.6.1. Endpoints for Update NAP and Update DCP/MRP National Data

There are two endpoints released for UC08 Update Product Scenario 2 Update a single Product – Common & National data for NAP and National data for DC/MR procedures

Request header of is_update = true should be used for both endpoints.

Another endpoint to Update Common Data for DC/MR/SR procedures will be implemented in a future release.

5.6.1.1. Nationally authorised procedure product (NAP)

- As specified in SPOR API v2 Specification section 6.4.12
- POST /v{version} {root of server for this version}
- UAT environment for example is: POST https://spor-uat.azure-api.net/pms/api/v2

5.6.1.2. Update National Data for DCP/MRP/SRP procedure product

- POST /upd/api/v1/national-data-bundle/
- Refer to API Manage developer portal
- UAT environment for example is: POST https://spor-uat.azure-api.net/upd/api/v1/national-data-bundle/
- Known issue UPD-6933 for Accept request header: As a workaround need to use value of "application/fhir+json" or "*/*"

5.6.2. 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

5.6.3. How to use update product endpoint

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	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 • "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

5.7. API Manage document

5.7.1. 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 : 7a88176d-10f9-4db3-8fa0-4e4ae4594df7

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_1.5.1-0_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)

5.7.2. 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 = 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/600000152000

GET /v2/DocumentReference?type=100000155538

GET /v2/DocumentReference?related=MedicinalProductDefinition/600000152000&_summary=true

5.7.3. 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/4056a317-5a2e-45ba-87c2-f0fa3873047f

5.7.4. 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_1.5.1-0_Doc_EP402_GetDocument_version1.XML
- Update posted: UPD_1.5.1-0_Doc_EP404_UpdateDocument_BasedOnVersion1.XML
- Response to POST: UPD_1.5.1-0_Doc_EP404_ResponseAfterUpdate.XML
- GET of document after update: UPD_1.5.1-0_Doc_EP402_GetDocument_AfterEP404Update_version2.XML

6. MAH UI

6.1. Scope of this release for MAH UI

This was included in the scope of the completed UAT and will be used in Production from January 2022.

- 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

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

Authorisation has not been implemented in this release to control menu items based on the users role.

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 a 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 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. Send an email requesting access to the MAH UI in the UAT environment to UPD-Registration@ema.europa.eu. Please send the request from your MAH email address so that EMA can verify it.
    - 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, email UPD-Registration@ema.europa.eu.

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

Requests for access in production for MAH users will not be approved for this release.

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 writing to UPD-User-Support@ema.europa.eu .

In order 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

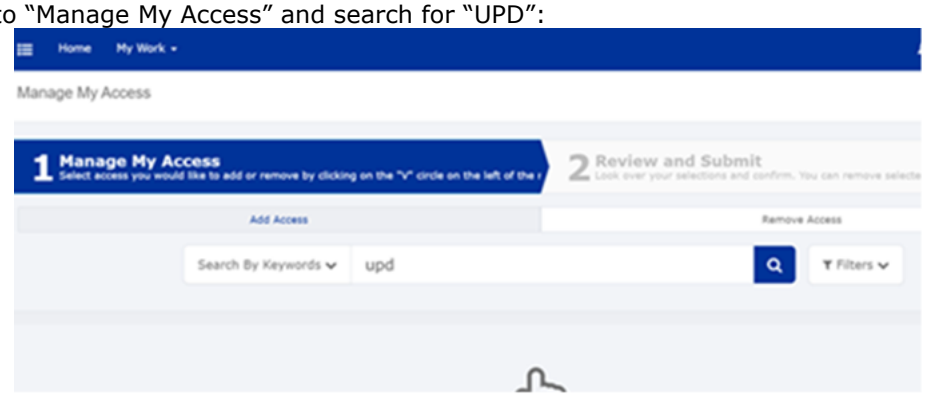
9. References

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_1.5.1-0_ReleaseNotes_ExampleFilesForAPI (zip file)
10. Nomination letter for EAM CA Super user role

