UPD Release Notes 1.4.4-0

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 1.4.4-0. The main difference with the previous version, v 1.4.3 released on 18 October 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.

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
    - NCA can create NAP products (data and documents)
    - NCA can update NAP products (data only)
    - Search/view/export product (data and documents)
    - Notifications for Create and Update of products
    - View Volume of Sales information
- MAH UI:
    - Search/view/export product (data and documents)
    - Notifications for Create and Update of products
    - Download, Submit and View Volume of Sales information
- 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 between now and January 2022.

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 1.4.3-0

2.1. New functionality

API:

- RMS and CMS can complement DCP/MRP product with national DCP/MRP data and documents

NCA UI:

- RMS and CMS can complement DCP/MRP product with national DCP/MRP data
- NCA can update NAP products (data)
- View Volume of Sales

MAH UI:

- Search/view/export product (data and documents)
- Notifications for Create and Update of products
- Submit and View Volume of Sales

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

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	Issue reference	Vet EUIG Chapter 2 section	Issue that has been resolved
API EP311 Update product *API only*	UPD-2922		Adding a new Target Species no longer results in the existing Target species entries being duplicated
API EP311 Update product *API only*	UPD-2664		Adding a new Route of Administration no longer results in the existing Route of Administration entries being duplicated
API EP311 Update product *API only*	UPD-5186		When adding a Package to a product, the package identifier no longer needs to be populated to get around an incorrect validation error. Package identifier is a system generated value and should not be provided.
UC01 Create Products *UI only*	UPD-5122 UPD-5123	1.7.2 ATC vet code(s) 1.7.3 ATC vet code(s) flag	The ATC vet code(s) flag may now be used and the work around to select the closest ATC Vet code is no longer required.
UC01 Create Products *UI only*	UPD-5383		Now able to select any term, including "Tablet" or "Suspension", from Pharmaceutical Dose Form for Manufactured Dose Form or Authorised pharmaceutical form.
UC01 Create Products *UI only*	UPD-5952	5.7.2 Availability status	When creating a legacy product, the default value populated for availability status is now using the value of "No data provided" as per Chapter 4 rules
UC01 Create Products *UI only*	UPD-6359 UPD-6542		Intermittent issue no longer exists when Create product (NAP or DCP) and received a validation error related to RegulatedAuthorization.resource-create, and this is not related to any invalid values that had been submitted.

Use Case	Issue reference	Vet EUIG Chapter 2 section	Issue that has been resolved
UC01 Create Products *UI only*	UPD-6860	4 Ingredient	Create NAP or DCP: If you start to add a new Ingredient and have selected a Substance from the pop-up dialog and returned to the main create screen, you are now able to delete the substance if you don't wish to proceed to add that Ingredient.
UC03 Search Products *UI only*	UPD-5146		Search of a NAP that was created via UI by authorisation number now works
UC03 Search Products *UI only*	UPD-5147		Search of a NAP that was created via UI by authorisation country now works
UC03 Search Products *UI only*	UPD-5875		Production environment only: When you select a product from the search results table, the extended details pane (product card) is now populated and you may view the product.
UC03 Search Products UC05 View Products *UI only*	UPD-5139		Product identifier is now displayed in the search results extended details pane and on the View product screen
UC05 View Products *UI only*	UPD-4289	Documents	All documents that have been loaded for a product are displayed. You may now view the document by clicking on the link.

2.3. New issues

Use Case	Issue reference	Vet EUIG Chapter 2 section	New issue included in release notes
API EP309 create product *API only*	UPD-7015	5.6	UC01 Create - doesn't reject Create payload if there is no ManufacturedItemDefinition resource

Use Case	Issue reference	Vet EUIG Chapter 2 section	New issue included in release notes
API EP309 create product *API only*	UPD-7014	5.6.4	UC01 Create NAP Legacy - rejects without Ingredient for Manufactured Item but this is not Mandatory in Chapter 4
API EP309 create product & EP311 update product *API only*	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
API EP309 create product & EP311 update product *API only*	UPD-7160	1.12.2	UC01 Create & UC08 Update - all procedure types - missing Validation error if Reference product identifier contains alpha value that includes a space resulting in ERR-1001 (crossReference).
API EP309 create product & EP311 update product *API only*	UPD-5764		UC01 Create UC08 Update - should reject if Marketing Authorisation Number is populated at both Product and Package Level (known issue from previous releases but hadn't been included in release notes)
API EP309 create product *API only*	UPD-6997	1.12	UC01 Create NAP/DCP - Cross referenced product is not saved in the created products
API EP311 update product *API only*	UPD-7148	1.4	UC08 Update SC2 NAP - should reject update with validation error message if MedicinalProductDefinition.id is not populated
API EP311 update product *API only*	UPD-6996		UC08 Update SC2 NAP - get validation error attempting to update cross referenced product (regression issue)

