UPD Release Notes 1.4.2-0

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 1.4.2-0. The main difference with the previous version, v 1.4.1 released on 6 September 2021, is 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.

The high-level functionality provided in this release is:

- API:
    - RMS can create DCP / MRP 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)
- UI:
    - RMS can create DCP products (data and documents)
    - NCA can create NAP products (data and documents)
    - Search/view/export product (data and documents)
    - Notification
- 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 to 1.4.1-0

2.1. New functionality

- Login button repositioned on the Home page

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 EP309 Create product *API only*	UPD-1889	5.5 Marketing authorisation (package level)	This has now been implemented and it is now possible to specify at product or package level. Please refer to the new examples of how RegulatedAuthorization resource should be populated.
UC01 Create product *UI only*	UPD-3192		Details of validation errors are now displayed when user is advised "Create unsuccessful". The error messages are the same validation errors received if an API user submitted an invalid create payload, and therefore quite technical and will not refer to the UI field label. However, they are useful as for many types of errors you will be able to understand the problem in the submitted values. In addition, it will help when reporting issues to User support.
UC01 Create product *UI only*	UPD-5121	1.5 (Authorised) pharmaceutical form	It is now possible to also select any term from the "Combined Term" or "Combined Package" lists.
UC01 Create product *API only*		3.5 Administrable dose form	Validation has now been implemented and the term code `200000018781` must be used.

Use Case	Issue reference	Vet EUIG Chapter 2 section	Issue that has been resolved
UC08 Update product *API only*	UPD-4290		Update DCP/MRP procedure product to add National data – values for Responsible authority and Product Owner are now saved. Please note: in order to resolve this issue, when DCP is created the Responsible authority and Product Owner are populated with a dummy value of *LOC-100020264 "European Medicines Agency"* in each product. These dummy values should be overwritten when loading National data.

2.3. New issues

Use Case	Issue reference	Vet EUIG Chapter 2 section	New issue included in release notes
UC08 Update product *API only*	UPD-5999	5.5 Marketing authorisation (package level)	Not able to update product if Marketing Authorization Number is populated at Package Level - get Validation error "UUIDs must start with urn: uuid"
UC01 Create product *API only*	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.
UC01 Create product *API only*	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.
UC03 Search *UI only*	UPD-6234		Search results for Centralised procedure products incorrectly shows for Country the RMS Term code of 100000000390 instead of "European Union"
UC01 Create DCP *API only*	UPD-6560 UPD-6561	2.11 Reference member state 2.12 Concerned member states	UPD-UC01-AC047 Validation missing; it is possible to select non-EU/EEA country as RMS or CMS.
UC03 Search *UI and API*	UPD-5538	5.5 Marketing authorisation number	Not able to search using marketing authorisation number if has been specified at package level.

Use Case	Issue reference	Vet EUIG Chapter 2 section	New issue included in release notes
UC01 Create product *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 not easily able to change your mind if you don't wish to proceed to add that Ingredient. You must complete the mandatory values for strength and add the Ingredient. Then you are able to remove the Ingredient from the table in order to create product without it.

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

UPD version 1.4.1-0 is based on the July 2021 version of the Vet EU IG.

Note that three 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. Administrable Dose Form

Administrable Dose form section 3.5 Chapter:

- Products created using the NCA UI do not yet use the new dummy value "pharmaceutical dose form not applicable". Currently is using term 100000073664 Tablet. This will be changed in a future version – *it is not visible to any users*.

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 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

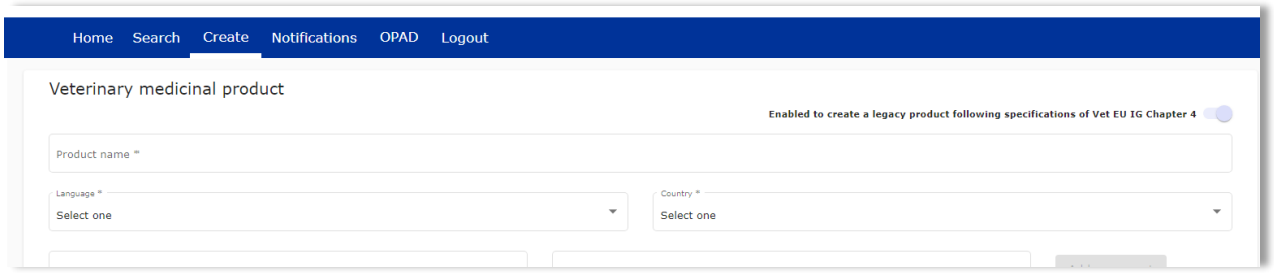
Other menu items or the edit option to update a product should not be used as these are not in scope for this release and are not fully implemented.

Supported browsers for the NCA UI are Chrome and Edge.

4.2. Apply Chapter 4 Legacy or Chapter 2 Validation rules

There is a 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 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-5122 UPD-5123	1.7.2 ATC vet code(s) 1.7.3 ATC vet code(s) flag	The ATC vet code(s) flag should not be used. Select the closest ATC Vet code from the list. If you do select the flag and submit the create it will go into an endless loop showing the *in-progress* control.
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.
	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. 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	1.11.4 (Attached document) type	"Public Assessment Report" can't be used as this results in a validation error and the product is not created.