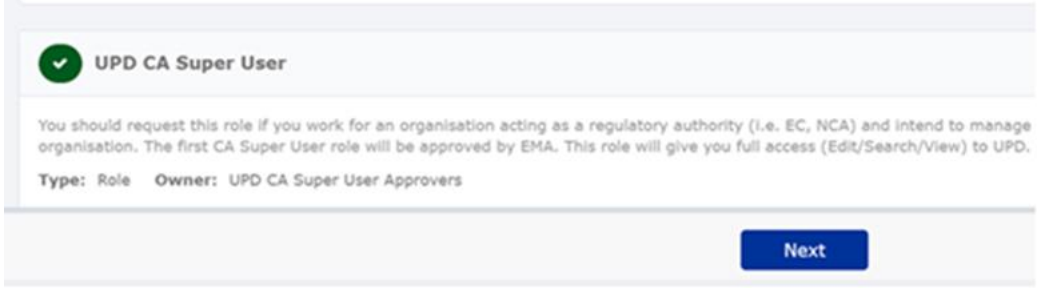
Annex 1: UPD-Specific Screenshots for Registration for an Account for the UI

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":

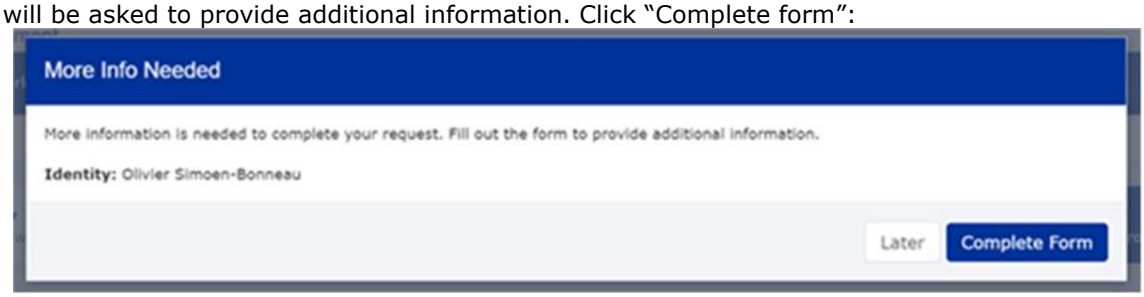


3. Select "UPD Super User"

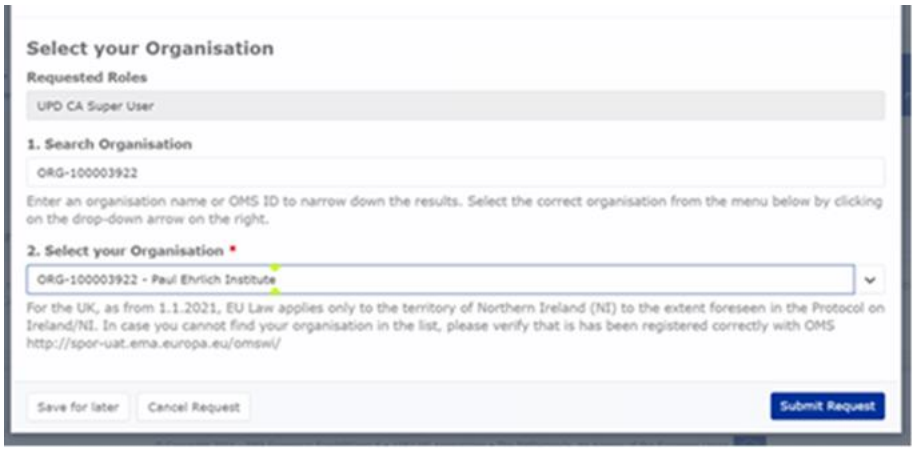


4.Upload a document (see paperclip button to the right) to show your affiliation to your organisation. For now, just upload any document (We'll need the formal document later and will also need this for production)

