UPD Production release notes for version 01.02 March 2021

Release version 01.02 - release date: 16 March 2021

Overview of functionality and business value in this release:

This release is the next iterative version of the Union Product Database, v 01.02. This version provides:

- Additional functionality for the components of the UPD that were delivered in release 01.00, i.e. the core UPD Repository and Application Programming Interface (API), including document management and extended validation functionality. This allows for interoperability between IT systems of National Competent Authorities and the Union product database to test uploading NCA product information(1) and documents to the UPD. The sections below contain all required information to register and connect to the API and to use the available functionality.
- The first version of the NCA User Interface, providing search, view and create functionality for NAP product information and providing search and view functionality for CAP product information.

The scope of the functionality made available at this point is limited to CAP and NAP. Functionality related to MRP/DCP will be provided in the next release, v 01.03 planned for July 2021.

This release of UPD is compliant with the July 2020 version of the Vet EU Implementation Guide. The next release of UPD, v 01.03, will be compliant with the version of the Implementation Guide that has been published on 21 January 2021 and is currently still in consultation. As there is a possibility that the upgrade to this version of the Implementation Guide might require changes in the structure of the data exchanged with UPD and we can therefore not guarantee that any data entered will be retained between now and July, we do not recommend to use this release of UPD for production purposes yet. UPD 01.02 should be considered a release to be used for testing purposes. The release planned for July will allow production entry of all product information (incl. MRP/DC) that will be retained in the database.

More functionality and additional components will be made gradually available between now and January 2022.

(1): Note that the API has initially been designed to allow NCAs to fulfil their legal obligation to provide product information once the UPD is operational from January 2022 onwards, but can also be used to upload legacy information as per article 155 of Regulation 2019/6.

This release is based on FHIR version R5 Preview #2, http://hl7.org/fhir/2020May/resourcelist.html and the Draft Vet EU IG Chapter 2_Initial submission (published in July 2020)

NCA UI

Scope of this release

- UC01 Create Product via UI Scenario 1: Create Product - CAP/NAP
- UPD UC03 Search Product via UI
- UPD UC05 View Product via UI
- UPD UC21 Manage Notifications via UI - only for created CAP/NAP via API/UI and updated CAP/NAP via API

Known issues

- Implementation is based on the July 2020 version of the Vet EU Implementation Guide.
- Mandatory fields that must be populated may not be aligned for all fields to the Vet EU IG.
- Updates will be made to the layout of the Create CAP/NAP screens in the next release when alignment is made to the January 21 version of the Vet EU IG.
- When creating a product:
    - PSMF number must be populated with the value "220000000071"
    - only populate Legal Status of Supply at the Package level and not at the Product level
    - Packaged medicinal product and Manufactured item sections: when there is a choice to select Unit of Presentation or Unit of Measurement, only select Unit of Measurement
    - The following fields are not shown as mandatory on the UI with a * beside the field name. A value is required.
        - Veterinary medicinal product: Legal basis
        - Active Ingredient section > Strength: a Unit of measurement must be selected for both the numerator and denominator
        - Active Ingredient section > Reference strength: if entering a reference strength, all fields must be populated
        - Pharmaceutical product section: Administrable dose form
        - Packaged medicinal product section: Unit of Presentation for the pack size
        - Packaged medicinal product section > Manufactured item: Manufactured dose form
- Search using product name may be used but there are known issues with many other criteria
- Manage notifications
    - search by the two flags has not been implemented: "Show only products under my responsibility" & "Exclude products where my role is RMS"
    - search results & view notification details isn't populating: date & organisation

Registration process for NCA UI access (temporary for this release)

- send an email requesting access to NCA UI in UAT to Nola.Balas@ext.ema.europa.eu Please send the email from your NCA email address so that EMA can verify access is only being granted to a user from a NCA
- once you have been verified as a NCA user, login credentials will be provided for NCA UI in the UAT environment
- registration for up to 2 users for each NCA will be accepted

Access to the UI

Once registered, the UI can be found at:

- User Acceptance Testing environment: Union product database (upd-portal-uat.azurewebsites.net)
- Production environment : Union product database (upd-portal-prod.azurewebsites.net). Access to the production environment will initially only be granted when needed and after having carried out some testing in the UAT environment.

