# UPD Release Notes 1.4.1-0

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 1.4.1-0

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 July21 Vet EU Implementation Guide.

The high-level functionality provided by 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 01.03

## *2.1. New functionality*

- UC04 Export search results

## *2.2. Resolved issues*

| Use Case | Issue reference | Vet EUIG Chapter 2 section | Issue that has been resolved |
|---|---|---|---|
| UI only: | UPD-1661 | | Search for cross-reference product by exact product name does not work |

| Use Case | Issue reference | Vet EUIG Chapter 2 section | Issue that has been resolved |
|---|---|---|---|
| UC01 Create Product | | | |
| UI only:<br>UC01 Create Product | UPD-2267 | | Submit create and advised create is successful. However, when view product there are no attached documents and only creation of the product has been successful.<br>This rarely occurs. |
| UI only:<br>UC01 Create product | UPD-5126 | 1.11.5 (Attached document) country | This is a mandatory attribute and a value must be selected to add the document.<br>However, the selected country is not displayed in the table of documents and the value is not saved when the product is created. |
| UI only:<br>UC01 Create product | UPD-5208 | | Search filter when you start typing to select value from a drop-down list for a term code is not working for the following lists:<br>- Authorised Pharmaceutical form<br>- Reference strength numerator<br>Reference strength denominator |
| UI only:<br>UC05 View product | UPD-4289 | Documents | All documents that have been loaded for a product are displayed.<br>If you click on the link to view the document you receive an error advising that you don't have permission to view. |
| UI only:<br>UC05 View product | UPD-4858 | Product header | The full list of product names should not be listed in the product header. |

## *2.3. New issues*

| Use Case | Issue reference | Vet EUIG Chapter 2 section | New issue included in release notes |
|---|---|---|---|
| UI only:<br>UC01 Create Product | UPD-5383 | | Not able to select "Tablet" or "Suspension" as term from Pharmaceutical Dose Form for Manufactured Dose Form or Authorised pharmaceutical form. |

| Use Case | Issue reference | Vet EUIG Chapter 2 section | New issue included in release notes |
|---|---|---|---|
| | | | 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. |
| API only:<br><br>UC14 API EP311 Update Product | UPD-5384 | 5.1 Package description | New Package description added to product is output in main package description attribute and not as a translation as expected |
| UI only:<br><br>UC01 Create Product | 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 |
| UI only:<br><br>UC03 Search Product | UPD-5875 | | Production environment only:<br><br>When you select a product from the search results table, the extended details pane (product card) is empty. Therefore not able to view product.<br><br>As a work-around, new products can be viewed by querying the Notification and selecting to view product. |
| UI only:<br><br>UC01 Create Product | 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 |
| API only:<br><br>UC13 API 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 |
| API only:<br><br>UC13 API EP309 | 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. |

| Use Case | Issue reference | Vet EUIG Chapter 2 section | New issue included in release notes |
|---|---|---|---|
| Create Product | | | However, response for GET OperationOutcome will show ERR-1002 |
| UI only:<br><br>UC01 Create UC03 Search UC05 View UC08 Update | UPD-6096 | | Embedded spaces within a product name are being removed when displayed in UI |

# 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 21 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:

- For Legacy products, the May21 Vet EUIG specified that this attribute is mandatory for legacy product.
- 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.

### 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

# 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

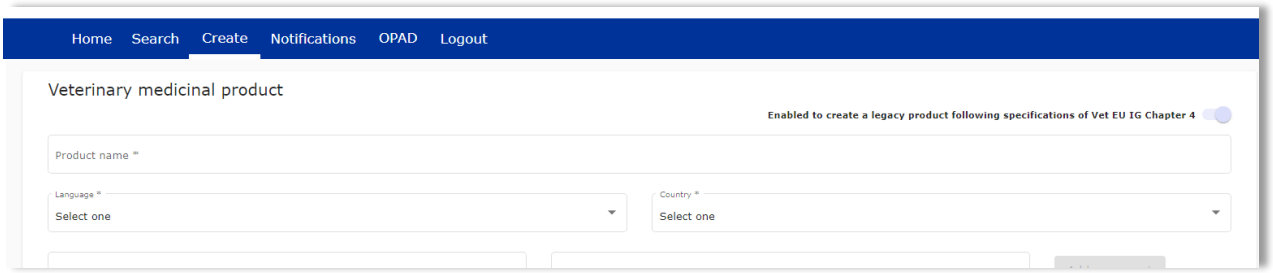
Other menu items or the edit option to update a product should not be used as these are not in scope for this release and are not fully implemented.