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



6. Search and Select your organisation:

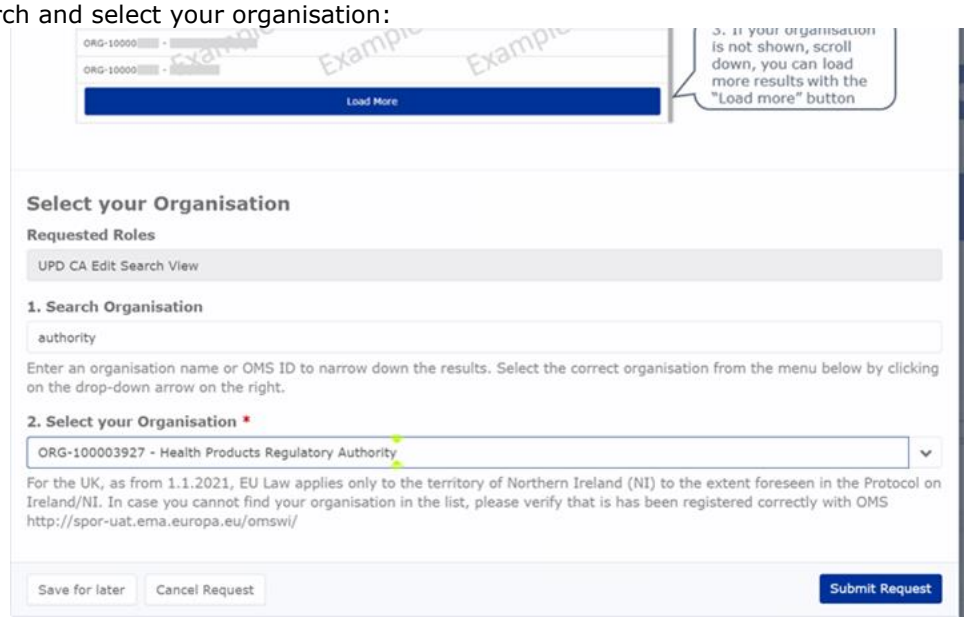


7. "Submit Request"

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 5.2. 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 5.2. 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

Use Case	Affects API and/or UI user	Issue reference	Vet EUIG Chapter 2 section	Issue Description
UC08 Update product	API	UPD-7273	1.2 Product Record Status	UC08 Update SC2 Update National - API - UPD-UC08-AC016 - Missing Validation error when update Product Status from Current to Provisional & product has been updated
UC08 Update product	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
UC08 Update product	API & NCA UI	UPD-7713	1.5 (Authorised) pharmaceutical form	Update NAP via API or UI - every update is 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 will show several entries for this attribute and the duplicated entries need to be removed when submitting an update to the API.
UC08 Update product	NCA UI	UPD-7508	1.6 Legal status of supply	Update DCP/MRP/SRP National data: Legal status of supply at Product level is a national field and this is not included as an editable field on the screen. Therefore it is not possible to populate this when adding or updating national data.The update will be successful without this populated.
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.

Use Case	Affects API and/or UI user	Issue reference	Vet EUIG Chapter 2 section	Issue Description
UC08 Update product	NCA UI	UPD-8376	1.8 Veterinary medicinal product name	When updating a product (any procedure type) you will receive a validation error regarding the List ID for Country of the Product Name. The system has incorrectly changed the ID from the value for the Country list to that of the Country Grouping List. Error message will be similar to: "Unknown code 'http://spor.ema.europa.eu/v1/lists/100000000003#100000000395' for 'http://spor.ema.europa.eu/v1/lists/100000000003#100000000395'" Workaround: select "Edit" for name, and then "Save changes". No actual change needs to be made to the product name text or dropdown values selected for country or language.
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 **UC08 Update product**	API & NCA UI	UPD-4746	1.8.3 Country / Language	DCP create was not being rejected when product name country is not European Union and/or language is not English; and only a national product name was provided. However, ticket remains open and included in the known issues list. You should be able to submit a create payload that contains both European/Common and RMS National product names. When