UPD API

API Supported product service endpoints:

API Spec v2 section	API Manager
EP301 Search Product	MedicinalProductDefinition - Search for a MedicinalProductDefinition resource or resources
EP302 Search Product Part - AdministrableProductDefinition	AdministrableProductDefinition - Search for a AdministrableProductDefinition resource or resources
EP302 Search Product Part - Ingredient	Ingredient - Search for a Ingredient resource or resources
EP302 Search Product Part - ManufacturedItemDefinition	ManufacturedItemDefinition - Search for a ManufacturedItemDefinition resource or resources
EP302 Search Product Part - PackagedProductDefinition	PackagedProductDefinition - Search for a PackagedProductDefinition resource or resources
EP302 Search Product Part - RegulatedAuthorization	RegulatedAuthorization - Search for a RegulatedAuthorization resource or resources
EP303 Get Product	MedicinalProductDefinition - Get a MedicinalProductDefinition ID
EP304 Get Product Full	Everything Current - Get $everything for a a MedicinalProductDefinition ID Please note: without any of the query parameters
EP305 Get Product Part - AdministrableProductDefinition	AdministrableProductDefinition - Get a AdministrableProductDefinition by ID
EP305 Get Product Part - Ingredient	Ingredient - Get a Ingredient resource by ID
EP305 Get Product Part - ManufacturedItemDefinition	ManufacturedItemDefinition - Get a ManufacturedItemDefinition resource by ID
EP305 Get Product Part - PackagedProductDefinition	PackagedProductDefinition - Get a PackagedProductDefinition resource by ID
EP305 Get Product Part - RegulatedAuthorization	RegulatedAuthorization - Get a RegulatedAuthorization resource by ID
EP306 Get Product Version	**New this release** MedicinalProductDefinition Version - Get specified version of MedicinalProductDefinition ID
EP306a Get Product Version Full	**New this release** Everything Versioned - Get $everything for a version of MedicinalProductDefinition ID
EP307 Get Product Versions	**New this release** MedicinalProductDefinition - Get all versions of MedicinalProductDefinition ID
EP309 Create Product	POST Bundle to create a product
EP309 Create Product - for use with this EP	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	**New this release** POST Bundle to update a product

EP318 Validate Product	**New this release** Verify the POST of a Create Bundle Response of 200 OK if there are no validation errors
EP51 Create document	**New this release** DocumentReference - Create a DocumentReference POST Bundle
EP51 Retrieve document by Id	**New this release** DocumentReference - Get a DocumentReference by Id Note: Provide the FHIR ID returned on successful creation of a document
EP51 Search document by Id	**New this release** DocumentReference - Search a DocumentReference by Id Note: Provide the FHIR ID returned on successful creation of a document
EP51 Update document by Id	**New this release** DocumentReference - Update a DocumentReference by Id Please note: API Manager method shows as PUT however please use POST with a header is_update=true. The parameter docid parameter is not required. In the next release this will be corrected.

API EP309 Create product key changes to note in this release

	Resource	Attribute	Change	Snippet of XML from previous release (1.1.8-0A)	Snippet of XML showing format for this release (1.2.9-0)

1	All resources	Bundle.entry.request	The request attribute is now mandatory
			
			Bundle.entry.request.method = "POST"
			
			Bundle.entry.request.url = *resource*
				`</MedicinalProductDefinition>`
				`</resource>`
				`</entry>`
				`<entry>`
				`<fullUrl value="urn:uuid:5e788137-188b-4825-a783-PkgProdDef01"/>`
				`<resource>`
				`<PackagedProductDefinition>`
					`</MedicinalProductDefinition>`
					`</resource>`
					`<request>`
					`<method value="POST" />`
					`<url value="MedicinalProductDefinition" />`
					`</request>`
					`</entry>`
					`<entry>`
					`<fullUrl value="urn:uuid:5e788137-188b-4825-a783-bbccddeeff01"/>`
					`<resource>`
					`<PackagedProductDefinition>`