Use Case	Issue reference	Vet EUIG Chapter 2 section	New issue included in release notes
API EP309 create product & EP311 update product *API & 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 - getting Validation error
UC01 Create product UC08 Update product *API & UI*	UPD-5114		UC01 UC08 All procedure types - leading and trailing spaces in free-text fields should be removed by the system before validation (known issue from previous releases but hadn't been included in release notes)
UC01 Create product UC08 Update product *UI only*	UPD-6618		UC01 Create or UC08 Update - Legacy only - not able to change mind and remove Location for PSMF
UC01 Create product UC08 Update product *UI only*	UPD-6941		UC01 Create DCP - Documents are not added to all products (may be intermittent issue)
UC01 Create product *UI only*	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 *UI only*	UPD-5676		UC01 Create & UC08 Update - all procedure types - tool tips for 2.2 5.5.1 Authorisation number are out-of-date and not aligned with IG (known issue from previous releases but hadn't been included in release notes)
UC05 View product *UI only*	UPD-7004		UC05 View - Product Identifier is not displayed on the screen

Use Case	Issue reference	Vet EUIG Chapter 2 section	New issue included in release notes
Landing page *UI only*	UPD-6987		Landing Page – After logging in the Logout button and user name is not always visible
UC21 Notifications *UI only*	UPD-6845		UC21 Notifications – new search criteria of "Authorisation Country" is incorrectly mandatory and you need to select a value for any search to be successful (the value you select for country is ignored and not included as a search criteria)
UC21 Notifications *UI only*	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". (known issue from previous releases but hadn't been included in release notes)

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).

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

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.

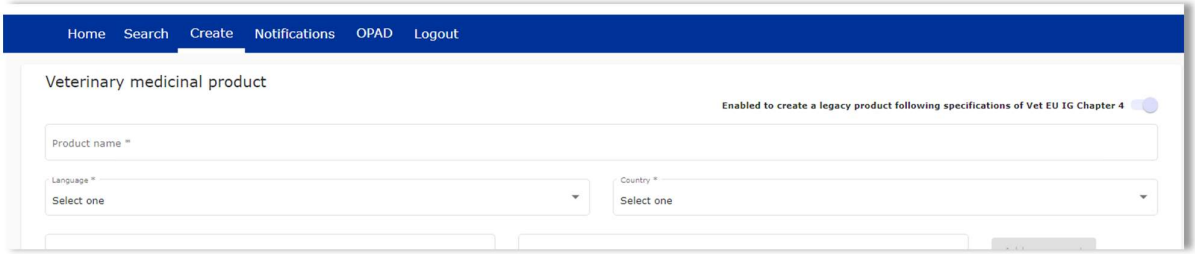
Authorisation has not been implemented in this release to control menu items based on the users role.

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. Use of flag for MAH/NCA user role

Authorisation is not fully implemented in this release and for testing Volume of Sales related functionality a button has temporarily been added to the UI.

For all NCA UI related functionality to search, view, create or update product this button can be ignored and has no effect.

Before using OPAD > View Volume of Sales, you should select NCA so it has a dark=blue background. This will ensure that the Volume of Sales functionality is correct as a NCA user.

4.4. 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-5109	1.9 (Pharmacovigilance System) Master file	This should not be mandatory for Legacy products. A value must be provided in this release. • use value of 999 for PSM file code • use the same PSMF location as used for QPPV or MAH
UPD-4863	5.6.4 Ingredient (in Manufactured item)	This should not be mandatory for Legacy products. An ingredient must be selected in this release for create of a NAP product. It is no longer mandatory for a DCP.
	4.3.2.1.1 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.

Issue reference	Vet EUIG Chapter 2 section	Issue and Workaround
		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.

4.5. Known issues for UC01 Create product

In addition to the issues documented with a work-around, the following are known issues.

Issue reference	Vet EUIG Chapter 2 section	Issues for UC01 Create product
UPD-4269	All attributes entered using structured data	For those structured data elements which have a drop-down list of RMS terms, please select a value from the list and do not copy/paste the term name from some other source. If you do it is likely that the submission of your create is not successful and you will lose all data entered.
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.
UPD-3319	1.12 Product cross-reference	It is not possible to save any product cross-reference. When you search for and select a product as the cross-reference this is not displayed on the create screen and is not saved when the product is created.
UPD-6998	1.12.1 Product cross-reference type	After retrieving the cross reference product, the cross reference type shows as "undefined"
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 is not possible to identify which manufactured item to select as the manufactured dose form is not shown.
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.