Use Case	Affects API and/or UI user	Issue reference	Vet EUIG Chapter 2 section	Issue Description
				Creating a DCP or Updating Common Data for a DCP any national product names should be silently ignored and not give a validation error. In this release there is a validation error if any national product names are also included. This has partially been resolved and there will be a validation error if no European/Common name is provided.
UC01 Create product **UC08 Update product**	NCA UI	UPD-6618	1.9.4 (PSM) File location	UC01 Create or UC08 Update - Legacy only - not able to change mind and remove Location for PSMF
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
UC01 Create product **UC08 Update product**	NCA UI	UPD-6910	1.9.4 (PSM) File location 1.10.3 QPPV Location	The Validate button doesn't highlight PSMF or QPPV Location as missing mandatory fields if the code/contact value s populated but no location selected (PSMF for Chapter 2 only)
UC08 Update product	API	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
UC01 Create product	API	UPD-6437	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)
UC01 Create product	NCA UI	UPD-6941	1.11 Attached Document	UC01 Create DCP - Documents are not added to all products (may be intermittent issue)
UC18 Manage document	API	UPD-8603	1.11.1 (Attached document) identifier	EP404 Update Document - Update of a document is being treated as a create and a new DocumentReference is being added with new DocumentReference.id
UC01 Create product	API & NCA UI	UPD-4752	1.11.3 (Attached document) type	"Public Assessment Report" can't be used as this results in a validation error and the product is not created.
UC18 Manage document	API	UPD-5143	1.11.4 (Attached document) country	Population for Attached document country incorrectly is rejected with a validation error
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

Use Case	Affects API and/or UI user	Issue reference	Vet EUIG Chapter 2 section	Issue Description
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.
UC08 Update product	NCA UI	UPD-6995	1.12 Product cross-reference	UC08 Update SC2 UPD-UC08-AC035 NAP - UI only - existing Product Cross Reference values not populated when select to Edit product
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 **UC08 Update product**	API	UPD-7159	1.13.2	UC01 Create & UC08 Update - Any procedure type - Validation is missing if manufacturingBusinessOperation.type.code is missing or has no value
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 results in ERR-1002. As a workaround, if the Manufacturing Business Operation is deleted and then readded with all of the required manufacturing activities the update is successful
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

Use Case	Affects API and/or UI user	Issue reference	Vet EUIG Chapter 2 section	Issue Description
UC21 Manage notifications	NCA UI & MAH UI	UPD-4293	2.3 Country	Authorisation country is not populated in search results
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-7220	2.5 Authorisation status	UC08 Update SC2 DCP National Data - UI Only - UPD-UC08-AC015 - Authorisation status in the updated product is not the value entered on the screen and is always updated to "Valid"
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 **UC08 Update product**	API	UPD-5771	2.6 Date of authorisation status change	For Legacy products May21 Vet EUIG specified that this attribute was mandatory for legacy load. July21 Vet EUIG has changed this and it is no longer mandatory. The validation rules will be updated in a future release. For this release, a value will still need to be provided.
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

Use Case	Affects API and/or UI user	Issue reference	Vet EUIG Chapter 2 section	Issue Description
				GmbH" /> </holder>
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
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	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
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	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 **UC08 Update 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 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.
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

Use Case	Affects API and/or UI user	Issue reference	Vet EUIG Chapter 2 section	Issue Description
				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-7228	4.3.2.1 & 4.3.2.2	UC01 Create & UC08 Update Product - POST should be valid where Reference Strength is populated but there is no Substance Strength; or if specify Substance Strength a Reference Substance and no Reference Substance Strength. Instead there is a validation error and Substance Strength must always be specified
UC01 Create product **UC08 Update product**	API & NCA UI	UPD-5771	4.3.2.1.1 Strength (presentation single value)	May21 Vet EUIG specified that the denominator may be a term from the Unit of Presentation or the Unit of Measurement list. July21 Vet EUIG has updated this and the denominator may only be a term from the Unit of Presentation (UOP) list. Therefore, please only use a term from the UOP list so that products created comply with this change. The validation rules for presentation strength will be updated in a future release.
UC08 Update product	API & NCA UI	UPD-4736	4.3.3.1.2 Reference strength (Presentation single value) 4.3.3.2.1 Reference strength (Concentration single value)	Update product: When the reference strength for an Ingredient is changed from being a presentation to concentration value (the denominator changes from a Term ID in the Units of Presentation list a Term ID in the Units of Measurement list) the update is successful and the new Term ID is saved. The List ID should be updated by the system from Unit of Presentation to Unit of Measurement but this update is not made. Therefore an Update via the UI will fail with a valdiation error due to this mismatch. When updating via the UI NAP or Common Data for DCP/MRP/SRP the Ingredient can be edited and the correct List and Term ID can be re-selected as a workaround. When upating via the API based on a Get