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. Workaround 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-5121 | 1.5 (Authorised) pharmaceutical form | You can't select any term from the "Combined Term" or "Combined Package" lists.<br><br>Select the closest term from "Pharmaceutical Dose Form" or "Combined Pharmaceutical Dose Form" lists. |
| UPD-5122<br><br>UPD-5123 | 1.7.2 ATC vet code(s)<br><br>1.7.3 ATC vet code(s) flag | The ATC vet code(s) flag should not be used.<br><br>Select the closest ATC Vet code from the list.<br><br>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 (Pharmocovigilance System) Master file | This should not be mandatory for Legacy product.<br><br>A value must be provided in this release.<br>• use value of 999 for PSM file code<br>• use the same location as used for QPPV |
| UPD-4863 | 5.6.4 Ingredient<br><br>(in Manufactured item) | This should not be mandatory for Legacy product.<br><br>An ingredient must be selected in this release. |
| | 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.<br><br>July21 Vet EUIG has updated this and the denominator may only be a term from the Unit of Presentation list.<br><br>When entering strength for an ingredient and selecting a Unit of Measurement term for the denominator (for Per), please only select "Concentration single value".<br><br>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. |

| Issue reference | Vet EUIG Chapter 2 section | Issues for UC01 Create product |
|---|---|---|
| | | If you do it is likely that the submission of your create is not successful and you will loose 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. |
| 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<br>(in Package) | If there are two or more Manufactured Items with the same Ingredient(s), and no Unit of Presentation:<br>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<br>(in Manufactured item) | Each ingredient must be selected at least one in one of the manufactured items.<br>This rule is not currently validated.<br>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-3192 | | Details of validation errors are not displayed. User is only advised "Create unsuccessful" |
| 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. |

| Issue reference | Vet EUIG Chapter 2 section | Issues for UC01 Create product |
|---|---|---|
| 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 | 2.13.1 Procedure number | For NAP product (both Legacy Chapter 4 or Chapter 2 rules), the procedure number should not be mandatory. It is not marked as mandatory on the UI screen but the "Create product" button will not be enabled without inputting a value. |
| UPD-5383 | | Not able to select "Tablet" or "Suspension" as term from Pharmaceutical Dose Form for Manufactured Dose Form or Authorised pharmaceutical form.<br><br>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 | | 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. |

## *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 |
| UPD-5144 | Search by Marketing authorisation holder does not work |

| Issue reference | Issues for UC03 Search product |
|---|---|
| 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:<br>When you select a product from the search results table, the extended details pane (product card) is empty. Therefore not able to view product.<br>As a work-around, new products can be viewed by querying the Notification and selecting to view product. |
| UPD-6096 | Embedded spaces within a product name are being removed when displayed in UI |

## 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<br>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. |
| UPD-4289 | Documents | All documents that have been loaded for a product are displayed.<br>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 |

| Issue reference | Section & attribute | Issues for UC05 View product |
|---|---|---|
| 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 | | 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*

| SPOR API Specification v2 | API Manager |
|---|---|
| EP301 Search Product | **GET** MedicinalProductDefinition - Search for a MedicinalProductDefinition resource or resources |
| EP302 Search Product Part - AdministrableProductDefinition | **GET** AdministrableProductDefinition - Search for a AdministrableProductDefinition resource or resources |
| EP302 Search Product Part - Ingredient | **GET** Ingredient - Search for a Ingredient resource or resources |
| EP302 Search Product Part - ManufacturedItemDefinition | **GET** ManufacturedItemDefinition - Search for a ManufacturedItemDefinition resource or resources |
| EP302 Search Product Part - PackagedProductDefinition | **GET** PackagedProductDefinition - Search for a PackagedProductDefinition resource or resources |
| EP302 Search Product Part - RegulatedAuthorization | **GET** RegulatedAuthorization - Search for a RegulatedAuthorization 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 |

| SPOR API Specification v2 | API Manager |
|---|---|
| EP305 Get Product Part<br>- AdministrableProductDefinition | GET AdministrableProductDefinition - Get a AdministrableProductDefinition by ID |
| EP305 Get Product Part - Ingredient | GET Ingredient - Get a Ingredient resource by ID |
| EP305 Get Product Part<br>- ManufacturedItemDefinition | GET ManufacturedItemDefinition - Get a ManufacturedItemDefinition resource by ID |
| EP305 Get Product Part<br>- PackagedProductDefinition | GET PackagedProductDefinition - Get a PackagedProductDefinition resource by ID |
| EP305 Get Product Part<br>- RegulatedAuthorization | GET RegulatedAuthorization - Get a RegulatedAuthorization resource by 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<br>DCP: POST dcp-bundle - Submit a DCP payload<br>Refer to **5.5.1. Endpoint for NAP and DCP** |
| EP309 Create Product<br>EP311 Update Product<br>- for use with these EP | GET OperationOutcome - Get a resource by ID<br>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<br>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<br>Note: previous release referred to EP51 and now changed to the correct EP number of EP402. |
| EP403 Create document | POST DocumentReference - Create a DocumentReference |