2	All resources	Bundle.entry.resource.*resourcename*.subject	subject must be populated for every Resource		For ManufacturedItemDefinition and Ingredient, this is in an extension. Ingredient should reference the appropriate AdministrableProductDefinition resource. Refer to the example bundles
3	All resources	All URI values in any extension	extension.url "extension/" has been added	<extension url="https://ema.europa.eu/fhir/parallelTradeWholesaler">	<extension url="http://ema.europa.eu/fhir/extension/parallelTradeWholesaler">
4	All resources	Non SPOR list code systems URLs start with http (as per API spec)	used to accept https	For example: RegulatedAuthorization.case.identifier.system <system value="https://ema.europa.eu/fhir/ProcedureIdentifierNumber" />	<system value="http://ema.europa.eu/fhir/ProcedureIdentifierNumber" />
5	All resources	URI • Coding system URL • Identifier system URL • Extension URL	http and not https is used		

6	MedicinalProductDefinition	masterFile	File type for PSMF is now specified in an extension	`<masterFile>`
				`<type value="220000000071" />`
				`<identifier>`
				`<system value="LOC-100030103" />`
				`<value value="1.1.8-0A C4 VetEUIG All Mapped mst fle value" />`
					`<masterFile>`
					`<extension url="http://ema.europa.eu/fhir/extension/masterFileType">`
					`<valueCoding>`
					`<system value="http://spor.ema.europa.eu/v1/lists/220000000070" />`
					`<code value="220000000071" />`
					`</valueCoding>`
					`</extension>`

				<pre> </identifier> </masterFile></pre>	<pre> <identifier> <system value="http://spor.ema.europa.eu/v1/locations/LOC-100030103" /> <value value="C6 Mand VetIG RegAuthAtMedProd mst fle 01 value" /> </identifier> </masterFile></pre>

7	MedicinalProductDefinition	manufacturingBusinessOperation.manufacturer	Change from using manufacturer.reference to manufacturer.identifier	<pre><manufacturer>
				  <reference value="https://spor.ema.europa.eu/v1/locations/LOC-100001710" />
				  <display value="Frilab" />
				</manufacturer></pre>
					<pre><manufacturer>
					  <identifier>
					  <system value="http://spor.ema.europa.eu/v1/locations" />
					  <value value="LOC-100001710" />
					  </identifier>
					  <display value="Frilab" />
					</manufacturer></pre>

8	MedicinalProductDefinition	productClassification where system = http://ema.europa.eu/fhir/chemical-biological-vaccine	This attribute is not in Vet EUI Implementation Guide, but had been required in previous release in order to conform with the PMS PDM.
			
			This limitation has been removed and this attribute no longer needs to be populated in a create bundle.
			
			Note: when you do a GET MedicinalProductDefinition for a created product, you will find this attribute is still populated in this release.
				<pre><productClassification>
				  <coding>
				  <system value="http://ema.europa.eu/fhir/chemical-biological-vaccine" />
				  <code value="not-chemical-biological-vaccine" />
				  </coding>
				
				</productClassification></pre>
					No longer required to be populated in Create bundle

9	RegulatedAuthorization	holder	Change from using holder.reference to holder.identifier		Same change as illustrated for manufacturer above
10	RegulatedAuthorization	regulator	Change from using regulator.reference to regulator.identifier		Same change as illustrated for manufacturer above

11	RegulatedAuthorization	relatedDate.type	system url must now be provided		<pre><relatedDate>
					  <dateDateTime value="1998-07-14T22:00:00Z"/>
					  <type>
					  <coding>
					  <system value="http://ema.europa.eu/fhir/code-systems/authorisation-date-type" />
					  <code value="dateOfFirstAuthorisation"/>
					  </coding>
					  </type>
					</relatedDate></pre>

12	Ingredient	manufacturer	Change from using manufacturer.reference to manufacturer.identifier		Same change as illustrated for manufacturer above
13	All resources	Validation	Validation rules have been introduced		Refer to the example bundles. Mandatory attributes that were missing from the previous example: • MedicinalProductDefinition.marketingStatus.dateRange.start • PackagedProductDefinition.package.quantity Some previously populated attributes have been removed from the example bundles. In some cases these had been included in the previous examples in error. For example: • RegulatedAuthorization.case.application • Ingredient.substance.strength.extension for presentationStrengthText & concentrationStrengthText

Other changes

1. When using Try it option in API Manager for GET OperationOutcome, you had to specify a header of "Accept". This is no longer required.

API EP309 Create product Known issues

1. Validation: there are some missing validation rules and instead of the POST rejected with response status of 400 Bad Request, the bundle is accepted and a product is created. These missing validation rules will be implemented in the next release UPD 01.03 subject to the rules in Vet EUIG Jan21
    a. Ingredient resource: the subject is not to a AdministrableProductDefinition resource
    b. Ingredient.substance.strength class is not populated
    c. Ingredient.substance.strength without either presentation or concentration child populated

d. If concentration strength and any of these are not populated: Ingredient.substance.strength.concentration.numerator.code Ingredient.substance.strength.concentration.denominator.code Ingredient.substance.strength.concentration.numerator.value Ingredient.substance.strength.concentration.denominator.value
e. If presentation strength and any of these are not populated: Ingredient.substance.strength.presentation.numerator.code Ingredient.substance.strength.presentation.denominator.code Ingredient.substance.strength.presentation.numerator.value Ingredient.substance.strength.presentation.denominator.value
f. ManufacturedItemDefinition: the subject is not to the MedicinalProductDefinition resource
g. ManufacturedItemDefinition.ingredient class is not populated
h. ManufacturedItemDefinition.ingredient.reference not populated
i. MedicinalProductDefinition.manufacturingBusinessOperation class is not populated with at least one entry
j. PackagedProductDefinition.package.containedItem class is not populated

2. 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. This validation will be applied in a future release.

API EP309 Create product examples

Examples for EP309 Create Product. Please note that the purposes of these examples is to illustrate the FHIR attributes to be populated and don't represent a valid set of data according to the business rules for any specific procedure type.

XML format: Release_1.2.9-0_C6_Mandatory_VetIG_RegAuthAtMedProdOnly.XML Release_1.2.9-0_C102_VetEUIG_AllData_RegAuthAtMedicinalProductLevel.XML

JSON format: Release_1.2.9-0_C6_Mandatory_VetIG_RegAuthAtMedProdOnly.JSON Release_1.2.9-0_C102_VetEUIG_AllData_RegAuthAtMedicinalProductLevel.JSON

API EP311 Update product

How to use update product endpoint - Update product name

- Update product name

Create product via API	POST Bundle	Sample XML bundle used Create_XML.txt
Check operation outcome	MSG_CREATED message expected	
EP304 Get Product Full	Edit the response (eg update product name)	
Update product via API	Update product name - POST Bundle with header "is_update=true"	Sample JSON bundle used Update_JSON.txt
Check operation outcome	MSG_CREATED message expected	
EP304 Get Product Full	Check the response for product name change	

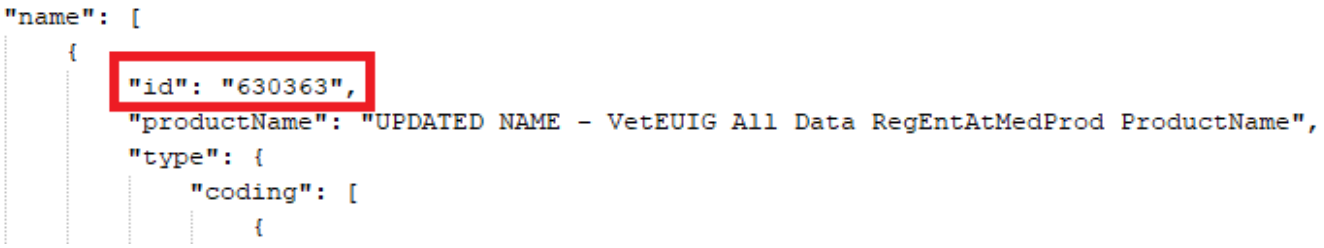
How to use update product endpoint - Add a new package

- Add new package and manufactured item

Create product via API	POST Bundle	Sample XML bundle used as above
Check operation outcome	MSG_CREATED message expected	
EP304 Get Product Full	Edit the response (eg update product name)	
Update product via API	Add new package - POST Bundle with header "is_update=true"	Sample XML bundle used Update_XML.txt
Check operation outcome	MSG_CREATED message expected	
EP304 Get Product Full	Check the response for new package addition change	

Points to note

- We can edit existing attributes, add new attributes and add new sections for a medicinal product
- Deletes and Nullifications are not implemented
- DO NOT edit or remove the IDs returned by EP304 under each resource (example below)



- There are no validation rules implemented for Update product yet
- Existing issues encountered for creates are expected to affect updates as well
- No migrated CAP products can be updated, because of outstanding data issues. We suggest to use only products created via API

API EP51 Manage document

How to create and retrieve document

- Upload document

Create document via API for an existing medicinal product ID	POST Bundle	Sample XML bundle Create_document_XML.txt
Check operation outcome	Document with version 1 and ID returned Note : ID expected format example : 7a88176d-10f9-4db3-8fa0-4e4ae4594df7	
Retrieve document - Get Document by ID		Sample JSON response Get_document_by_ID_JSON.txt

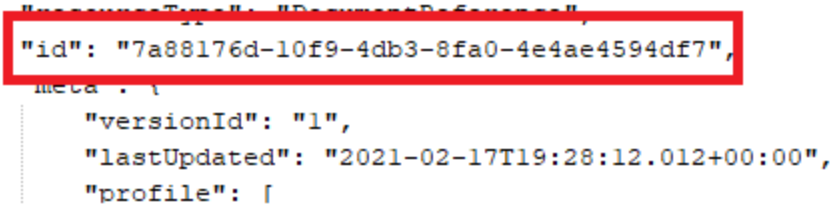
How to update and search document

- Update document

Update document via API for an existing medicinal product ID	POST Bundle	Sample JSON bundle Get_document_by_ID_JSON.txt
Check operation outcome	Document with version 1 and ID returned Note : ID expected format example : 7a88176d-10f9-4db3-8fa0-4e4ae4594df7	
Retrieve document - Search Document by ID		

Points to note

- Association of multiple medicinal products to a document is possible
- DO NOT edit or remove the IDs returned by Get document by ID (example below)



- Document type is pointing to list "Master file type" values, which is incorrect
- Document status value is case-sensitive (eg: current will work; CURRENT will fail)
- Document language value is case-sensitive (eg: en will work; EN will fail)
- Document date works only in the format as in example here : "2021-01-27T08:45:35.789+00:00"
- Deletes within update document are not implemented

References

1. Production API and Registration Process (pdf document)
2. SPOR-API-Specification V2.pdf API specifications for SMS and PMS, based on FHIR
3. HL7 FHIR Release 5 Preview 2: the authoritative source for the FHIR specifications used by EMA to implement SMS and PMS API
4. Presentation to the UPD project group about PMS / ISO IDMP / FHIR (PowerPoint format)
5. Referentials Management System
    a. Additional information
6. Organisations Management System
    a. Additional information
7. Use cases implemented in the NCA UI:
    a. UC01 Create Product via UI Scenario 1: Create Product - CAP/NAP
    b. UC03 Search Product via UI
    c. UC05 View Product via UI
    d. UC21 Manage Notifications via UI - only for created CAP/NAP via API/UI and updated CAP/NAP via API