Use Case	Affects API and/or UI user	Issue reference	Vet EUIG Chapter 2 section	Issue Description
				MedicinalProductDefintion/$everything response, the List ID should be corrected.
UC08 Update product	NCA UI	UPD-7492	4.3.3.2 Reference strength (concentration)	Update DCP/MRP/SRP National data: if one of the Ingredients in the product has a Reference Strength as concentration, with denominator from the Units of Measurement list, there will be a validation error when update is submitted. Since this is Common data it can't be updated to correct the issue and there submit an update for that product.
UC01 Create product	API	UPD-3097	4.3.3.2.1 Reference strength (Concentration)	Create product: When the reference strength for an Ingredient on create is a concentration value (the denominator is from the Units of Measurement list) the create is successful. The List ID should be populated by the system as the Unit of Measurement but instead it is always populating as the Unit of Presentation list. When updating via the UI NAP or Common Data for DCP/MRP/SRP the Ingredient will need to be edited and the correct List and Term ID re-selected as a workaround. When updating via the API based on a Get MedicinalProductDefinition/$everythiing response the list ID needs to be corrected in order to successfully submit the Update
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
UC08 Update product	API & NCA UI	UPD-8289	5.1 Package description	Update National Data for DCP/MRP/SRP - the national Package description added by RMS or CMS are not being saved even although advised update has been successful
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
UC05 View product	NCA UI & MAH UI	UPD-5131	5.2 Pack size	Only the numeric quantity is displayed and not the term name for Unit of presentation.
UC08 Update product	API	UPD-7198	5.3 Package idenitifier	UC08 Update SC2 NAP - API only - should reject update with valid error message if Package Identifier in PackageProductDefinition.identifier is missing

Use Case	Affects API and/or UI user	Issue reference	Vet EUIG Chapter 2 section	Issue Description
UC01 Create product	API	UPD-6016	5.5 Marketing authorisation number	There is no validation error if submit payload to create NAP with 2 packages, and marketing authorisation number is only specified at Package level for one of the packages
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	NCA UI	UPD-7007	5.5.1 Marketing authorisation number (package level)	UC08 Update SC2 NAP UPD-UC08-AC035 - Marketing authorisation number at Package level has been populated with value which is at Product level on screen after selecting to edit product from view screen
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-8400	5.6 Manufactured item (in Package)	UPD-UC08-AC041 User should not be able to remove a Manufactured Item used in a package
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
UC01 Create product **UC08 Update product**	NCA UI	UPD-7983	5.6.2 Manufactured item quantity	Millilitre(s) has to be typed in full in order to select from Unit of Measurement drop down list for Manufactured item quantity within Package section
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
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 has incorrect numeric and term code values on screen after selecting to edit product from view screen
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.

Use Case	Affects API and/or UI user	Issue reference	Vet EUIG Chapter 2 section	Issue Description
UC01 Create product **UC08 Update product**	NCA UI	UPD-4863	5.6.4 Ingredient (in Manufactured item)	This should not be mandatory for Legacy products. An ingredient must be selected in this release for the create of a NAP product. It is no longer mandatory for a DCP.
UC01 Create product	NCA UI	UPD-8033	5.7 Availability status	Create DCP - UI only - Availability Status entries are output for RMS & all CMS in each product. The system should only populate for that Country within each of the products created
UC08 Update product	NCA UI	UPD-7221	5.7 Availability status	UC08 Update SC2 DCP National data - UI only - UPD-UC08-AC015 - Availability status information entered on screen is 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.
Authorisation	NCA & MAH UI	UPD-8434		Authorisation : User is not able to use the UPD portal as expected when assigned to multiple roles for different organizations
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-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	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	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	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 **UC08 Update product**	NCA UI	UPD-5114		UC01 UC08 All procedure types - leading and trailing spaces in free-text fields should be removed by the system before validation