| SPOR API Specification v2 | API Manager |
|---|---|
| | 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<br><br>Please note: API Manager method shows as PUT however please use POST with request header is_update=true.<br><br>Note: previous release referred to EP51 and now changed to the correct EP number of EP404. |

## 5.2. API Manager product subscription

There are now 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.

You will be unsubscribed from any existing subscriptions to PMS products.

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

| | |
|---|---|
| | Bundle<br>type value="transaction-response<br>entry<br>response (states id of created resource)<br>[entry<br>response (for other linked child resources)<br>] * |

**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

Implementation is now aligned with July21 Vet EU Implementation Guide. As a consequence there are a number of changes from the previous release. Please refer to the examples provided.

Some of the key changes are:

| Attribute | Change |
|---|---|
| 1.5 (Authorised) pharmaceutical form | MedicinalProductDefinition<br><br>Was: combinedPharmaceuticalDoseForm<br>Now: extension.authorisedDoseForm |
| 1.8 Veterinary medicinal product name | Previous examples included MedicinalProductDefinition name.type.<br><br>This attribute is no longer required. |
| 1.9 PSMF masterFile | MedicinalProductDefinition<br><br>Values are populated within a contained resource of type DocumentReference.<br>Please refer to the example bundles. |
| 1.10 QPPV contact | MedicinalProductDefinition<br><br>Values are populated within a contained resource of type PractionerRole.<br>Please refer to the example bundles. |

| Attribute | Change |
|---|---|
| 3 Pharmaceutical product | Previous examples included population of:<br>• AdministrableProductDefinition.unitOfPresentation<br><br>This attribute is no longer required. |
| 4.3.2 Strength | Previous examples included population of both:<br>• Ingredient.substance.strength.presentation<br><br>And<br><br>• Ingredient.substance.strength.concentration<br><br>Only one value should be provided – either as presentation or concentration. |
| 5 Packaged medicinal product | Previous examples included population of the following attributes:<br>• PackagedProductDefinition.package.type<br>• PackagedProductDefinition.package quantity<br><br>These attributes are no longer required. |
| 5.6 Manufactured item | Previous examples included population of: ManufacturedItemDefinition.property with type of "unit-of-measurement"<br><br>This attribute is no longer required. |

### 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<br><br>May21 Vet EUIG specified that this attribute was mandatory for legacy load.<br><br>July21 Vet EUIG has changed this and it is no longer mandatory.<br><br>The validation rules will be updated in a future release.<br><br>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.<br><br>July21 Vet EUIG has updated this and the denominator may only be a term from the Unit of Presentation (UOP) list.<br><br>Therefore, please only use a term from the UOP list so that products created comply with this change. |

| Issue reference | Resource & attribute | Issues for EP309 Create product |
|---|---|---|
| | | 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:<br>letters allowed are only a to f to form the hexadecimal set from 0 to f<br>pattern of 8-4-4-4-12<br>The post may not be rejected or may not give an error message that clearly identifies this as being the issue |
| 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-1889 | 5.5 Marketing authorisation (package level) | This has not been implemented.<br>In this release it is only possible to specify this at product level. |
| 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. |

| Issue reference | Resource & attribute | Issues for EP309 Create product |
|---|---|---|
| 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.<br><br>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.<br><br>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 | 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 |

### 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_01.03_DCP_Chpt2_C2_Mandatory_VetIG.JSON<br><br>UPD_01.03_DCP_Chpt2_C2_Mandatory_VetIG.XML<br><br>UPD_01.03_DCP_Chpt2_C110_VetEUIG_AllData.JSON |