Issue reference	Vet EUIG Chapter 2 section	Issues for UC01 Create product
		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.
UPD-5126		Attached document country value is not populated into table of attached documents, and this value is not saved when product is created and the documents saved. Therefore, when view product the document country value is not displayed.
UPD-5116	1.13.2 Manufacturing activity	Legacy create is not being rejected if there is not at least one Manufacturing business operation for "Batch release" activity
UPD-4746		DCP create is not being rejected when product name country is not European Union and/or language is not English
UPD-2235 UPD-5708		NAP Create – implementation for Marketing authorisation at package level is incomplete. Authorisation country at Package level should be optional but currently this is mandatory.
UPD-1663		Search for cross-reference product by marketing authorisation number does not work
UPD-6096		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.
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
UPD-7215	All dates	If you type in a date using the suggested format, the system changes the value of the date when you move focus to another field on the screen. All dates should be entered using the date picker widget.
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 - getting Validation error
UPD-6618		UC01 Create or UC08 Update - Legacy only - not able to change mind and remove Location for PSMF
UPD-6941		UC01 Create DCP - Documents are not added to all products (may be intermittent issue)

Issue reference	Vet EUIG Chapter 2 section	Issues for UC01 Create product
UPD-6932		UC01 Create DCP - Products are created but a token error was generated when submitting the request (intermittent issue)
UPD-5114		UC01 UC08 All procedure types - leading and trailing spaces in free-text fields should be removed by the system before validation

4.6. Known issues for UC03 Search product

Issue reference	Vet EUIG Chapter 2 section	Issues for UC03 Search product
UPD-5149		Search using both name and authorisation procedure type does not work
UPD-5144		Search by Marketing authorisation holder does not work
UPD-4758		Authorisation status value is N/A in extended details
UPD-1506		Search by authorisation status does not work
UPD-5164		Search by product identifier does not work
UPD-6096		One of consecutive embedded spaces within a product name are being removed when displayed in UI
UPD-5538		Not able to search using marketing authorisation number if has been specified at package level. Affects UI and API
UPD-6987		Landing Page – After logging in the Logout button and user name is not always visible

4.7. Known issues for UC04 Export search results

Issue reference	Vet EUIG Chapter 2 section	Issues for UC04 Export search results
UPD-5468		If substance name contains a comma, the text after the comma is output in the Target species column and all other values are shifted by one or more columns to the right

4.8. Known issues for UC05 View product

Issue reference	Vet EUIG Chapter 2 section	Issues for UC05 View product
UPD-5129	Package > Manufactured item	Where a package has more than one manufactured item these are not all listed and only values for one are displayed.
UPD-5131	Package > Pack size	Only the numeric quantity is displayed and not the term name for Unit of presentation.
UPD-4758		Authorisation status value is N/A
UPD-5138	Manufacturing Business Operation	Active substances where manufacturer has been populated are not listed in the Manufacturing business operation section.
UPD-5137	Package > Manufactured item	Manufactured dose form and Ingredient(s) are not displayed
UPD-4262		Cross-referenced products are not displayed
UPD-2169		Marketing authorisation number may not always display the correct value
UPD-6096		One of consecutive embedded spaces within a product name are being removed when displayed in UI
UPD-6621		Select to Edit NAP product and get error message advising there is a problem and try again later. However, even if you try later will still get same error message, and will not be able to update that particular NAP product via the UI. You may also receive this error if you attempt to edit a DCP/MRP/SRP procedure product. Updating of those procedure types using the UI is not in scope of this release.
UPD-3747	3.4 Withdrawal period	Withdrawal periods are not displayed beside the corresponding Target Species within the Route of Administration. Instead they are listed as a single column for that Route of Administration (issue existed in prior release but hadn't been included in the release notes)
UPD-7004		UC05 View - Product Identifier is not displayed on the screen

4.9. Known issues for UC08 Update product

Issue reference	Vet EUIG Chapter 2 section	Issues for UC08 Update product
UPD-2235 UPD-5708		NAP Update – implementation for Marketing authorisation at package level is incomplete. Authorisation country at Package level should be optional but currently this is mandatory.
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
UPD-5999	5.5.1 Marketing authorisation number (package level)	Not able to update product if Marketing Authorization Number was populated at Package Level using the API as get a Validation error
UPD-6096		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.
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
UPD-6962		UC08 - Update SC2 DCP National data – New national documents are not saved when updating product to add National data, even although you receive successful update message. Updates to national data will have been saved.
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
UPD-7250		UC08 - Update DCP SC2 National data - Able to successfully edit Procedure number which is Common data so should be non-editable
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
UPD-7233		UC08 - Update DCP SC2 National data - Refreshing edit page using browser refresh option changes the URL and takes back to search screen

Issue reference	Vet EUIG Chapter 2 section	Issues for UC08 Update product
UPD-7232		UC08 - Update DCP SC2 National data - Substance is Common data but able to add a new Ingredient (Update is not successful and there is an error even if advised on UI was successful)
UPD-7231		UC08 - Update SC2 DCP National data - Availability status date format is incorrect in the UI after selecting a value
UPD-7220		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"
UPD-7221		UC08 Update SC2 DCP National data - UI only - UPD-UC08-AC015 - Availability status information entered on screen is not saved in the updated product
UPD-7219		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 are swapped in updated product. Workaround: when updating National data for the time, input the date for Marketing authorisation in the field labelled Date of authorisation status change; and input value for Date of authorisation status change in field labelled Marketing Authorisation.
UPD-7003		UC08 Update SC2 NAP UPD-UC08-AC035 - Marketing authorisation date and Date of authorisation status change are swapped around on screen after selecting to edit product from view screen. However, when doing a second or subsequent update to national data no corrective action is required (as issue in UPD-7219 will actually update the correct values in the product). If you wish to change one of the dates you will need to use the same workaround as noted for UPD-7219.
UPD-7198		UC08 Update SC2 NAP - API only - should reject update with valid error message if Package Identifier in PackageProductDefinition.identifier is missing
UPD-7285		UC08 Update SC2 NAP - Adding a new package fails because of empty package identifier field
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
UPD-7006		UC08 Update SC2 NAP UPD-UC08-AC035 - It is not possible to edit Target Species or Withdrawal Period on screen after selecting to edit product from view screen

Issue reference	Vet EUIG Chapter 2 section	Issues for UC08 Update product
UPD-7007		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
UPD-7001		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
UPD-7005		UC08 Update SC2 NAP UPD-UC08-AC035 - Withdrawal period values are incorrect on screen after selecting to edit product from view screen
UPD-7012		UC08 Update SC2 NAP UPD-UC08-AC035 - incorrectly have CAP update screen and fields on screen with no data for selected NAP product after selecting to edit product from view screen (issue affects some products and not all)
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
UPD-6995		UC08 Update SC2 UPD-UC08-AC035 NAP - UI only - existing Product Cross Reference values not populated when select to Edit product
UPD-6999		UC08 Update SC2 NAP/DCP National data & SC2 DCP Common data - UI only - UPD-UC08-AC035 - QPPV Location and MAH Holder are swapped around on screen after selecting to edit product from view screen
UPD-7000		UC08 Update SC2 NAP/DCP National data & SC3 Common data - UI only - UPD-UC08-AC035 - Pack size quantity is incorrect value on the screen after selecting to edit product from view screen
UPD-7002		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
UPD-7011		UC08 Update SC2 SC3 SC5 - pop-up dialogs to confirm Update or to confirm Cancellation refer to "create" and not "update"
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 - getting Validation error
UPD-6618		UC01 Create or UC08 Update - Legacy only - not able to change mind and remove Location for PSMF

Issue reference	Vet EUIG Chapter 2 section	Issues for UC08 Update product
UPD-5114		UC01 UC08 All procedure types - leading and trailing spaces in free-text fields should be removed by the system before validation
UPD-6884		UC08 Update SC2 DCP Update National Data - While trying to make a second update of a DCP product, the edit form is incorrectly labelled as Edit Centralised product and values from the selected product have not been populated (is not an issue for all products)
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)

4.10. Known issues for UC21 Manage notifications

Implemented of Authorisation is not complete and in this release any logged on user may view all Notifications.

Issue reference	Vet EUIG Chapter 2 section	Issues for UC21 Manage notifications
UPD-5155		Sorting of search results table doesn't work for all columns
UPD-5153		Search by Product identifier does not work
UPD-4294		Product identifier is not populated in search results
UPD-4293		Authorisation country is not populated in search results
UPD-6845		UC21 Notifications – new search criteria of "Authorisation Country" is incorrectly mandatory and you need to select a value for any search to be successful (the value you select for country is ignored and not included as a search criteria)
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". (known issue from previous releases but hadn't been included in release notes)

4.11. Registration process for access to the NCA 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 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.

4.12. 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:

- Send an email requesting access to NCA UI in PROD to UPD-Registration@ema.europa.eu . Please send the request from your NCA email address so that EMA can verify it. Access will only be granted to NCA staff with an NCA email address, otherwise requests will be rejected.

- Once you have been verified as an NCA staff, the UPD registration team will provide you with the login instructions. Registration to the NCA UI in the PROD environment may take up to 3 working days.
- Once registered, the UI in PROD can be found at:

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

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

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

Please 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.

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

Request Header: Key	Value	Validation rules applied
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.

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
	None

5.5.4. Known issues for API EP309 Create product

Issue reference	Vet EUIG Chapter 2 section	Issues for EP309 Create product
	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.
	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.
	URN UUID	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
UPD-5116	1.13.2 Manufacturing activity	Legacy create is not being rejected if there is not at least one Manufacturing business operation for "Batch release" activity
UPD-4746		DCP create is not being rejected when product name country is not European Union and/or language is not English
UPD-4279		Submit of a request bundle for DCP procedure with national data populated to the Endpoint for NAP procedure is not rejected
UPD-3872	1.12 Product cross-reference	Cross-reference values are not being saved and therefore when retrieve the product those values are not included

Issue reference	Vet EUIG Chapter 2 section	Issues for EP309 Create product
UPD-3097	4.3.3.2.1 Reference strength (Concentration)	The incorrect list ID is populated when view product details of the create product. It always has the list ID in the denominator for Unit of Presentation. Therefore, when submitting an Update based on the Get MedicinalProductDefinition/$everythiing response the list ID needs to be corrected in order to successfully submit the Update
UPD-4747		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.
UPD-3096		Create is not rejected if Ingredient.strength.presentation or Ingredient.strength.concentration has the wrong list and term ID
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.
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.
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
UPD-5975 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
UPD-6047	2.2 & 5.5 Marketing authorisation number	There is no validation error if submit payload to create NAP with 2 packages, and marketing authorisation number is not specified at either Product or Package Level

Issue reference	Vet EUIG Chapter 2 section	Issues for EP309 Create product
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
UPD-6560 UPD-6561	2.11 Reference member state 2.12 Concerned member states	UPD-UC01-AC047 Validation missing as able to select non-EU/EEA country as RMS or CMS
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.
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).
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. 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.
UPD-7015	5.6	UC01 Create - doesn't reject Create payload if there is no ManufacturedItemDefinition resource
UPD-7014	5.6.4	UC01 Create NAP Legacy - rejects without Ingredient for Manufactured Item but this is not Mandatory in Chapter 4
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

Issue reference	Vet EUIG Chapter 2 section	Issues for EP309 Create product
UPD-7160	1.12.2	UC01 Create & UC08 Update - all procedure types - missing Validation error if Reference product identifier contains alpha value that includes a space resulting in ERR-1001 (crossReference).
UPD-6997	1.12	UC01 Create NAP/DCP - Cross referenced product is not saved in the created products
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 - getting Validation error
UPD-5764		UC01 Create UC08 Update - should reject if Marketing Authorisation Number is populated at both Product and Package Level (known issue from previous releases but hadn't been included in release notes)

5.5.5. 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 not a valid permanent identifier from UAT or PROD.

Procedure type	Validation rules	Example file
DCP	Chapter 2	UPD_1.4.2-0_DCP_Chpt2_C2_Mandatory_VetIG.JSON UPD_1.4.2-0_DCP_Chpt2_C2_Mandatory_VetIG.XML UPD_1.4.2-0_DCP_Chpt2_C110_VetEUIG_AllData.JSON UPD_1.4.2-0_DCP_Chpt2_C110_VetEUIG_AllData.XML
DCP	Chapter 4 Legacy	UPD_1.4.2-0_DCP_Legacy_C2_Mandatory_VetIG.JSON UPD_1.4.2-0_DCP_Legacy_C2_Mandatory_VetIG.XML UPD_1.4.2-0_DCP_Legacy_C110_VetEUIG_AllData.JSON UPD_1.4.2-0_DCP_Legacy_C110_VetEUIG_AllData.XML
NAP	Chapter 2	2.2 Authorisation/registration/entitlement number is specified at Product level

Procedure type	Validation rules	Example file
		UPD_1.4.2-0_NAP_Chpt2_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel.JSON UPD_1.4.2-0_NAP_Chpt2_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel.XML UPD_1.4.2-0_NAP_Chpt2_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel.JSON UPD_1.4.2-0_NAP_Chpt2_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel.XML --- 5.5 Marketing authorisation (package level) UPD_1.4.2-0_NAP_Chpt2_C111_VetEUIG_AllData_MANumber_AtPackageLevel.JSON This example contains 2 packages. There are 3 RegulatedAuthorization resources: • One with subject reference = MedicinalProductDefinition resource; populated with attributes from Section 2 (Vet EUIG Chapter 2), excluding the marketing authorisation number • One with subject reference = 1st PackagedProductDefinition resource; populated with the Marketing authorisation number for Package 1 • One with subject reference = 2nd PackagedProductDefinition resource; populate with the Marketing authorisation number for Package 2 • 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_1.4.2-0_NAP_Legacy_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel.JSON UPD_1.4.2-0_NAP_Legacy_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel.XML

Procedure type	Validation rules	Example file
		UPD_1.4.2-0_NAP_Legacy_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel.JSON UPD_1.4.2-0_NAP_Legacy_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel.XML
NAP	Chapter 4 Legacy	UPD_1.4.2-0_NAP_Legacy_Cx_ManyAttributesAndResources_MANumberAtMedicinalProductLevel.XML This example contains: • 2 or more values for those attributes that are repeatable. For example Product name, ATC Vet Code, Manufacturing Business Operation • 2 Packages (PackagedProductDefinition) • 2 Manufactured Items (ManufacturedItemDefinition) • 3 Ingredients (Ingredient)

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_1.4.2-0_NAP_Legacy_C110_VetEUIG_AllData_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 - removed inline attribute id for Target species and Withdrawal Period to workaround issue UPD-4714	Sample XML of Get Everything response used as a starting point: UPD_1.4.2-0_EP311_UpdateProduct_GetEverything_version1.XML Update bundle prepared: UPD_1.4.2-0_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_1.4.2-0_EP311_UpdateProduct_GetEverything_version2.XML

5.6.4. Known issues for API EP311 Update product

Many of the issues affecting EP309 Create product are also applicable to EP311 Update product and are not repeated in this section. Only those specific to an update are listed.

Issue reference	Vet EUIG Chapter 2 section	Issues for EP311 Update product
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 and MedicinalProductDefinition.masterFile • AdministrableProductDefinition.routeOfAdministration, AdministrableProductDefinition.routeOfAdministration.targetSpecies, AdministrableProductDefinition.routeOfAdministration.targetSpecies .withdrawalPeriod
UPD-4812		Change to procedure number not saved if existing inline attribute id is not included in the request body
UPD-4811		Change to Responsible authority or Product Owner is not saved if existing inline attribute id is not included in the request body
UPD-4810		Change to Authorised pharmaceutical for results in both old and new value in updated product if existing inline attribute id is not included in the request body
UPD-4796		Change to QPPV name is not saved if existing inline attribute id is not included in the request body
UPD-4736		Change to Ingredient reference strength from presentation to concentration saves new term code. However, updated product still has list id for the Unit of Presentation list and not the Unit of Measurement list id that was provided.
UPD-4734		Change of manufacturer in an Ingredient results in no manufacturer being populated in the updated product for that Ingredient
UPD-4733		Change to PSMF File location is not saved if existing inline attribute id is not included in the request body
UPD-4732		Change to QPPV File location is not saved (whether existing inline attribute id is included or not in the request body)
UPD-3313		Validation that Term code is from the specified List ID is missing for Manufactured item quantity

Issue reference	Vet EUIG Chapter 2 section	Issues for EP311 Update product
UPD-5187		When adding an Ingredient, the update post is successful. However the new ingredient has not been saved and therefore not included when you retrieve the updated product.
UPD-5192		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.
UPD-5384		New Package description added to product is output in main package description attribute and not as a translation as expected
UPD-5999		Not able to update product if Marketing Authorization Number is populated at Package Level - get Validation error "UUIDs must start with urn: uuid"
UPD-6985		UC08 Update SC2 NAP - API only - Should reject update for NAP using common-data-bundle endpoint
UPD-7160		There is no validation error if the provided product reference is an alphanumeric value that contains an embedded space. 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.
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
UPD-7245		UC08 Update SC2 Update DCP National - API - UPD-UC08-AC015 - National package description is not saved in updated product
UPD-7286		UC08 Update SC2 Update National - API - UPD-UC08-AC016 - Missing Validation if not all Mandatory attributes populated when Update National
UPD-7273		UC08 Update SC2 Update National - API - UPD-UC08-AC016 - Missing Validation error when update Product Status from Current to Provisional & product has been updated
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

Issue reference	Vet EUIG Chapter 2 section	Issues for EP311 Update product
UPD-7160	1.12.2	UC01 Create & UC08 Update - all procedure types - missing Validation error if Reference product identifier contains alpha value that includes a space resulting in ERR-1001 (crossReference).
UPD-7148	1.4	UC08 Update SC2 NAP - should reject update with validation error message if MedicinalProductDefinition.id is not populated
UPD-6996		UC08 Update SC2 NAP - get validation error attempting to update cross referenced product (regression issue)
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 - getting Validation error
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 "*/*"
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.

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_01.03_EP403_CreateDocument

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/600000027688

GET /v2/DocumentReference?type=100000155538

GET /v2/DocumentReference?related=MedicinalProductDefinition/600000027688&_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/7a88176d-10f9-4db3-8fa0-4e4ae4594df7

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_01.03_EP402_GetDocument_version1.XML
- Update posted: UPD_01.03_EP404_UpdateDocument_BasedOnVersion1.XML
- Response to POST: UPD_01.03_EP404_ResponseAfterUpdate.XML
- GET of document after update: UPD_01.03_EP402_GetDocument_AfterEP404Update_version2.XML

5.7.5. Known issues for Manage Document

Issue reference	Vet EUIG Chapter 2 section	Issues for Manage Document
UPD-5143		Population for Attached document country incorrectly is rejected with a validation error

5.8. Known issues for API EP301 Search product

Issue reference	Vet EUIG Chapter 2 section	Issues for EP309 Create product
UPD-1024		Search should be accent insensitive when using the exact modifier and it's not
UPD-140		Sort of search results does not work

6. MAH UI

6.1. Scope of this release for MAH UI

This is the first release of functionality for the MAH UI. This will be included in the scope of UAT 2 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

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. Use for MAH/NCA user role

Authorisation is not fully implemented in this release, therefore in order to use some MAH related functionality a button has temporarily been added to the UI.

For all MAH UI related functionality, please use the default option of MAH – it should have a dark-blue background. This will ensure that the Volume of Sales functionality is correct as a MAH user.

6.3. Known issues for Search, Export and View Products

For known issues relating to Search, Export and View products please refer to the following sections:

- 4.6. Known issues for UC03 Search product
- 4.7. Known issues for UC04 Export search results
- 4.8. Known issues for UC05 View product

6.4. Known issues for Notifications

For known issues relating to Notifications please refer to the following section:

- 4.10. Known issues for UC21 Manage notifications

6.5. Known issues for Volume of Sales

Issue reference	Vet EUIG Chapter 2 section	Issues for Volume of Sales
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 is using the Target Species list. **As a workaround for this release:** you will need to use a valid term from the Target Species list when submitting a VoS file.
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
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.
UPD-7236		UC07 Submit VoS - function execution takes more than 30 minutes for some files and may time out. In this release recommend that only files with up to 10 rows are submitted.
UPD-5566		UC07 - Volume of Sales - Submission of VoS - No Notification generated upon successful submission
UPD-5670		UC07 - Volume of Sale - Download - Column headers in the downloaded file have more than 1 space in between the words
UPD-6559		UC27 - Volume of Sales - UPD-UC27-AC021 Not able to view submissions that are in progress
UPD-6496		UC27 - Volume of Sales - View - For a particular package, system does not overwrite the submission made for the same Month/Year
UPD-7216		UC27 - Volume of Sales - View - Not always able to download Sales for a user affiliated with multiple organisations

Issue reference	Vet EUIG Chapter 2 section	Issues for Volume of Sales
UPD-6356		UC27 - Volume of Sales - View - To download Sales, filtering by defining a time period is not working correctly for all time periods
UPD-6526		UC27 - Volume of Sales - View submissions - The uploaded file name from the user's machine and the displayed file name in View submissions do not match
UPD-6520		UC27 - Volume of Sales - View submissions as MAH - Navigating directly to this page from UPD Home makes the page stuck
UPD-6056		UC27 - Volume of Sales - View values as MAH/NCA - system defaulting Volume of Sales to 0 has not been implemented

6.6. 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.

6.7. 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. 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

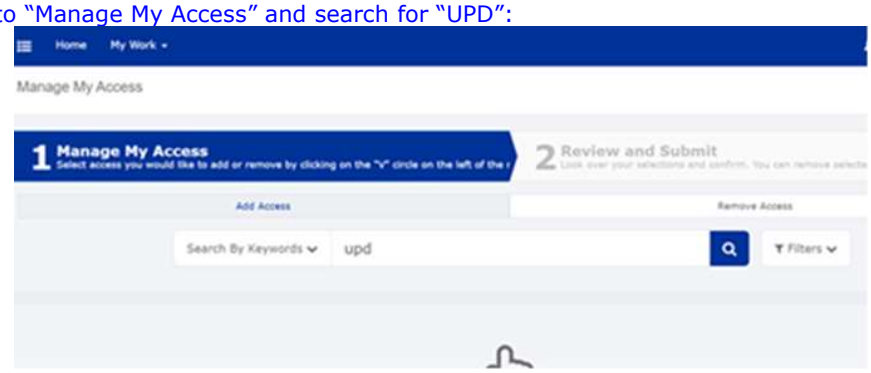
8. References

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_1.4.4-0_ReleaseNotes_ExampleFilesForAPI (zip file)

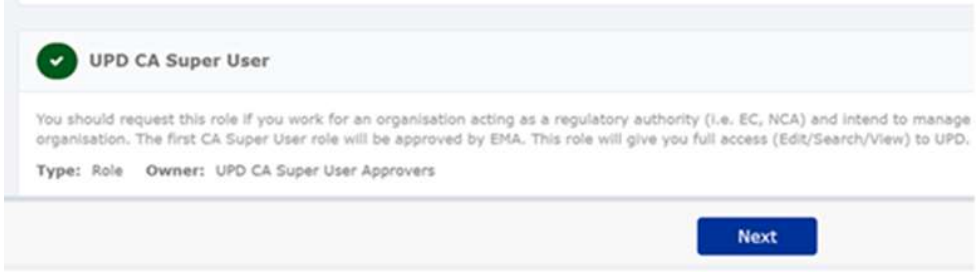
Annex 1:
UPD-Specific Screenshots for Registration for a UAT Account

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":

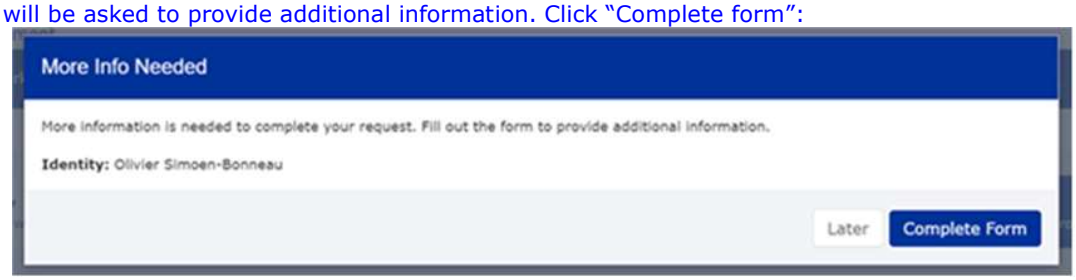


3. Select "UPD Super User"

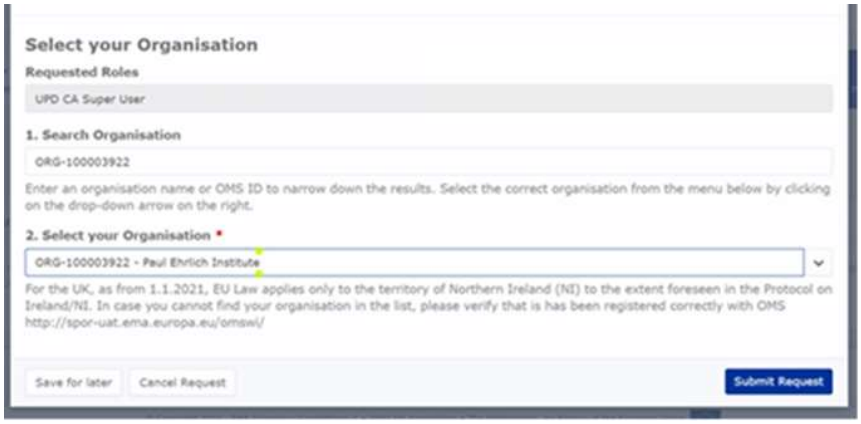


4.Upload a document (see paperclip button to the right) to show your affiliation to your organisation. For now, just upload any document (We'll need the formal document later and will also need this for prod)

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



6. Search and Select your organisation:

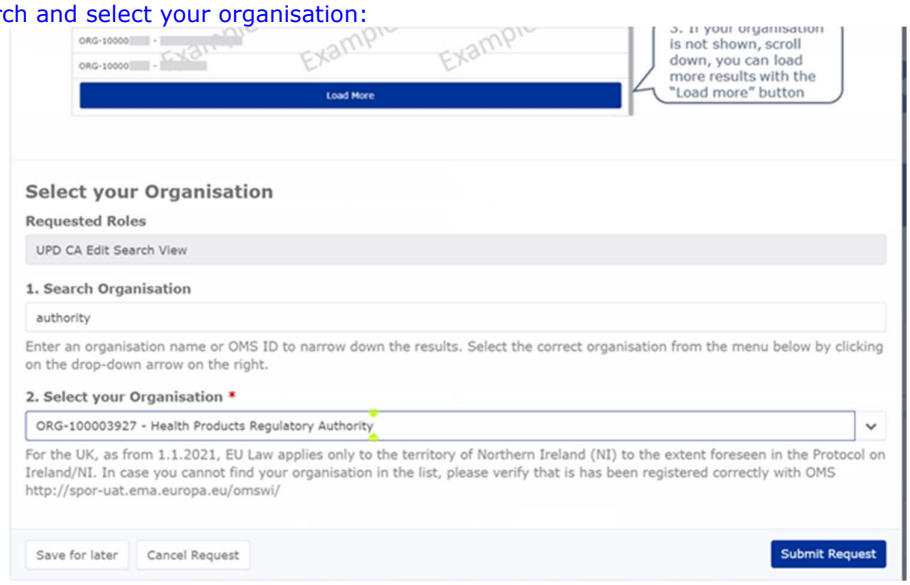


7. "Submit Request"

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.