Issue reference	Vet EUIG Chapter 2 section	Issues for UC01 Create product
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-5135	4 Ingredient	Create is not being rejected if there is not at least 1 Ingredient with role of *Active*.
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 one 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.
UPD-5132		List of languages doesn't include Icelandic and Norwegian
UPD-5126		Attached document country is not populated into table of attached documents, and is not saved when product is created
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		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-5134		Some mandatory fields may not have a * on the screen. For example: Unit of measurement for the Period is mandatory if a Withdrawal period is being specified.
UPD-4901 UPD-6060	2.13.1 Procedure number	For NAP product (both Legacy Chapter 4 or Chapter 2 rules), the procedure number should not be mandatory at either product or package level. It is incorrectly

Issue reference	Vet EUIG Chapter 2 section	Issues for UC01 Create product
		marked as mandatory at the product level on the UI screen.
UPD-5383		Not able to select "Tablet" or "Suspension" as term from Pharmaceutical Dose Form for Manufactured Dose Form or Authorised pharmaceutical form. Issue exists if there are more than 20 terms containing the single term name with a starting letter prior to the first letter of that single term.
UPD-5625		Package description and Manufactured item quantity numeric value & Unit of Presentation term not saved correctly when there are 2 or more packages. The values from one of the packages are used in each of the other packages
UPD-5952	5.7.2 Availability status	When creating a legacy product, the default value populated for availability status is using the value according to Chapter 2 rules of "Not marketed" and not value of "No data provided" as per Chapter 4 rules
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-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 not easily able to change your mind if you don't wish to proceed to add that Ingredient. You must complete the mandatory values for Strength and add the Ingredient. Then you are able to remove the Ingredient from the table in order to create product without it.

4.5. Known issues for UC03 Search product

Issue reference	Issues for UC03 Search product
UPD-5149	Search using both name and authorisation procedure type does not work
UPD-5147	Search NAP created via UI by authorisation country does not work
UPD-5146	Search NAP created via UI by authorisation number does not work

Issue reference	Issues for UC03 Search product
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-5875	Production environment only: When you select a product from the search results table, the extended details pane (product card) is empty. Therefore not able to view product. As a work-around, new products can be viewed by querying the Notification and selecting to view product.
UPD-6096	One of consecutive embedded spaces within a product name are being removed when displayed in UI
UPD-6234	Search results for Centrallsed procedure products incorrectly shows for Country the RMS Term code of 100000000390 instead of "European Union"
UPD-5538	Not able to search using marketing authorisation number if has been specified at package level. Affects UI and API

4.6. Known issues for UC04 Export search results

Issue reference	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

4.7. Known issues for UC05 View product

Issue reference	Section & attribute	Issues for UC05 View product
UPD-5132	Name Package	The RMS Term code and not the RMS Term name is displayed for some countries or languages.
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.

Issue reference	Section & attribute	Issues for UC05 View product
UPD-4289	Documents	All documents that have been loaded for a product are displayed. If you click on the link to view the document you receive an error advising that you don't have permission to view.
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-5139		Product identifier is not displayed in search results extended details or on View product
UPD-6096		One of consecutive embedded spaces within a product name are being removed when displayed in UI

4.8. Known issues for UC21 Manage notifications

Issue reference	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

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

To request access:

- 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.
- 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 UAT environment may take up to 3 working days.

- Once registered, the UI in UAT can be found at:

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

4.10. 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

SPOR API Specification v2	API Manager
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 these EP	GET OperationOutcome - Get a resource by ID Note: use this to query the outcome of Create when response to Post is "202 Accepted"
EP311 Update Product	POST Bundle - Create/Update resources in the bundle
EP318 Validate Product	POST Validate Bundle – To validate a bundle and the resources in the bundle
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
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
- For Legacy upload of MRP: RMS creates as DCP; and then each product needs to be updated and the procedure type changed from DCP to MRP
- 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
3.5 Administrable dose form	Validation has now been implemented and the term code 200000018781 must be used

5.5.4. Known issues for API EP309 Create product

Issue reference	Resource & attribute	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

Issue reference	Resource & attribute	Issues for EP309 Create product
UPD-5135	4 Ingredient	Create is not being rejected if there is not at least 1 Ingredient with role of Active
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
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-4750		DCP Legacy create incorrectly rejects if Ingredient is not specified for a Manufactured item
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.

Issue reference	Resource & attribute	Issues for EP309 Create product
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	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
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

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

Procedure type	Validation rules	Example file
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 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
NAP	Chapter 4 Legacy	UPD_1.4.2-0_NAP_Legacy_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel.JSON

Procedure type	Validation rules	Example file
		UPD_1.4.2-0_NAP_Legacy_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel.XML 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

5.6. API EP311 Update product

5.6.1. Change in request bundle

The only change in this release is the same as that for EP309 Create product.

Attribute	Change
3.5 Administrable dose form	Validation has now been implemented and the term code 200000018781 must be used

5.6.2. Recommended approach to prepare update request bundle

The recommended approach for preparing a request bundle to update a product 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 returned by EP304 for each resource and in-line within each resource

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	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

	Period to workaround issue UPD-4714	
Update product via API	POST Bundle with request header "is_update=true"	
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	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-2922	Adding a new Target Species results in the existing Target species entries being duplicated
UPD-2664	Adding a new Route of Administration results in the existing Route of Administration entries being duplicated
UPD-1675	Not able to update the permanent identifier in cross-reference entry
UPD-4812	Change to procedure number not saved if existing inline attribute id is not included in the request body

Issue reference	Issues for EP311 Update product
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
UPD-5186	When adding a Package to a product, the package identifier should not be populated as this is a system generated value. Incorrectly receive a validation error without populating a value for this identifier, and if provided the system does not overwrite with a system generated value.
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"

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	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	Issues for EP309 Create product
UPD-1024	Search should be accent insensitive when using the exact modifier and it's not

Issue reference	Issues for EP309 Create product
UPD-140	Sort of search results does not work

6. 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

7. 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_1.4.2-0_ReleaseNotes_ExampleFilesForAPI (zip file)