Use Case	Affects API and/or UI user	Issue reference	Vet EUIG Chapter 2 section	Issue Description
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-7997		Create/Update of a Product - Error Messages need to be more meaningful
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
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	API & NCA UI & MAH UI	UPD-1506		Search by authorisation status does not work
UC03 Search product	API & NCA UI & MAH UI	UPD-5149		Search using both name and authorisation procedure type does not work
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 & 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	NCA & MAH UI	UPD-8432		Search Products has issue for several users - fails intermittently and shows no search results. After logging out and logging in again it works and able to search products.
UC03 Search product	NCA & MAH UI	UPD-8435		Number of search results may differ for two users with same roles for same organization
UC03 Search product	NCA UI & MAH UI	UPD-7970		User unable to Search products though after clearing cache it worked again (intermittent issue)
UC03 Search product	NCA UI & MAH UI	UPD-7984		Search product works intermittently. Relogging in with same credentials works
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

Use Case	Affects API and/or UI user	Issue reference	Vet EUIG Chapter 2 section	Issue Description
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 UI & MAH UI	UPD-8030		Information of the 'Active Substance and Strength' incorrectly displayed in the Search results table
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-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-8061		Under the Manufacturer business operations section, the manufacturer for the active substances detail is missing
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-7962		Submit VNRA - after selecting Products, the MAH is not displaying the correct name
UC06 Submit VNRA	MAH UI	UPD-8439		UC06 Submit VNRA UPD-UC06-AC027 Adding more products to the list of VNRA replaces already existing products and instead should have added to the existing products
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-8441		Removing variation from one product removed variations of other product as well
UC06 Submit VNRA	MAH UI	UPD-8466		Date of implementation is changed to a common date after submitting the variation if different dates have been input for each combination of variation and product
UC07 Submit Volume of Sales	MAH UI	UPD-7029		UC07 Volume of Sales SC1 Download packages - page is getting stuck on clicking the 'Download' button - have in-progress control until session times out

Use Case	Affects API and/or UI user	Issue reference	Vet EUIG Chapter 2 section	Issue Description
UC07 Submit Volume of Sales	MAH UI	UPD-7213		UC07 - Volume of Sales - SC2 Submission of VoS - After automatic redirection on successful submission, status of the newly submitted file cannot be seen. New search needs to be submitted to view the new submission.
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-7466		Volume of Sales - Download - Pack size has the incorrect numeric value, and doesn't have term code or term description populated
UC07 Submit Volume of Sales	MAH UI	UPD-7659		Volume of Sales: Updates to Business Rules for submission file validation. 1. The sum of % of the split sales per species needs to be 100% within all EEA countries. The same rule needs to be applied separately to the non-EEA countries. 2. System should allow the User to submit VoS for same package in different countries 3. System should allow the User submit files even when non-mandatory fields are empty. In case that User fills the non-mandatory fields, System should store them in UPD.
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 MM/YYYY - this will be changed to be YYYY/MM
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
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-7988		Volume of Sales: User sometimes cannot see the Volume of Sales for products for which submission was successful
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-7992		Volume of Sales: Error incorrectly triggered by the system in the error file after the submission of VoS

Use Case	Affects API and/or UI user	Issue reference	Vet EUIG Chapter 2 section	Issue Description
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-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-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
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	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	API	UPD-6933		UC08 Update SC2 National data update - error when POST with request header "Accept" specifying response format in xml format (as used for other POST Endpoints). As a workaround need to use value of “application/fhir+json” or “*/*”
UC08 Update product	API	UPD-6985		UC08 Update SC2 NAP - API only - Should reject update for NAP using common-data-bundle endpoint

Use Case	Affects API and/or UI user	Issue reference	Vet EUIG Chapter 2 section	Issue Description
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-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"]
				}
				]
				}

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 & 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 & 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	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

Use Case	Affects API and/or UI user	Issue reference	Vet EUIG Chapter 2 section	Issue Description
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	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-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	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-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-7249		UC08 - Update DCP SC2 National data - Edit package button does not get enabled even after filling all the fields - not able to add National Package description or Legal status of Supply
UC08 Update product	NCA UI	UPD-7507		Update SRP National Data: sometimes selecting to edit National data from the View product screen displays the update page but is stuck with a loading animation and eventually times out
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-8380		Update National Data DCP/MRP/SRP - many Common Data attributes are editable and should be read only
UC09 Approve/Reject VNRA	NCA UI	UPD-8056		UC09 Approve/Reject VNRA - no message if submission was successful or failed; & first 2-3 times Submit Approval/Rejection get an error message and on 2nd-3rd attempt it is Accepted
UC09 Approve/Reject VNRA	NCA UI	UPD-8057		Approve/Reject VNRA After viewing a product from a VNRA Submission, when user selects to return to Search results the user is taken to the Submit VNRA screen and not back to the Submission they were viewing
UC09 Approve/Reject VNRA	NCA UI	UPD-8202 UPD-8438		Date of decision that is saved is not the value entered by NCA. It appears to be the Date of implementation + 1 month
UC09 Approve/Reject VNRA	NCA UI	UPD-8436		Decision comment still shown in variation summary even after removing it (after entering and deleting before submitting the approval or rejection)

Use Case	Affects API and/or UI user	Issue reference	Vet EUIG Chapter 2 section	Issue Description
UC21 Manage Notifications	NCA & MAH UI	UPD-8037		Search by authorization country is not functioning.
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	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 UI & MAH UI	UPD-5153		Search by Product identifier does not work
UC21 Manage notifications	NCA UI & MAH UI	UPD-5155		Sorting of search results table doesn't work for all columns
UC21 Manage notifications	NCA UI & MAH UI	UPD-5678		UC21 Notifications - additional partially populated entries with date 01/01/1970, Action type of "C" and no Permanent Identifier are listed in the search results for the Create of a DCP product. Please ignore these entries and refer to those with an Action type of "Create".
UC21 Manage Notifications	NCA UI & MAH UI	UPD-7901		Sometimes when selecting to view a product from a Notification by clicking on the hyperlink in product name or Permanent Identifier, there is an error displayed with a pink line. As a workaround you can copy the Permanent Identifier from the notifications screen and use the Search product screen to search and view that product.
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 UI & MAH UI	UPD-8031		Notifications: Search by product name fails if product name has more than one word. It is only possible to search using the first word of the product (either full or partial value for the first word)
UC21 Manage Notifications	NCA UI & MAH UI	UPD-8032		Notifications - Product name, Procedure Number & Regulatory Entitlement don't have correct values in Search result table
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-6056		UC27 - Volume of Sales - View values as MAH/NCA - system defaulting Volume of Sales to 0 has not been implemented

Use Case	Affects API and/or UI user	Issue reference	Vet EUIG Chapter 2 section	Issue Description
UC27 View Volume of Sales	NCA UI & MAH UI	UPD-7477		Volume of Sales - View of Sales results is displaying an entry for each submission made for a particular package & product. This not correct and the results table should show one entry per product irrespective of how many submissions have been made for that product
UC27 View Volume of Sales	NCA UI & MAH UI	UPD-7697		When you download the Volume of sales for a product you may receive different results depending on which record has been selected to be downloaded. This is due to the issue described in UPD-7477. There should be one record per product displayed to then select to download the VoS
UC28 View VNRA	MAH UI	UPD-7322		UC28 View VNRA "Author of Decision" is to be removed from the MAH View
UC28 View VNRA	NCA & MAH UI	UPD-8201		Responsible Authority now shows label in field of "Responsible authority (organisation)" and need to hover over to view name
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-7486		View VNRA: The date formatting is wrong in the "view VNRA submissions" Page
UC28 View VNRA	NCA UI & MAH UI	UPD-7963		View VNRA Submission - Responsible Authority name is not displayed correctly when view a Submission