| Procedure type | Validation rules | Example file |
|---|---|---|
| | | UPD_01.03_DCP_Chpt2_C110_VetEUIG_AllData.XML |
| DCP | Chapter 4 Legacy | UPD_01.03_DCP_Legacy_C2_Mandatory_VetIG.JSON<br>UPD_01.03_DCP_Legacy_C2_Mandatory_VetIG.XML<br>UPD_01.03_DCP_Legacy_C110_VetEUIG_AllData.JSON<br>UPD_01.03_DCP_Legacy_C110_VetEUIG_AllData.XML |
| NAP | Chapter 2 | UPD_01.03_NAP_Chpt2_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel.JSON<br>UPD_01.03_NAP_Chpt2_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel.XML<br>UPD_01.03_NAP_Chpt2_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel.JSON<br>UPD_01.03_NAP_Chpt2_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel.XML |
| NAP | Chapter 4 Legacy | UPD_01.03_NAP_Legacy_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel.JSON<br>UPD_01.03_NAP_Legacy_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel.XML<br>UPD_01.03_NAP_Legacy_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel.JSON<br>UPD_01.03_NAP_Legacy_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel.XML |

## *5.6. API EP311 Update product*

### 5.6.1. Change in request bundle

As well as changes in attributes as for EP309 Create product, there are two additional changes in the request bundle for an update.

| Attribute | Change |
|---|---|
| Bundle.type | Must be “transaction” |
| For every Bundle.entry | Previously for every Bundle.entry ( each resource ) only attributes within Bundle.entry.resource had to be populated.<br>Now Bundle.entry.request must also be populated.<br>Bundle.entry.request.method should be:<br>• PUT to update an existing resource |

| Attribute | Change |
|---|---|
| | • POST to add a new resource<br>Bundle.entry.request.url should be:<br>• 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>
```

## 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  refer to section 5.6.1. Change in request bundle
- 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:<br><br>UPD_01.03_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<br>e.g.<br>- modify product name<br>- add another ATC Vet code<br>- add another ManufacturedItemDefinition | Sample XML of Get Everything response used as a starting point:<br><br>UPD_01.03_EP311_UpdateProduct_RequestBundle.XML |
| Update product via API | POST Bundle with request header "is_update=true" | Sample XML bundle used:<br><br>UPD_01.03_EP311_UpdateProduct_RequestBundle.XML |
| Check operation outcome | MSG_CREATED message expected | |
| EP304 Get Product Full | Check the response for modifications | Sample XML of GET everything after update:<br><br>UPD_01.03_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.<br><br>The validation message will say that the resource is not included and is mandatory, with no other validation errors in the response<br><br>As a workaround, remove the existing inline ID from one attribute so there is no longer duplicate values.<br><br>This may occur and most frequently affects:<br><br>• MedicinalProductDefinition.contact and MedicinalProductDefinition.masterFile<br><br>• AdministrableProductDefinition.routeOfAdministration, AdministrableProductDefinition.routeOfAdministration.targetSpecies, |

| Issue reference | Issues for EP311 Update product |
|---|---|
| | 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 |
| 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-4290 | Update DCP/MRP procedure product to add National data – values for Responsible authority and Product Owner are not saved |
| 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. |

| Issue reference | Issues for EP311 Update product |
|---|---|
| UPD-5384 | New Package description added to product is output in main package description attribute and not as a translation as expected |
| | |

## *5.7. API Manage document*

### 5.7.1. EP403 Create document

#### Resource Information

| **Endpoint** | POST /v {version}/DocumentReference |
|---|---|
| **Request** | |
| Accept | application/fhir+xml<br>application/fhir+json |
| Body | <DocumentReference<br>..<br></DocumentReference> |
| Content-type | application/fhir+xml<br>application/fhir+json |
| **Response** | |
| Body | Document with version 1 and document ID returned<br><br>Note : ID expected format example :<br>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<br>application/fhir+json |
| Body | n/a |
| Content-Type | n/a |
| **Response** | |

| | |
|---|---|
| Body | Bundle of <DocumentReference>(s)<br><br>e.g.<br>Bundle<br>Total value=N<br>[entry<br>{DocumentReference Resource Type}<br>] * |

### Path Parameters

| Name | Description |
|---|---|
| **Version** | Service version number<br>**Example value:**<br>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.<br><br>If = true, the contents of the document is not populated in the response in DocumentReference.content.atttachement,data.<br><br>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<br>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<br>**Example value:**<br>7a88176d-10f9-4db3-8fa0-4e4ae4594df7 |
| **version** | Service version number<br>**Example value:**<br>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<br>application/fhir+json |
| Body | <DocumentReference><br><id value="fcd2c31c-0ef9-455c-99a0-75149b888a27"/><br>..<br></DocumentReference> |
| Content-type | application/fhir+xml<br>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 |
| 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 01.03 ReleaseNotes ExampleFilesForAPI (zip file)

10. Use cases implemented in the NCA UI: