Union Product Database (UPD) release notes
Referring to version 1.6.42

Release date: 12 February 2024

Version 2

Changes made in revised version of release notes:

- Issue **150848 has been resolved** in PROD with a Hotfix release of 1.6.42 and is now listed as a 'Resolved Issue'
  - ○ Submission of Bulk upload was successful but failed with Notification action of "Bulk upload doc fails". This issue has affected CAP products where the original document had a missing attribute in the meta data. Therefore the next bulk upload failed.

Overview of key changes:

With every new release, the UPD release notes are updated to highlight to the user the changes compared to previous versions by detailing new/updated functionalities and/or issues that have been resolved, are known, and/or are newly reported.

Compared to the previous UPD version (**1.6.40**, released on 8 December 2023), new functionalities (detailed information in section 2.1) are available and **25** defects (detailed information in section 2.2) have been considered resolved.

Overview of new functionality(ies):

- Allow national treatment of VNRA Codes affected by national data when impacting MRP/DCP/SRP. **The CMS will now approve/reject VNRA codes A.1.a, C.10.a and C.10.c and no longer the NCA users acting on behalf of the RMS**

- For CAP products only: Packages other than Marketing Authorisation Status VALID will be available for IRIS through UPD API. Therefore, any UPD API user will also see these packages included in the bundle when retrieving a CAP product. These packages will be excluded when viewing or downloading data values from UPD UI. Due to bug 152389 they are visible and will be resolved in a future release.

For full, complete information please refer to section 2 of this document.

Notes:

- In case of receiving an error file after the Availability Status (AvS) submission, MAHs are advised to follow these steps:

  - ○ If the errors in the file are due to business validations (see section 4.3.2 of Vet EU IG Chapter 7), **fix the errors and resubmit the file**.
  - ○ **If the file contains ER.36** (see section 4.3.1 of Vet EU IG Chapter 7), then you may receive two type of error files:
    - ▪ In the first case, **no updates have been processed successfully**. This can be evidenced by the fact that last column in the error report only contains ER.36 and values of type 'N/A'. In this case, capture the ER.36 errors in an Excel or CSV file and submit it as a ticket to EMA Service Now: https://support.ema.europa.eu/, and then **resubmit the part of the file containing values 'N/A'**.
    - ▪ In the second case, **some updates have been processed successfully**. This can be evidenced by the fact that last column in the error report contains ER.36 values and values of the type 'Database updated - Submission 0000 - Product 00000'. In this case, just capture the ER.36 errors in an Excel or CSV file and submit it as a ticket to EMA Service Now: https://support.ema.europa.eu/. No need to resubmit the part of the file containing values type 'Database updated - Submission 0000 - Product 00000'.

- Once the errors of type ER.36 have been addressed, incorporate the AvS of those products into the next submission, and if you again receive any error repeat all the above steps.

  Over time, as ER.36 issues are cleaned up, the size of the carry forward from month to month should diminish in size and eventually disappear.

- CA API user and zip file of example payloads

  - An updated zip file of example payloads has been provided

  - The example payloads for Create product as per section 5.5.7 have been revised to take into account recent validation changes. For example: only use Current Substances

  - The file naming convention has changed and the release ID within the filename is now the last part

- Related to the feature *F179: Substances (SMS terms) applicable for Update product process* that was released into production as part of the UPD version 1.6.40, an issue was identified (BUG 155503) preventing users to update products if these were having substances without strain (SVG code equal to 0). The issue has now been corrected and these substances are now able to be used when updating a product without receiving any validation error.

For information:
- EMA has changed the tool used for recording issues for UPD – from JIRA to Azure DevOps (ADO). ADO issue references are a number only without any prefix. The lists of issues within this document (Resolved, New & Outstanding) will continue to include the old JIRA Issue reference until such time as it is no longer deemed necessary.
- As a result of the change in the naming convention of the sprints from 2024, **after release of version 1.6.42, the naming of the releases will change**! For example the new format will be: 1.7.**2413. 24** stands for the year; **1** stands for the quarter; **3** stands for the sprint when the release reached the SIT environment.

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1. Overview of functionality and business value

1.1. Functionalities provided in this release

- API:
    - RMS can create DCP products (data and documents)
    - RMS can create MRP products (data and documents)
    - RMS can create SRP products (data and documents)
    - RMS and CMS can complement DCP/MRP/SRP products with national DCP/MRP/SRP data and documents
    - RMS can update Common data for DCP/MRP/SRP products (data and documents)
    - NCA can create and update NAP products (data and documents)
    - NCA can create & update Registered Homeopathic products (data and documents)
    - NCA can create & update Parallel Trade products (data and documents)
    - NCA can create & update Pet products (data and documents)
    - NCA can Nullify product
    - NCA can Search/view product (data and documents)
    - NCA can Search, View and Approve/Reject VNRA
    - NCA can View Volume of Sales data
- NCA UI:
    - RMS can create DCP products (data and documents)
    - RMS can create MRP products (data and documents)
    - RMS can create SRP products (data and documents)
    - RMS and CMS can complement DCP/MRP/SRP products with national DCP/MRP data (including documents)
    - RMS can update Common data for DCP/MRP/SRP products (data and documents)
    - NCA can create and update NAP products (data and documents)
    - NCA can create & update Registered Homeopathic products (data and documents)
    - NCA can create & update Parallel Trade products (data and documents)
    - NCA can create & update Pet products (data and documents)
    - NCA can save and retrieve drafts for product submissions
    - NCA can Nullify product
    - NCA can Bulk Upload Documents
    - NCA can Transfer Marketing Authorisation
    - Search/view/export products (data and documents)

- o Notifications for Create and Update of products and OPAD actions

- o View Volume of Sales information

- o View and Approve/Reject VNRA submissions

- o EMA and EC staff can update CAP products

- MAH UI:

  - o Search/view/export products (data and documents)

  - o Notifications for Create and Update of products and OPAD actions

  - o Download, Submit, and View Volume of Sales information

  - o Submit VNRA and View VNRA submissions

  - o Submit updates for Marketing authorisation status

  - o Download and Submit updates for Availability status

  - o Submit Products Grouping

  - o Submit 3rd country product names

- MAH Validation UI:

  - o Validate Volume of Sales submission file

- Authorisation for NCA & MAH UI:

  - o Integration with EMA Account Management (EAM) system for CA and Industry (MAH) roles

  - o CA users may search and view all Vet products

  - o MAH users may search and view only products under the responsibility of the organisations the user represents

- Banner for UPD UI:

  - o EMA can maintain messages to appear in banner of UPD UI

This release is based on FHIR version R5 Preview #2, http://hl7.org/fhir/2020May/resourcelist.html.

The sections below contain all the required information to register for the usage of the UI or API, connect to the API or UI, and use the available functionality.

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

Technical grouping:

Please note that the Technical grouping functionality for VNRAs involves a certain complexity, but the learning curve will be less steep if we can rely on the collaboration between all competent authorities (CAs) and marketing authorisation holders (MAHs). With this in mind, **we strongly recommend MAHs to only combine MRP/DCP and national VNRAs in such technical groupings, where only one RMS/NCA is responsible for the approval/reject action**. Combining several NCA is technically possible, but strongly discouraged as it would lead to great obstructions and significant delay in processing the VNRA's.

1.2. Functionality not included in this release

The following functionality is not included in this release.

NCA UI:

- None

MAH UI:

- None

2. Changes made compared with 1.6.40

2.1. New or re-released functionality

- **F197: Allow national treatment of VNRA Codes affected by national data when impacting MRP/DCP/SRP**

    o The CMS will now approve/reject VNRA codes affected by national data submitted to their products and no longer the NCA users acting on behalf of the RMS.

    o VNRA codes affected by national data: A.1.a, C.10.a and C.10.c.

- **F205: CAP products only: Packages other than VALID [with their Marketing Authorisation Status] available for IRIS through UPD for existing UPD CAPs**

    o For CAP products only: Packages other than Marketing Authorisation Status VALID will be available for IRIS through UPD API.

    o Therefore, any UPD API user will also see these packages included in the bundle when retrieving a CAP product.

    o CAP products will now record Marketing Authorisation Status at product level **and** at package level, as opposed to the rest of the products that will only have it at product level.

    o These packages will be excluded from CAP products when viewing or downloading data values from UPD UI. Due to bug 152389 they are visible and will be resolved in a future release

    o An updated version of Vet EU IG Chapter 2 will be published that contains the new attribute for CAP products of Marketing Authorisation Status at package level.

2.2. Resolved issues

Use Case	Affects API and/or UI	Issue reference (Old JIRA)	Issue reference (New ADO)	Resolved issues
UC01 Create product	NCA UI	UPD-13843	83371	If free text strength for an Ingredient was entered before selecting the Substance code, add button remained disabled. The workaround for this minor issue is no longer required (remove the free-text substance strength after selecting the substance code and then re-enter)
UC01 Create product **UC03 Search product** **UC08 Update product**	NCA UI		140423	A second search by Responsible Authority or Product Owner was not working correctly after using the Reset button
UC01 Create product **UC08 Update product**	NCA UI		144745	Parallel trade product - Substance ID was not displayed in table of Substances when creating or updating a product
UC03 Search product	NCA UI & MAH UI		144929	New products were not always included in search results immediately and sometimes had to wait up to 15 minutes after receiving Notification.
UC03 Search product **UC05 View Product**	API & NCA UI & MAH UI	UPD-13461	83294	The 'Organisation Name' from OMS not always displayed for a Product Owner on the Search and View Product screens
UC04 Export	NCA UI & MAH UI		100748	When export search results the limit of 10,000 records in the export file was not applied correctly and products in the csv were not the related to the results in the UI
UC06 Submit VNRA	MAH UI		149651	The Accept button to select products from the product search screen remained disabled if attempting to select products of a different procedure type to those previously selected for the Submission. This issue has been resolved.
UC06 Submit VNRA	MAH UI		151154	When submitting a VNRA and retrieving products: The Accept button was disabled in new Search when already retrieved and selected 2 (or more) products
UC07 Submit Volume of Sales	MAH UI		145137	Download Packages for Volume of Sales: Deleted packages with a description containing newline characters were not handled the same way as active packages. In a Deleted package this was being treated as the end of the row with the remaining text and other values for subsequent columns spread over several rows. Therefore those rows were not in the correct format to be used in a Submission file.

UC07 Submit Volume of Sales	MAH UI		145381	Some users received a Timeout error when downloading list of packages
UC08 Update product	NCA UI		143675	All procedure types: When edit an Ingredient, the Substance Id and status were not displaying for Reference Strength
UC08 Update product	NCA UI		139441	PET product - User was not able to edit Unit of measurement for the Reference Strength when updating a PET product
UC08 Update product	NCA UI	UPD-7247	82571	Update DCP/MPR/SRP National data – Were able to add a new Pharmaceutical Product which is a Common data. Validation error is now received when submit the update.
UC08 Update product	NCA UI		143731	Update Common Data DCP/MRP/SRP when adding package the update transaction may have remained with status of In-Progress (when checking status via API GET OperationOutcome). This will not occur for new transactions. Previously submitted updates that were affected by this issue will not be processed and should be resubmitted. Log a user support ticket if you encounter any issues.
UC08 Update product	NCA UI	UPD-12905	83246	Update National Data DCP/MRP/SRP - Visually looked like could delete a CMS as had an "x". There is no longer any option to remove a CMS
UC08 Update product	NCA UI		143857	Update National data DCP/MRP/SRP based on Chapter 4 rules: if PSMF code and location had already been populated and selected to Update National data for the product and remove PSMF values there was a validation error "Resource has invalid reference: #mf1". There is now no validation error since PSMF is optional under Chapter 4 rules.
UC08 Update product	NCA UI		83393	Update National Data DCP/MRP/SRP products - CA was able to edit some common data fields as part of the national data update. These fields are no longer enabled in the UI.
UC08 Update product	API & NCA UI		155503	When updating a product, a validation error was being displayed for those substances containing the SVG code equal to 0, meaning substances without strain. This validation was also preventing the update of the product affected. This was incorrect and these substances are now able to be used when updating a product without receiving any validation error.
UC09 Approve/Reject VNRA	NCA UI		147051	When a VNRA with automated codes which belong to both National data[C5] and Common data[A4] update was approved, only A4 data was updated and C5 failed with "Automatic update failure" action in notifications. This issue has been resolved and now updates for all variations are applied.
UC21 Manage Notifications	NCA UI & MAH UI	UPD-12454	83211	Notifications were sometimes missing for some actions. For example Create DCP - only notifications received for some CMS even although transaction had been completed successfully and products had been created. Issue has been resolved and Notifications will be received for all updates made from now on.

Use Case	Affects API and/or UI	Issue reference (Old JIRA)	Issue reference (New ADO)	Resolved issues
UC24 Marketing authorisation status	MAH UI	UPD-12092	83188	When MAH selected to update a product that has some data quality issue, the screen hung on submission. This validation error is now shown to the user.
UC27 View Volume of Sales	NCA UI & MAH UI		146897	After clicking the Reset button, the previously selected product was still highlighted
UC28 View VNRA	MAH UI		145880	When view VNRA as MAH, submissions were highlighted when product country matches the country of the Organisation that the logged on user is affiliated to. There is now no highlighting of submissions for a MAH user
UC28 View VNRA	NCA UI & MAH UI		144225	When viewing a VNRA submission, the link to download the VNeeS zip file was not displayed.
UC31 Manage VNRA Submissions via API	API		140318	Approve/Reject VNRA was giving an error. This issue has been resolved and CA may now Approve/Reject VNRA via API endpoint
UC34 Bulk Upload for Documents	NCA UI		150848	**Resolved 12/02/2024 in a Hotfix release:** Submission of Bulk upload was successful but failed with Notification action of "Bulk upload doc fails". This issue has affected CAP products where the original document had a missing attribute in the meta data. Therefore the next bulk upload failed.

2.3.
New known issues for functionality in previous release

This table is ordered by Use Case number. This section lists known issues in this release that have not previously been included in the Release Notes. Some issues had existed in a previous release, and some are new issues in this new release.

Use Case	Affects API and/or UI	Issue reference (Old JIRA)	Issue reference (New ADO)	Resolved issues
UC01 Create product	API & NCA UI		151180	CAP: incorrect Availability values have been assigned by the system (according to chapter 2) to a new CAP authorised under the new Regulation 2019/6 at the time of creation
UC01 Create product	NCA UI		151167	DCP: expected validation error is not displayed if submit Create DCP with same country as RMS and CMS. Submission is not possible with same value for both but there is no error message

UC01 Create product	API & NCA UI		151748	DCP/MRP/SRP: When create a DCP/MRP/SRP the Availability Status value is not displaying "not marketed" as default term
UC01 Create product	API & NCA UI		152291	NAP: When Create a NAP the Availability Status is not displaying "not marketed" as default term. The default values for Availability status are not populated into each Package
UC01 Create product UC08 Update product	NCA UI & API		154083	(Marketing authorisation application) Legal basis : Vet EU IG Chapter 2 section 1.7.1 : some terms from the RMS list are missing
UC01 Create product UC08 Update product	API & NCA UI		154001	NAP: It is possible to add duplicate product name for same Country/Language during Create and Update of NAP product. This should give a validation error and not allow the submission of the Create or Update
UC01 Create product UC08 Update product	NCA UI		151471	When create or update products (NAP/DCP/MRP/SRP), the button to Retrieve reference product should be activated only for specific options selected in the Legal basis field. Instead it is always activated
UC03 Search product	NCA UI & MAH UI		152101	Searching products using product name filter containing Bulgarian Letter (й) does not list product even if it includes that letter in the product name
UC05 View product	API & NCA UI & MAH UI		156128	CAP product: Authorisation status is not being re-updated to Valid in UPD after it has been changed to Suspended (in error) and then changed again to Valid
UC05 View product	API & NCA UI & MAH UI		156046	Product Owner displays old OMS name in UPD UI after organisation name has been updated in OMS
UC06 Submit VNRA	MAH UI		152295	It is not possible to submit a VNRA if the Date of implementation at Submission information level is not filled in
UC08 Update product	API & NCA UI		152242	CAP product only: after updating product in UPD there is a duplicated Pack size attribute. This duplicate attribute is only seen view Retrieve product via API. Subsequent updates via UPD for affected products are successful
UC08 Update product	NCA UI		156077	If Strength (free text) or Reference Strength (free text) is present, deleting or editing the free text disables the 'Edit Ingredient' button
UC09 Approve/Reject VNRA	NCA UI		151292	Automated C1/C5/C6: Where MAH has populated new values at product level only and left fields at VNRA level empty when VNRA was submitted: when view VNRA submission the fields on the VNRA level are populated with the values of the first product card

UC25 Update Availability status	MAH UI		149382	After downloading Availability status for one or more products and clicking Reset button, then selecting other product(s), the downloaded file contains products previously download
UC25 Update Availability status	MAH UI		149816	When select to download a second time after previously selecting a product and then deselecting one or more products - the download file still contains the deselected products
UC28 View VNRA	NCA UI		154201	Approve/Reject VNRA: When CMS enters decision for their product and before they submit, the summary table may incorrectly update the user name and decision date for some other CMS product as well as the CMS product; or may incorrectly only populate the Decision maker field on the CMS product. After decision has been submitted the status table is correctly updated and redisplayed showing updates only for the CMS variations where decision was submitted
UC28 View VNRA	NCA UI		152323	DCP/MRP/SRP products only: The VNRA card is not always highlighted for the decision maker user
UC28 View VNRA	NCA UI		152369	DCP/MRP/SRP products only: Where there is a submission for two or more variations where one variation the CA cannot approve and one variation the CA can approve: both variations are highlighted. Only the variation that the logged on CA can approved (based on their role as RMS/CMS) should be highlighted
UC28 View VNRA	MAH UI		150814	When MAH user views submission the decision maker field is fill in with MAH user Organisation name
UC33 Manage Third Country Product Names	MAH UI		150681	Download Third Country Product Names file: the Delete column is filled with "null " values and new column added with no header and with "null" values. As a workaround to use the download file for a submission: remove the additional column that has been added in the file; and delete the "null" values in the Delete column.
UC33 Manage Third Country Product Names UC38 Products Grouping	MAH UI		151721	If the logged on MAH has more than 10,000 products, the download files for Third Country Product Names and Products Grouping only contain the first 10,000 products
UC21 Manage Notifications	NCA UI & MAH UI		156686	Upload document notification is not generated after the creation of a NAP product where documents were provided

2.4. Known issues for new functionality in this release

This table is ordered by Use Case number.

New functionality[1]	Use Case	Affects API and/or UI	Issue reference (New ADO)	New Issue description
F205	UC05 View product	NCA UI & MAH UI	152389	CAP products only: Surrendered packages are included when View Product in UPD UI and they should have been excluded
F205	UC08 Update product	NCA UI	156132	CAP product: Not able to update CAP product that has packages with Authorization status values of both Valid and Surrendered. The update page never finishes loading

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[1] Note for information: in previous release notes the prefix for new functionalities was 'UPD-BR-xx'.

3. Veterinary EU Implementation Guide versions for this release

This UPD release is based on the following Vet EU IG versions:

- **Chapter 2:** Format for the electronic submission of veterinary medicinal product information – December 2023

- **Chapter 4:** Process and format for the submission of legacy data on veterinary medicinal products – July 2021

- **Chapter 6:** Examples for submission of legacy data – December 2021

- **Chapter 7:** Submission of other post-authorisation (OPAD) data – December 2023

- **Chapters 1, 3, and 5**: May 2021

3.1. *Providing Strength or Reference Strength for an Ingredient*

The following is an explanation of the workaround that is recommended to be used for issue UPD-7228

> UC01 Create & UC08 Update Product – this should be valid where Reference Strength is populated but there is no Substance Strength; or if specify Substance Strength a Reference Substance and no Reference Substance Strength. Instead, there is a validation error and Substance Strength must always be specified. In addition, if you add a Reference Substance you must always add a Reference Substance Strength.

The following table illustrates the possible combinations that should be valid and a workaround to use until this issue is resolved.

- Green tick ✓ indicates this combination is working in this release

- Red tick ✓ indicates this combination should be valid but is not working in this release.

The values in the Substance, Substance Strength, Reference Substance and Reference Substance Strength illustrate what values should be populated as a recommendation until this issue is resolved.

	(Active/Adjuvant) Substance	Substance Strength	Reference Substance	Ref. Substance Strength	Example in SPC	Working	Work around
1	✓ Amoxicillin 3H2O	✓ 300 mg/tablet			Amoxicillin 3H2O 300 mg/tablet	Yes	
2	Amoxicillin	500 mg/tablet	✓	✓	Amoxicillin 500 mg/tablet	No and not able to resolve as this is a FHIR requirement to always have substance specified	Report as substance
3	✓ Amoxicillin	500 mg/tablet	✓	✓	Amoxicillin 3H2O expressed as amoxicillin 500 mg/tablet	No – bug to fix UPD-7228	Recommendation: Report the reference substance as substance.
4	✓ Amoxicillin 3H2O	✓ 300 mg/tablet	✓		Amoxicillin 3H2O 300 mg/tablet expressed as amoxicillin	No and not able to resolve as it is a FHIR requirement to always have Reference Strength if Reference Substance is specified	Recommendation: just report the substance + strength and do not report Ref Substance
5	✓ Amoxicillin 3H2O	✓ 300 mg/tablet	✓ Amoxicillin	✓ 500 mg/tablet	Amoxicillin 3H2O 300 mg/tablet expressed as amoxicillin 500 mg/tablet	Yes	

4. NCA UI

4.1. Scope of this release for NCA UI

- UC01 Create Product via UI

    o Scenario 1 Create Product – NAP & Registered Homeopathic – Manual Key In

    o Scenario 2 Create Product – Decentralised Procedure – Manual Key In

    o Scenario 3 Create Product – MRP & SRP

    o Scenario 4 Create Product – Parallel Trade

    o Scenario 5 Cancel Create Product

    o Scenario 7 Create Product - for animals exclusively kept as pets

    o Able to create products based on Chapter 4 Legacy or Chapter 2 Validation rules

- UPD UC03 Search Product via UI

- UPD UC04 Export search results

- UPD UC05 View Product via UI

- UPD UC08 Update Product via UI

    o Scenario 1 Transfer of ownership

    o Scenario 2 Update a single Product – Common & National data for CAP, NP & Registered Homeopathic and National data for DC/MR/SR procedures (data and documents)

    o Scenario 3 Update Common Data for products under DCP/MRP/SRP (data and documents)

    o Scenario 4 Update Parallel Trade

    o Scenario 5 Cancel Update Product

    o Able to update products based on Chapter 4 Legacy or Chapter 2 Validation rules

- UPD UC19 Nullify Product

- UPD UC21 Manage Notifications via UI

    o The flags for "Show only products under my responsibility" and "Exclude products where my role is RMS" are not in scope for this release and are not implemented

- UPD UC26 Manage Draft Products

- UPD UC34 Bulk Upload of Documents

- UPD UC27 View Submissions of Volume Sales via Form

    o Scenario 1 and 3 – View and Download Volume of Sales as a CA or MAH

- UC28 View Variation not Requiring assessment via UI

- UC09 Approve/Reject Variation Not Requiring Assessment via UI

Supported browsers for the NCA UI are Chrome and Edge.

4.2. Apply Chapter 4 Legacy or Chapter 2 Validation rules

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

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

Click the button to toggle to use Chapter 2 validation rules.

4.3. Workarounds required to Create or Update products

There are some workarounds that are required in this release when creating products.

Issue reference	Vet EUIG Chapter 2 section	Issue and Workaround
82440 UPD-4863	5.6.4 Ingredient (in Manufactured item)	This should not be mandatory for Legacy products. An ingredient must be selected in this release for create of a NAP product. It is no longer mandatory for a DCP.

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

To request access:

- If you do not already have an EMA account in the Test environment:

    o EAM-Test can be found at: https://register-test.ema.europa.eu/identityiq/login.jsf

    o *Create a new EMA account* Reference guide: https://register-test.ema.europa.eu/identityiq/help/selfregister.html (note: links in the documentation are for the production environment)

- Log into EAM-Test once registration is complete to Request Access to one of the UPD NCA UI roles

    o select *Request Access for Organizations*. Reference guide: https://register-test.ema.europa.eu/identityiq/help/requestaccess.html

    o choose your country and Organization ID.

    o use "UPD" as a search option to filter available roles

    o select appropriate role:

        ▪ **UPD CA Super User** (**reminder**: **attach document** as evidence of your authority to manage users for your organisation)

        ▪ **UPD CA Edit Search View**

        ▪ **UPD CA Search View**

- Some UPD-specific screenshots can be found in Annex 1.

- The request for the first "UPD CA Super User" for your organisation will be approved by EMA. Access is only being granted to NCA staff.

- The approved "UPD CA Super User" will manage all other access requests for your organisation.

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

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

If you have questions or encounter issues, contact the VMP-Reg User Support via https://servicedesk.ema.europa.eu/jira/servicedesk/customer/portal/283/group/506.

4.5. Registration process for access to the NCA UI in production (PROD) environment

We strongly recommend that before you request access to the UPD PROD environment, you have:

- Participated (viewed recording) in the training/demo on how to submit legacy data in UPD of 4 August 2021

- Carried out some testing in the UAT environment compliant with the latest version of the EU Implementation Guide.

To request access:

- If you do not already have an EMA account in the Production environment:

    o EAM Production can be found at: https://register.ema.europa.eu/identityiq/login.jsf

    o *Create a new EMA account* Reference guide: https://register.ema.europa.eu/identityiq/help/selfregister.html

- Log into EAM Production once registration is complete to Request Access to one of the UPD NCA UI roles

    o select *Request Access for Organizations.* Reference guide: https://register.ema.europa.eu/identityiq/help/requestaccess.html

    o choose your country and Organization ID.

    o use "UPD" as a search option to filter available roles

    o select appropriate role:

        ▪ **UPD CA Super User (reminder**: **attach** Nomination **document** as evidence of your authority to manage users for your organisation)

        ▪ **UPD CA Edit Search View**

        ▪ **UPD CA Search View**

- Some UPD-specific screenshots can be found in Annex 1.

- The request for the first "UPD CA Super User" for your organisation will be approved by EMA. Access is only being granted to NCA staff.

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If you have questions or encounter issues, contact the VMP-Reg User Support via https://servicedesk.ema.europa.eu/jira/servicedesk/customer/portal/283/group/506.

5. UPD API to Maintain Products and Product Documents

5.1. Scope of this release for API

- Create DCP based on Chapter 4 Legacy or Chapter 2 rules

- Create MRP based on Chapter 4 Legacy or Chapter 2 rules

- Create SRP based on Chapter 4 Legacy or Chapter 2 rules

- RMS can update Common Data for products under DCP/MRP/SRP (data and documents)

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

- Create NP & Registered Homeopathic based on Chapter 4 Legacy or Chapter 2 rules

- Update NP & Registered Homeopathic product based on Chapter 4 Legacy or Chapter 2 rules

    o Edit existing, add new, or delete an existing non-mandatory attribute

    o Add new resources. For example: add an Ingredient or add another Package

    o Delete an existing non-mandatory resource. For example: remove an Ingredient

- Create & Update Parallel trade based on Chapter 4 Legacy or Chapter 2 rules

- Create & Update Pet products based on Chapter 4 Legacy or Chapter 2 rules

- Search and retrieve products

- Nullify product

- Upload, search, retrieve, and update Documents (for product under any procedure type)

5.2. UPD API supported Product Service endpoints

EP302 Search Product Part and EP305 Get Product Part endpoints are no longer available.

SPOR API Specification v2	API Manager
EP301 Search Product	**GET** MedicinalProductDefinition - Search for a MedicinalProductDefinition resource or resources
EP303 Get Product	**GET** MedicinalProductDefinition - Get a MedicinalProductDefinition ID
EP304 Get Product Full	**GET** Everything Current - Get $everything for a MedicinalProductDefinition ID
EP306 Get Product Version	**GET** MedicinalProductDefinition Version - Get version of MedicinalProductDefinition ID
EP306a Get Product Version Full	**GET** Everything Versioned - Get $everything for a version of MedicinalProductDefinition ID
EP307 Get Product Versions	**GET** MedicinalProductDefinition - Get history of MedicinalProductDefinition ID

SPOR API Specification v2	API Manager
EP309 Create Product	NAP: `POST` Bundle - Create/Update resources in the bundle DCP: `POST` dcp-bundle - Submit a Create DCP payload MRP: `POST` mrp_bundle – Submit a Create MRP payload SRP: `POST` srp_bundle – Submit a Create SRP payload Registered homeopathic: `POST` Bundle - Create/Update resources in the bundle Parallel trade: `POST` ptp-bundle - Create/Update resources in the bundle Pet: `POST` pet-bundle - Create/Update resources in the bundle Refer to 5.5.2. Create and Update endpoints
EP309 Create Product EP311 Update Product for use with any Create or Update	`GET` OperationOutcome - Get a resource by ID Note: use this to query the outcome of Create or Update when response to Post is "202 Accepted"
EP311 Update Product	NAP: `POST` Bundle - Create/Update resources in the bundle Update National Data: `POST` /upd/api/v1/national-data-bundle/ - Submit an Update National Data payload for DCP/MRP/SRP products Update Common Data: `POST` /upd/api/v1/common-data-bundle/ - Submit an Update Common Data payload for DCP/MRP/SRP products
EP318 Validate Product	`POST` Validate Bundle – To validate a bundle and the resources in the bundle Used for all procedure types; for both chapter 2 or legacy validation rules; and for both Create & Update
EP UC19 Nullify Product	`POST` /upd/api/v1/vmp-nullification/
EP401 Search document	`GET` DocumentReference - Search for DocumentReference No
EP402 Get/Retrieve document by Id	`GET` DocumentReference - Get a DocumentReference by Id Note
EP403 Create document	`POST` DocumentReference - Create a DocumentReference

SPOR API Specification v2	API Manager
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.

5.3. API Manager product subscription

Any new API users should register a user and subscribe to the product Authorised - UPD API - Milestone 3 (UPD 1.03) in API Manager.

The credentials for this new product can be used for all supported endpoints as listed in section 5.2. UPD API supported Product Service endpoints

Refer to the document Registration Process for UPD API in Production/UAT listed in the References section.

5.4. Apply Chapter 4 Legacy or Chapter 2 Validation rules

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

Please note that each type of update may use a different value for the Key.

Value	Validation rules applied
Request header not included	Vet EUIG Chapter 2
false	Vet EUIG Chapter 2
true	Vet EUIG Chapter 4 Legacy

5.5. API EP309 Create, EP311 Update & Nullify product endpoints

5.5.1. Request headers applicable for all Create, Update & Nullify POST

When submitting a POST for EP309 Create Product or EP311 Update or Nullify Product, the same Request headers are used for all endpoints that specify the format for the request and response.

Request Header: Key	Values	Purpose
Content-type	application/fhir+xml application/fhir+json	Specifies the format of the request body that is being submitted
Accept	application/fhir+xml application/fhir+json	Specifies the format for the response body of the POST if there are any validation or other errors

5.5.2. Create and Update endpoints

- As specified in SPOR API v2 Specification section 6.4.12

- Refer to API Manager developer portal

- The Request body is a Bundle (type=transaction) of MedicinalProductDefinition and other resources

- For all the Update endpoints, the Bundle should be based on all data in the existing product. This includes Update Common Data DCP/MRP/SRP where all existing National data should also be included in the bundle even although it is only Common data that will be updated

- Create MRP is an update to an existing NP product. The Bundle should be based on all national data in that product, with the additional Common data added, and the procedure type updated to MRP

- Create SRP is an update to an existing DCP/MRP/SRP product. The Bundle should be based on all national data in that product, with the additional Common data added

- Please refer to the example bundles and recommended approach sections

Type and Procedure	POST Endpoint	Request header Key for validation rules	Additional Request header
Create NP	/pms/api/v2	chapter4	
Update NP	/pms/api/v2	chapter4	is update = true
Create DCP	/upd/api/v1/dcp-bundle/	chapter4	
Update Common Data DCP/MRP/SRP	/upd/api/v1/common-data-bundle/	chapter4	is update = true
Update National Data DCP/MRP/SRP	/upd/api/v1/national-data-bundle/	chapter4	is update = true
Create MRP	/upd/api/v1/mrp-bundle/	chapter4	
Create SRP	/upd/api/v1/srp-bundle/	chapter4	
Create Registered Homeopathic	/pms/api/v2	homeopathicschapter2 = true OR homeopathicschapter4 = true	
Update Registered Homeopathic	/pms/api/v2	homeopathicschapter2 = true OR homeopathicschapter4 = true	is update = true

Type and Procedure	POST Endpoint	Request header Key for validation rules	Additional Request header
Create Parallel Trade	/upd/api/v1/ptp-bundle/	parallelchapter2 = true OR parallelchapter4 - true	
Update Parallel Trade	/upd/api/v1/ptp-bundle/	parallelchapter2 = true OR parallelchapter4 - true	is update = true
Create Pet	/upd/api/v1/pet-bundle/	chapter4	
Update Pet	/upd/api/v1/pet-bundle/	chapter4	is update = true
To Validate any Create or Update bundle	/pms/api/v2/$Validate	Use appropriate request header to apply validation rules based on the procedure type	Use is update = true when validating the following bundles: • Update NP • Update Registered Homeopathic • Update Parallel Trade • Update Pet • Update Common Data DCP/MRP/SRP • Update National Data DCP/MRP/SRP • Create MRP • Create SRP

5.5.3. Nullify endpoint

Type and Procedure	POST Endpoint	Request header Key for validation rules	Additional Request header
Nullify product	/upd/api/v1/vmp-nullification/	not required	

Content-Type	Request body
| JSON | ```
{
    "permanentId": "Permanent Identifier"
}
```<br><br>For example:<br><br>```
{
    "permanentId": "600011984989"
}
``` |
| XML | `<root><permanentId> Permanent Identifier </permanentId></root>`

For example:

`<root><permanentId>600011353107</permanentId></root>` |

Response to POST:

- Response code 202 Accepted indicates the nullification has been successfully submitted
- Response code 400 Bad request indicates there is a validation error and the Response body will contain error message. For example:
  "Resource type 'Bundle' with id '600011984989' couldn't be found."

5.5.4. Response to POST for Create, Update or Nullify and use of Get OperationOutcome

When POST for Create, Update or Nullify is successful and it cannot be honoured timely it is automatically queued. The Response header **Content-Location** contains an id that can be used to obtain the status of the operation.

Content-Location has two parts: **post-operation**/**operation-outcome-id**

The status of the operation can be consulted, it is one of:

- QUEUED
- IN_PROGRESS
- MSG_CREATED
- ERROR

Upon successful creation, update or nullification of the medicinal product, the operation outcome will show a status of MSG_CREATED along with the unique Permanent identifier(s) of the product(s).

The endpoint GET OperationOutcome/**operation-outcome-id** is used to query the status of the operation and this should be repeated until it is successful with MSG_CREATED or has ERROR.

The format of the Content-Location is showing in the following table, and the response value can be used for Get OperationOutcome.

POST	Content Location example showing format of the operation-outcome-id
Create NP	OperationOutcome/baab996e-8e58-4825-89d1-90a8f30458db
Update NP	OperationOutcome/c2e2275c-141c-4631-a42e-045726d95adb
Create DCP	Release 1.6.16 and prior: dcp-operation-outcome/ddb9f96b-10f5-4428-9503-170feb5c58db-DCP Release 1.6.20 is now: OperationOutcome/ddb9f96b-10f5-4428-9503-170feb5c58db-DCP
Update Common Data DCP/MRP/SRP	Release 1.6.16 and prior: common-data-operation-outcome/f4d76850-358a-48f1-a9bb-3fb4b1615bdb-CD Release 1.6.20 is now: OperationOutcome/ f4d76850-358a-48f1-a9bb-3fb4b1615bdb-CD
Update National Data DCP/MRP/SRP	Release 1.6.16 and prior: national-data-operation-outcome/b371f2db-dd29-4c60-b6ab-63b0abf95bdb-ND Release 1.6.20 is now: OperationOutcome/ b371f2db-dd29-4c60-b6ab-63b0abf95bdb-ND
Create MRP	Release 1.6.16 and prior: mrp-operation-outcome/2f89089c-3ad7-4427-9311-7ea491395ddb-MRP Release 1.6.20 is now: OperationOutcome/2f89089c-3ad7-4427-9311-7ea491395ddb-MRP
Create SRP	Release 1.6.16 and prior: srp-operation-outcome/cf7af9a9-b34d-4db9-a551-89d40c077306-SRP Release 1.6.20 is now: OperationOutcome/cf7af9a9-b34d-4db9-a551-89d40c077306-SRP
Create & Update Registered Homeopathic	OperationOutcome/a588416b-7a0b-40b1-8d03-a88ea4668f8f
Create & Update Parallel Trade	OperationOutcome/04b5bc00-16f4-4ea0-b33e-1a95029d8f8f-PTP
Create & Update Pet	OperationOutcome/2664fdf2-6aef-4540-8254-b6df6451b8af-PET

5.5.5. Creating products for DCP or Update Common Data 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.

The same applies for Update Common Data. The RMS should populate the complete Update bundle for their RMS product containing all existing Common and National Data. Only Common Data will be updated to the RMS product and the CMS products under the Product identifier.

5.5.6. Key changes in valid request bundle for create and update

Attribute	Change
None	

5.5.7. API EP309 Create product example request bundles

Examples for EP309 Create Product for NP and DCP. Please note that the purpose of these examples is as illustration of the FHIR attributes to be populated.

The value for MedicinalProductDefinition as a cross referenced product is a valid permanent identifier from UAT.

Please note: the naming convention for these example files has changed to put release ID as the final part

Procedure type	Validation rules	Example file
DCP	Chapter 2	DCP_Chpt2_C2_Mandatory_VetIG_UPD_1.6.42.JSON
		DCP_Chpt2_C2_Mandatory_VetIG_UPD_1.6.42.XML
		DCP_Chpt2_C110_VetEUIG_AllData_UPD_1.6.5-6.JSON
		DCP_Chpt2_C110_VetEUIG_AllData_UPD_1.6.5-6.XML
DCP	Chapter 4 Legacy	DCP_Legacy_C2_Mandatory_VetIG_UPD_1.6.42.JSON
		DCP_Legacy_C2_Mandatory_VetIG_UPD_1.6.5-6.XML
		DCP_Legacy_C110_VetEUIG_AllData_UPD_1.6.5-6.JSON
		DCP_Legacy_C110_VetEUIG_AllData_UPD_1.6.5-6.XML
NAP	Chapter 2	2.2 Authorisation/registration/entitlement number is specified at Product level
		NAP_Chpt2_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel_UPD_1.6.1-4.JSON
		NAP_Chpt2_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel_UPD_1.6.42.XML
		NAP_Chpt2_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel_UPD_1.5.1-0.JSON

Procedure type	Validation rules	Example file
		NAP_Chpt2_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel_UPD_1.5.1-0.XML
		5.5 Marketing authorisation (package level)
		NAP_Chpt2_C111_VetEUIG_AllData_MANumber_AtPackageLevel_UPD_1.5.1-0.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	NAP_Legacy_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel_UPD_1.6.42 NAP_Legacy_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel_UPD_1.6.42.XML NAP_Legacy_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel_UPD_1.5.1-0.JSON NAP_Legacy_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel_UPD_1.5.1-0.XML
NAP	Chapter 4 Legacy	NAP_Legacy_Cx_ManyAttributesAndResources_MANumberAtMedicinalProductLevel_UPD_1.5.1-0.XML This example contains: • 2 or more values for those attributes that are repeatable. For example, Product name, ATC Vet Code, Manufacturing Business Operation • 2 Packages (PackagedProductDefinition) • 2 Manufactured Items (ManufacturedItemDefinition) • 3 Ingredients (Ingredient)

Procedure type	Validation rules	Example file
NAP	Chapter 2	NAP_Chpt2_ExampleForStrengthAsPresentationOrConcentration_UPD_1.6.42.XML This example contains Ingredient resources that illustrate how to specify Substance and Reference Strength as either Presentation or Concentration.
NAP	Chapter 2	NAP_Chpt2_Create_BR-178_StrengthFreeTextExample_1.6.42.XML F178: This example contains Ingredient resources that illustrate how to specify free-text substance or reference substance strength
Registered Homeopathic	Chapter 2	HOM_Chpt2_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel_UPD_1.6.42.JSON HOM_Chpt2_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel_UPD_1.6.1-4.JSON
Parallel Trade	Chapter 2	PTP_Chpt2_C2_Mandatory_VetIG_UPD_1.6.42.JSON PTP_Chpt2_C110_VetIG_AllData_UPD_1.6.8-4.JSON
Pet	Chapter 2	PET_Chpt2_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel_1.6.42.JSON PET_Chpt2_C110_AllData_VetIG_MANumber_AtMedicinalProductLevel_1.6.34-5.JSON

5.5.8. Recommended approach to prepare update request bundle

The recommended approach for preparing a request bundle to update a product (any procedure type) is:

- Use the response from EP304 GET MedicinalProductDefinition/{permanent identifier}/$everything as a starting point

- Add Bundle.entry.request for each resource and update Bundle.type

Attribute	Change
Bundle.type	Must be "transaction"
For every Bundle.entry	Bundle.entry.request must also be populated. Bundle.entry.request.method should be: • PUT to update an existing resource • POST to add a new resource Bundle.entry.request.url should be: • Same value as Bundle.entry.fullUrl

For example:

```xml
<?xml version="1.0" encoding="utf-8"?>
<Bundle xmlns="http://hl7.org/fhir">
    <id value="600000022531" />
    <meta>
        <versionId value="1" />
        <lastUpdated value="2021-07-07T08:52:51.607+00:00" />
    </meta>
    <type value="transaction" />
    <entry>
        <fullUrl value="MedicinalProductDefinition/600000022531" />
        <resource>
            <MedicinalProductDefinition>
        </resource>
        <request>
            <method value="PUT" />
            <url value="MedicinalProductDefinition/600000022531" />
        </request>
    </entry>
    <entry>
        <fullUrl value="PackagedProductDefinition/170427" />
        <resource>
            <PackagedProductDefinition>
        </resource>
        <request>
            <method value="PUT" />
            <url value="PackagedProductDefinition/170427" />
        </request>
    </entry>
```

- DO NOT edit or remove the IDs for each resource and in-line within each resource in the EP304 Get $everything response

5.5.9. How to use Update NP product endpoint and example bundle

Create product via API	POST Bundle	Sample XML bundle used: UPD_1.5.1-0_NAP_Legacy_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel.XML
Check operation outcome	MSG_CREATED message expected containing Permanent identifier	

EP304 Get Product Full	Prepare update bundle based on the response by updating Bundle.type to transaction and adding Bundle.entry.request.method for each resource.
	Edit the payload
	e.g.
	  - modify product name
	  - add another ATC Vet code
	  - add another ManufacturedItemDefinition including this into the existing PackagedProductDefinition
		Sample XML of Get Everything response used as a starting point:
		UPD_1.5.1-0_EP311_UpdateProduct_GetEverything_version1.XML
		
		Update bundle prepared:
		UPD_1.5.1-0_EP311_UpdateProduct_RequestBundle.XML

Update product via API	POST Bundle with request headers to /pms/api/v2 • "is_update=true" • "chapter4" = true or false for the validation rules to apply	
Check operation outcome	MSG_CREATED message expected containing Permanent identifier	
EP304 Get Product Full	Check the response for modifications	Sample XML of GET everything after update: UPD_1.5.1-0_EP311_UpdateProduct_GetEverything_version2.XML

5.5.10. How to use Update National Data DCP/MRP/SRP product endpoint and example bundle

EP304 Get Product Full	Prepare update bundle based on the response by updating Bundle.type to transaction and adding Bundle.entry.request.method for each resource. Edit the payload and add national data e.g. - Product name - Legal status of supply (product level) - Package description - Marketing authorisation number (product level) - Marketing authorisation status & dates - Responsible authority	Create DCP using this example file: UPD_1.6.16-5_CreateDCPForUpdateNationalData.XML Product Identifier: d0f4414c-cd65-478b-921e-f107c66f7a85 CMS for Italy **Permanent identifier:** 600000251886 Sample XML of Get Everything response used as a starting point: UPD_1.6.16_DCP_UpdateNationalData_600000251886_GetEverything_v1.XML Update bundle prepared: UPD_1.6.16_DCP_UpdateNationalData_600000251886_BasedOn_v1.XML
Update product via API	POST Bundle with request headers to /upd/api/v1/national-data-bundle/ • "is_update=true" • "chapter4" = true or false for the validation rules to apply	
Check operation outcome	MSG_CREATED message expected containing Permanent identifier	
EP304 Get Product Full	Check the response for modifications	Sample XML of GET everything after update: UPD_1.6.16_DCP_UpdateNationalData_600000251886_GetEverything_v2.XML

5.5.11. How to use Update Common Data DCP/MRP/SRP product endpoint and example bundle

EP304 Get Product Full	Prepare update bundle based on the response by updating Bundle.type to transaction and adding Bundle.entry.request.method for each resource.
	
	Edit the payload
	e.g.
	  - modify common product name
	  - add another ATC Vet code
	
	Important: any national data that has been populated should be also included in the update bundle.
		Sample XML of Get Everything response used as a starting point:
		
		UPD_1.5.3-4_DCP_UpdateCommonData_Product_600000149642_GetEverything_Version1.XML
		
		Update bundle prepared:
		
		UPD_1.5.3-4_DCP_UpdateCommonData_Product_600000149642_UpdateBundleBasedOnVersion1.XML

Update product via API	POST Bundle with request headers to /upd/api/v1/common-data-bundle/ • "is_update=true" • "chapter4" = true or false for the validation rules to apply	
Check operation outcome	MSG_CREATED message expected containing Permanent identifiers	
EP304 Get Product Full	Only the Common data in the RMS and CMS products under that Product Identifier will be updated	Please refer to Known issues section for any outstanding issues where national data submitted when updating common data is not being ignored.

5.5.12. How to use Create MRP product endpoint and example bundle

EP304 Get Product Full	Prepare update bundle based on the response by updating Bundle.type to transaction and adding Bundle.entry.request.method for each resource.	Sample XML of Get Everything response used as a starting point: UPD_1.5.3-4_CreateMRP_NP_600000184179_GetEverything_version1.XML
Prepare Create MRP Bundle	• Change procedure type from NP to MRP • Add Common Name with Country = EU and Language = English • Add Reference member state and Concerned member state • Add Common package description in English (if doesn't exist)	Create MRP bundle prepared: UPD_1.5.3-4_CreateMRP_BasedOn_NP_version1.XML

Create MRP via API	POST Bundle with request headers to /upd/api/v1/mrp-bundle/ • "chapter4" = true or false for the validation rules to apply	
Check operation outcome	MSG_CREATED message expected containing Permanent identifiers for RMS NP product and products created for each CMS	
EP304 Get Product Full	RMS: • Contains the Common data that was added CMS: • Each new product is only populated with Common data, with status of Provisional	

5.5.13. How to use Create SRP product endpoint and example bundle

EP304 Get Product Full	Prepare update bundle based on the response by updating Bundle.type to transaction and adding Bundle.entry.request.method for each resource.	Sample XML of Get Everything response used as a starting point: UPD_1.6.1-4_CreateSRP_RMSProduct_GetEverything_version1.XML
Prepare Create SRP Bundle	• Add new Concerned member state(s) • Update common data as required	Create SRP bundle prepared: UPD_1.6.1-4_CreateSRP_BasedOnRMSProduct_version1.XML
Create SRP via API	POST Bundle with request headers to /upd/api/v1/srp-bundle/ • "chapter4" = true or false for the validation rules to apply	
Check operation outcome	MSG_CREATED message expected containing Permanent identifiers for existing RMS & CMS products and products created for each new CMS	
EP304 Get Product Full	RMS & existing CMS: • Contains the new CMS • Procedure type remains unchanged • Contains the Common data that was updated New CMS: • Each new product is only populated with Common data, with status of Provisional, and procedure type of SRP	

5.6. API Manage document

5.6.1. EP403 Create document

Resource Information

Endpoint	POST /pms/api/v2/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: 3c46270e-3c3d-4869-a73c-ad4d7c3f2893

Query Parameters

None

Example Request

For UAT environment: POST https://spor-uat.azure-api.net/pms/api/v2/DocumentReference

Example file for request body: UPD_1.6.1-4_Doc_EP403_CreateDocument.XML

PDF document that was converted to base64: EP403_UploadDocument.PDF

- Document status value is case-sensitive (e.g.: current will work; CURRENT will fail)
- Document language value is case-sensitive (e.g.: en will work; EN will fail)

5.6.2. EP401 Search document

Resource Information

Endpoint	GET /pms/api/v2/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 set to 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 /pms/api/v2/DocumentReference?related=MedicinalProductDefinition/600000216133

GET /pms/api/v2/DocumentReference?type=100000155538

GET /pms/api/v2/DocumentReference?related=MedicinalProductDefinition/600000216133&_summary=true

5.6.3. EP402 Get/retrieve document

Resource Information

Endpoint	GET /pms/api/v2/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/3c46270e-3c3d-4869-a73c-ad4d7c3f2893

5.6.4. EP404 Update document

Resource Information

Endpoint	POST /pms/api/v2/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/pms/api/v2/DocumentReference

Example file for request body:

- GET of document before update: UPD_1.6.1-4_Doc_EP402_GetDocument_version1.XML

- Update posted: UPD_1.6.1-4_Doc_EP404_UpdateDocument_BasedOnVersion1.XML

- Response to POST: UPD_1.6.1-4_Doc_EP404_ResponseAfterUpdate.XML

- GET of document after update: UPD_1.6.1-4_Doc_EP402_GetDocument_AfterEP404Update_version2.XML

5.6.5. Changes for Create and Update document payload

- There are no changes to payload

6. UPD API for VNRA

6.1. Scope of this release for VNRA API

UPD-UC31 Manage VNRA Submissions via API

- Search and Retrieve VNRA

- Approve/Reject VNRA

6.2. UPD API supported VNRA endpoints

6.2.1. Query / Retrieve VNRA Submission

Query / Retrieve VNRA Submission	GET	**Returns the complete collection of submissions which the caller is entitled to view** */vnra-submission?permanentIdentifier={permanentId}* *upd/api/vnra/v3/vnra-submission?permanentIdentifier=600013438271*
APIM entry point	UAT	*https://spor-uat.azure-api.net/upd/api/vnra/v3/vnra-submission?permanentIdentifier=600013438271*
APIM entry point	PROD	*https://spor.azure-api.net/upd/api/vnra/v3/vnra-submission?permanentIdentifier=600013438271*
Query Parameters		**Query Parameters (All Are Optional)** *Note: Calls to base url , (without parameters) /vnra-submission will return the complete collection of submissions which the caller is entitled to view* 1. **productName : Product name – free text field and case insensitive** 2. **productIdentifier : Product identifier – free text field** 3. **permanentIdentifier : Permanent identifier – free text field** 4. **mah : OMS LOC_ID of Product owner – LOC-100005358** 5. **responsibleAuthority : OMS LOC_ID of Responsible authority (organisation) – LOC-100001603** 6. **maNumber : Authorisation/registration/entitlement number – free text field** 7. **procedureType : Procedure type – RMS Code** 8. **procedureNumber : Procedure number – free text field with "Starts with" and "Contains" and case insensitive** 9. **submissionIdentifier : Submission identifier – free text field** 10. **submissionStatus : Submission status – PENDING	APPROVED	PARTIALLY_APPROVED	REJECTED** 11. **dateFrom : Date From-To – calendar field to add interval "from"** 12. **dateTo : Date From-To – calendar field to add interval "to"** 13. **vnraStatus : VNRA Status – single selection field with list of VNRA status -PENDING	APPROVED	REJECTED** 14. **vnraClassificationIdentifier : vnraClassificationIdentifierClassification – field with list of VNRA classifications - RMS Code**

Headers

Headers

The following Headers will be provided / injected by APIM -

1. APIM-Correlation-ID Generated and Included with all POST / PUT / DELETE by default. For future BAM requirements include with GET
2. APIM-User-ID ==> From User's bearer token.
3. APIM-Org-ID ==> org affiliations are included.

Security Headers (Mandatory)

v3 of the API require a mandatory Bearer Token which is passed via the Authorization header

Oauth Bearer Token

```
curl -X GET \
  -H "Authorization: Bearer $(oauth-access-token)" \
 https://spor.azure-api.net/upd/api/vnra/v3/vnra-submission
```

Pagination

Pagination

Pagination is implemented using Spring Boot Pagination which returns the following standard **Pagination Payload.**
submission data are returned with in "content": [...],

PageSize is set using the _size parameter.
Iterating through the pages is managed via _page=x totalPages: y evaluation,
If totalPages=y and the consumer searches for the last page, then _number should be set to y-1.
https://spor.azure-api.net/**upd/api/vnra/v3/vnra-submission?** _size=5
https://spor.azure-api.net/**upd/api/vnra/v3/vnra-submission**? _size=5&_page=2

Pagination Payload

```json
{
    "content": [...],
    "pageable": {
  "sort": {
   "empty": false,
   "sorted": true,
   "unsorted": false
  },
  "offset": 0,
  "pageNumber": 0,
  "pageSize": 1,
  "paged": true,
  "unpaged": false
 },
 "totalPages": 485,
 "totalElements": 485,
 "last": false,
 "sort": {
  "empty": false,
  "sorted": true,
  "unsorted": false
 },
 "size": 1,
 "number": 0,
 "first": true,
```

```json
      "numberOfElements": 1,
      "empty": false
  }
```

Sample Payload

```json
{
  "content": [
    {
      "submissionId": 1588,
      "submissionDate": 1694433983143,
      "submissionComment": "NoComments",
      "submissionStatus": "PENDING",
      "products": [
        {
          "permanentId": "600001120431",
          "procedureType": "100000155062",
          "productRelationships": [
            {
              "organisationId": "ORG-100004089",
              "relationship": "Holder"
            },
            {
              "organisationId": "ORG-100003944",
              "relationship": "Regulator"
            }
          ]
        },
        {
          "permanentId": "600001120431",
          "procedureType": "100000155062",
          "productRelationships": [
            {
              "organisationId": "ORG-100004089",
              "relationship": "Holder"
            },
            {
              "organisationId": "ORG-100003944",
              "relationship": "Regulator"
            }
          ]
        }
      ]
    }
  ],
  "pageable": {
    "sort": {
      "empty": false,
      "sorted": true,
      "unsorted": false
    },
    "offset": 0,
    "pageNumber": 0,
    "pageSize": 1,
    "paged": true,
    "unpaged": false
  },
  "totalPages": 485,
  "totalElements": 485,
  "last": false,
  "sort": {
    "empty": false,
    "sorted": true,
```

```
    "unsorted": false
  },
  "size": 1,
  "number": 0,
  "first": true,
  "numberOfElements": 1,
  "empty": false
}
```

6.2.2. Retrieve a VNRA Submission

Retrieve a VNRA Submission	GET	Retrieve a specific VNRA submission identified by its submissionId */vnra-submission/<submissionId>?summary={true|false}* *upd/api/vnra/v3/vnra-submission/456?summary=true*
APIM entry point	UAT	*https://spor-uat.azure-api.net/upd/api/vnra/v3/vnra-submission/456?summary=false*
APIM entry point	PROD	*https://spor.azure-api.net/upd/api/vnra/v3/vnra-submission/456?summary=false*
Path Parameter		*/vnra-submission/<submissionId>* *<SubmissionId> is the ID of the submission to retrieve*
Query Parameters		**Query Parameter (All Are Optional)** summary (Optional) : _(true|false) Returns a summary view of the submission else a full view_

Headers		**Headers**
		The following Headers will be provided / injected by APIM -
		    1. APIM-Correlation-ID Generated and Included with all POST / PUT / DELETE by default. For future BAM requirements include with GET
		    2. APIM-User-ID ==> From User's bearer token.
		    3. APIM-Org-ID ==> org affiliations are included.
		
		Security Headers (Mandatory)
		v3 of the API require a mandatory Bearer Token which is passed via the Authorization header
		Oauth Bearer Token
		curl -X GET \
		  -H "Authorization: Bearer $(oauth-access-token)" \
		  https://spor.azure-api.net/upd/api/vnra/v3/vnra-submission/456?summary=false

Sample Payload
 	
Summary=false
		`{`
		  `"submissionId": 1596,`
		  `"submissionDate": 1694450625907,`
		  `"submissionComment": "Submit VNRA For NAP 11/09/2023",`
		  `"submissionStatus": "APPROVED",`
		  `"variations": [`
		    `{`
		      `"variationId": 16517,`
		      `"vnraGroup": "a458cce6-5553-4efb-b974-7147069d13fc",`
		      `"productName": "Automation Test Create NAP CH2 2023-09-11 GYxEGh",`

```
    "productIdentifier": "926d544f-3fd6-44a3-9150-
48bbb277fed6",
       "permanentIdentifier": "600001120724",
       "procedureNumber": "EMEA/V/C/777777",
       "responsibleAuthority": "LOC-100000065",
       "authorisationCountry": "100000000535",
       "marketingAuthorisationNumber": "EMEA/V/C/777777",
       "vnraCode": "200000018624",
       "implementationDate": 1694390400000,
       "decisionDate": 1694390400000,
       "decisionAuthor": "Beyond Automation",
       "decisionMaker": "ORG-100003944",
       "decisionComment": "Comment Beyond Automation",
       "status": "APPROVED",
       "marketingAuthorisationHolder": "LOC-100002851",
       "fieldChanges": []
     }
   ],
   "vnessFileName": "Test.zip"
}
```

Sample Payload Summary=true	```{ "submissionId": 1596, "submissionDate": 1694450625907, "submissionComment": "Submit VNRA For NAP 11/09/2023", "submissionStatus": "APPROVED", "vnessFileName": "Test.zip" }```

6.2.3. Download a VNeeS

Download a VNeeS	GET	Download a VNeeS linked to a VNRA Submission */vnra-submission/<submissionId>/vness* *upd/api/vnra/v3/vnra-submission/456/vness*
APIM entry point	UAT	*https://spor-uat.azure-api.net/upd/api/vnra/v3/vnra-submission/vness*
APIM entry point	PROD	*https://spor.azure-api.net/upd/api/vnra/v3/vnra-submission/456/vness*
Path Parameter		*/vnra-submission/<submissionId>* *<SubmissionId> is the ID of the submission to retrieve*
Query Parameters		None

Headers		**Headers**
		The following Headers will be provided / injected by APIM -
		    1. APIM-Correlation-ID Generated and Included with all POST / PUT / DELETE by default. For future BAM requirements include with GET
		    2. APIM-User-ID ==> From User's bearer token.
		    3. APIM-Org-ID ==> org affiliations are included.
		
		Security Headers (Mandatory)
		v3 of the API require a mandatory Bearer Token which is passed via the Authorization header

Oauth Bearer Token
```
curl -X GET \
   -H "Authorization: Bearer $(oauth-access-token)" \
  https://spor.azure-api.net/upd/api/vnra/v3/vnra-
submission/456?summary=false
```

6.2.4. Submit a decision for the VNRA

Submit a decision for the VNRA	PUT	VNRA submit decision - Approve/Reject VNRA */vnra-submission/<submissionId>/decision* *{* *upd/api/vnra/v3/vnra-submission/456/decision*
APIM entry point	UAT	*https://spor-uat.azure-api.net/upd/api/vnra/v3/vnra-submission/456/decision*
APIM entry point	PROD	*https://spor.azure-api.net/upd/api/vnra/v3/vnra-submission/456/decision*
Path Parameter		*/vnra-submission/<submissionId>* *<SubmissionId> is the ID of the submission containing the variation to approve*
Query Parameters		**None**
Headers		

Headers
The following Headers will be provided / injected by APIM -
1. APIM-Correlation-ID Generated and Included with all POST / PUT / DELETE by default. For future BAM requirements include with GET
2. APIM-User-ID ==> From User's bearer token.
3. APIM-Org-ID ==> org affiliations are included.

Security Headers (Mandatory)
v3 of the API require a mandatory Bearer Token which is passed via the Authorization header
Oauth Bearer Token
```
curl -X GET \
   -H "Authorization: Bearer $(oauth-access-token)" \
  https://spor.azure-api.net/upd/api/vnra/v3/vnra-
submission/456/decision
```

Sample Payload
```
{
  "vnraDecisionItems": [
    {
      "variationId": 3711,
      "vnraDecision": "APPROVED",
      "decisionComment": "Submission-decision-approve-all test
case",
      "decisionAuthor": "Beyond Automation",
      "decisionDate": "2022-05-03T12:00:00Z",
      "decisionMaker": "ORG-100003944",
      "utils": {}
    }
  ]
}
```

6.3. User registration for VNRA API

Access to the VNRA API is requested by the Super user of an NCA (i.e. user with the role "UPD - CA Super User"); who will request a new role of "UPD CA API".

On receipt of the email confirming API role has been approved, the API credentials can be used to obtain the OAuth bearer token required to use with the VNRA API endpoints.

Refer to the document Registration guide: Union product database for veterinary medicinal products listed in the References section.

7. UPD API for Volume of Sales Data

7.1. Scope of this release for Volume of Sales API

- Retrieve Volume of Sales Data

7.2. Endpoint, Authorisation header, Query Parameters, Pagination

Endpoint

UAT   `GET` https://spor-uat.azure-api.net/upd/api/vos/v3/vos-sales-json?

PROD   `GET` https://spor.azure-api.net/upd/api/vos/v3/vos-sales-json?

Request Security Header (Mandatory)
This endpoint requires a mandatory OAuth Bearer Token which is passed via the Authorization header

---

Query Parameters

Note: Calls to the base url without any parameters will return the complete collection of sales data for all products.

/upd/api/vos/v3/vos-sales-json?permanentId=
{permanentID}&yearFrom={yearFrom}&yearTo={yearTo}&modifiedDate={modifiedDate}

permanentId (optional) :- Permanent identifier of Medicinal Product. Will return sales for the provided Permanent identifier   e.g. permanentId=600000225806

yearFrom (optional) :- yearFrom={year-month} Start date for range of sales data to be returned

yearTo (optional) :- yearTo={year-month} End date for range of sales data to be returned

e.g. yearFrom=2020-01&yearTo=2021-07

modifiedDate (optional) :- Modified Date of Sales data of Medicinal Product. Will return sales modified since a date

The following prefixes apply to date comparisons against a stored (modified date) value. If no prefixes are specified, the default is eq.
• eq: equals, the exact stored value is inside the range defined by the precision of the parameter value
• gt: the exact stored value is greater than the exact parameter value

e.g. modifiedDate=2023-03-01   or with prefix modifiedDate=gt2023-03-01

Examples:
GET https://spor-uat.azure-api.net/upd/api/vos/v3/vos-sales-json?permanentId=600000225806&yearFrom=2020-01&yearTo=2021-07&modifiedDate=gt2023-01-01

GET https://spor-uat.azure-api.net/upd/api/vos/v3/vos-sales-json?yearFrom=2020-01&yearTo=2021-07

GET https://spor-uat.azure-api.net/upd/api/vos/v3/vos-sales-json?permanentId=600000225806

Pagination
Pagination is implemented using Spring Boot Pagination which returns the following standard **Pagination Payload.**

- sales data is returned within "content": [...],

- pageSize is set using the _size parameter

- iterating through the pages is managed using the _page=x parameter

- totalPages: y evaluation: If totalPages=y and the consumer searches for the last page, then page number parameter should be set to y-1.

Examples:
GET https://spor-uat.azure-api.net/upd/api/vos/v3/vos-sales-json?_size=5

GET https://spor-uat.azure-api.net/upd/api/vos/v3/vos-sales-json?_size=5&_page=2

Pagination Payload

```
{
  "content": [...],
  "pageable": {
   "sort": {
     "empty": false,
     "sorted": true,
     "unsorted": false
   },
   "offset": 0,
   "pageNumber": 1,
   "pageSize": 100,
   "paged": true,
   "unpaged": false
  },
  "totalPages": 6,
  "totalElements": 596,
  "last": false,
```

```
  "sort": {
    "empty": false,
    "sorted": true,
    "unsorted": false
  },
  "size": 100,
  "number": 0,
  "numberOfElements": 100,
  "first": true,
  "empty": false
}
```

Sample Response Payload

```
{
  "content": [
    {
      "productIdentifier": "c74a510c-1689-4f46-bdce-f3a5dd84b1da",
      "productName": "TEST-PRODUCT-NAME2-95363f02-c9b9-442b-8bdf-21a54bf15b2e-
VOS",
      "permanentIdentifier": "600013438271",
      "authorisationProcedureNumber": "VOS/TEST/HOLDER-
NAME2/TEST/EMEA/H/C/000175",
      "packageIdentifier": "be7bfd42-df3f-45e2-8af9-3d96a870f5f7",
      "packageDescription": "PACKAGE3-TEST-PRODUCT-NAME2-95363f02-c9b9-442b-8bdf-
21a54bf15b2e-VOS",
      "packSizeNumericValue": "94",
      "packSizeUnitOfPresentation": "Capsule",
      "packSizeUnitOfPresentationIdentifier": "200000002113",
      "country": "European Union",
      "countryIdentifier": "100000000390",
      "marketingAuthorisationNumber": "VOS/TEST/HOLDER-NAME2-1591819011837",
      "creationDateOfProduct": "2021-11-12",
      "yearMonth": "2021-03",
      "volumeOfSales": "111",
      "speciesIdentifier": "100000108926",
      "speciesPercent": "100.00",
      "doseFactor": "1.00",
      "comment": "Mandatory",
      "modifiedDate": "2023-06-14 09:06:28.047"
    }
  ],
  "pageable": {
    "sort": {
      "empty": true,
      "unsorted": true,
      "sorted": false
    },
    "offset": 0,
    "pageNumber": 0,
    "pageSize": 1,
    "paged": true,
    "unpaged": false
  },
  "totalElements": 5,
  "totalPages": 5,
```

```
  "last": false,
  "sort": {
    "empty": true,
    "unsorted": true,
    "sorted": false
  },
  "size": 1,
  "number": 0,
  "first": true,
  "numberOfElements": 1,
  "empty": false
}
```

7.3. User registration for Volume of Sales Data API

Access to the Volume of Sales API is requested by the Super user of an NCA (i.e. user with the role "UPD - CA Super User"); who will request a new role of "UPD CA API".

On receipt of the email confirming API role has been approved, the API credentials can be used to obtain the OAuth bearer token required to use with the VoS API endpoint.

Refer to the document Registration guide: Union product database for veterinary medicinal products listed in the References section.

8. MAH UI

8.1. Scope of this release for MAH UI

- UPD UC03 Search Product via UI

- UPD UC04 Export search results

- UPD UC05 View Product via UI

- UPD UC21 Manage Notifications via UI

- UPD-UC07 Download Packages and Submission of Volume Sales via Form

- UPD-UC27 View Submissions of Volume Sales via Form

    o   Scenario 1 and 3 – View and Download Volume of Sales as a CA or MAH

    o   Scenario 2 – View Submissions as MAH

- UC06 Submit VNRA via UI

- UC28 View Variation not Requiring assessment via UI

- UC24 Submit updates for Marketing authorisation status

- UC25 Download and Submit updates for Availability status

- UC33 Manage third country Product names (Name, Country, and Language)

- UC38 Manage Products grouping

Supported browsers for the MAH UI are Chrome and Edge.

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

To request access:

- If you do not already have an EMA account in the production environment:

    - EAM can be found at: https://register.ema.europa.eu/identityiq/login.jsf

    - *Create a new EMA account*   Reference guide: https://register.ema.europa.eu/identityiq/help/selfregister.html

- Log into EMA Production once registration is complete to Request Access to one of the UPD MAH UI roles

    - select *Request Access for Organizations.* Reference guide: https://register.ema.europa.eu/identityiq/help/requestaccess.html

    - choose your country and Organization ID.

    - use "UPD" as a search option to filter available roles

    - select the appropriate role:

        - **UPD Industry Super User (**reminder: attach document as evidence of your authority to manage users for your organisation)

        - **UPD Industry Edit Search View**

        - **UPD Industry Search View**

- Some UPD-specific screenshots can be found in Annex 1.

- The request for the first "UPD Industry Super User" for your organisation will be approved by EMA.

- The approved "UPD Industry Super User" will manage all other access requests for your organisation.

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

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

If you have questions or encounter issues, contact the VMP-Reg User Support via EMA Service Now: https://support.ema.europa.eu/.

9. MAH Validation UI for Volume of Sales Submission

There is a separate Validation UI available for MAH users to use to validate submission files for Volume of Sales.

Validation portal URL https://upd-portal-prod-validation.azurewebsites.net

Scope for Validation portal

- The Validation UI will 'Download packages' originating from the **same** store as the normal MAH UI

- The Validation UI 'Submit submission' goes to a **separate validation store**

- The Validation UI 'View Submissions' retrieves data from the **separate validation store**

- Submission to the validation store or normal store **are completely independent.** Therefore submissions made in Validation UI will not be seen in the normal MAH UI and vice-versa.

10. Known issues

Please refer to Annex 2.

Issue reference is an internal number used by the UPD Project team when managing issues. It has been included as User Support may refer to this reference number when responding to your queries. In addition, you can include this reference number when contacting user support on this topic and seeking clarification.

Filter the columns to find those tickets relevant to your role and for NCAs whether you are an API or NCA User or both.

11. User support

API and UI users may seek support in uploading their legacy data into UPD, by contacting the User Support via EMA Service Now: https://support.ema.europa.eu/.

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

12. References

1. Registration guide - Union Product Database for veterinary medicinal products (PDF document)
2. Registration Process for UPD API in UAT (See under section 'How to register')
3. Registration Process for UPD API in Production (See under section 'How to register')
4. SPOR API Specification V2_R5 (europa.eu) API specifications for SMS and PMS, based on FHIR
5. HL7 FHIR Release 5 Preview 2: the authoritative source for the FHIR specifications used by EMA to implement SMS and PMS API
6. Referentials Management System
7. Additional information on the Referentials Management System
8. Organisations Management System
9. Additional information on the Organisations Management System
10. UPD_1.6.42_ReleaseNotes_ExampleFilesForAPI (zip file)
11. Nomination letter for EAM CA Super user role

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

The overall aim of the new access request workflow is to **better guide our users through the entire process**, **minimise the number of rejections** and to ensure that users can **access EMA's applications and systems** in a swift and efficient manner.

Furthermore a new "**Manage Access**" tab allows users and users administrators to list and revoke access for themselves and for the users of the organisation they manage.

The **Search** bar can be used to filter results on organisations, users or roles.

Use the **export** buttons to export data and perform more complex filters

10 results are displayed, further results can be navigated using the paging buttons

The 'Manage my access' tab, marked in red in the visual below, became obsolete, with all procedures now being managed through the 'Request Access for organisations' tab and the 'Manage Access' tab, marked in green.

Further information on access-management aspects and procedures for requesting and managing access to EMA applications can be found in the recording of the "EMA Account Management training webinar".

12.1. Request the Super User Role for your Organisation in UAT

1. Connect to EMA test: https://register-test.ema.europa.eu/identityiq/login.jsf?prompt=true

2. Go to "Request Access for Organizations" and search for your country and your ORG ID:

3. Select "UPD" to find the roles:

4. Choose the UPD CA Super User role:

5. In the next screen, upload a document to show your affiliation to your organisation. For now, just upload any document (We'll need the formal document later and will also need this for production)

6. Click "Submit"

7. An EMA Super User Approver will now review your request and approve asap or get back to you for more information.

12.2. Request a Member User Role for your Organisation and Affiliate to your Organisation in UAT

1. Connect to EMA test: https://register-test.ema.europa.eu/identityiq/login.jsf?prompt=true

2. Go to "Request Access for Organizations" and search for your country and your ORG ID:

3. Select "UPD" to find the roles:

4. Choose the UPD CA Edit/Search/View or the UPD CA Search/View role.

5. Submit.

12.3. Request the Super User Role for your Organisation in Production

Note: This is at this point only relevant for UI usage. The model for the API accounts remains as per section 5.3. and the document referred to in section 12. .

1. Connect to EMA production: https://register.ema.europa.eu/identityiq/login.jsf?prompt=true

2. Go to "Request Access for Organizations" and search for your country and your ORG ID:

3. Select "UPD" to find the roles:

4. Choose the UPD CA Super User role (NCA) or the UPD Industry Super User role (MAH):

☐	UPD CA Super User	You should request this role if you work for an organisation acting as a regulatory authority (i.e. EC, NCA) and intend to manage (approve/reject/revoke) access to UPD for colleagues of your organisation. The first CA Super User role will be approved by EMA. This role will give you full access (Edit/Search/View) to UPD.	No
☐	UPD Industry Super User	You should request this role if you intend to manage (approve/reject/revoke) access to UPD for colleagues of your organisation. The first Industry Super User will be approved by EMA and you will need to attach a completed and signed copy of the "Affiliation Template Letter", as proof of authority to represent the organisation. This role will give you full access (Edit/Search/View) to UPD.	No

5. In the next screen, upload the nomination letter to show your affiliation to your organisation.

6. Submit.

7. An EMA Super User Approver will now review your request and approve asap or get back to you for more information.

12.4. Request a Member User Role for your Organisation and Affiliate to your Organisation in Production

Note: This is at this point only relevant for UI usage. The model for the API accounts remains as per section 5.3. and the document referred to in section 12. .

1. Connect to EMA production: https://register.ema.europa.eu/identityiq/login.jsf?prompt=true

See the screenshots in section 12.2. in this annex.

Contact the Super User of your organisation if in doubt on which the correct organisation ID is for your organisation.

Annex 2: Known issues

This table is ordered by Use Case number.

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Known Issue Description
All UC	MAH UI	UPD-9896	82803	All OPAD screens where MAH searches by Product Owner: if the Location in search criteria is for an Organisation that the user has no UPD role for, the screen is blocked with the progress control. User needs to refresh the page to get out of this. The search should return a message of no results found
All UC	NCA UI & MAH UI	UPD-13297	83277	CAP products - some products with status of Withdrawn or Surrendered have been loaded into UPD from EMA's source system (SIAMED) with status of Valid
All UC	API & NCA UI & MAH UI		143996	CAP: there are now two products for Exzolt and expected there just to be one
All UC	API & NCA UI	UPD-13623	92757	OMS to UPD updates: New or Updated Organisations and Locations from OMS are not available in UPD
API Manager	API	UPD-10952	82994	API Manager has duplicate Products listed for "UPD API" (v1 and v3 versions of EP); and exposes many EP not intended to be used by API NCA Users. There should only be the one product at this time with v1 Endpoints
Data fix	NCA UI & MAH UI	UPD-13448	83291	Data Fix Parallel Trade products: where Source Member State product had two or more Ingredients, the first Ingredient from that product was duplicated in the new Parallel trade product. This was due to bug UPD-13162. EMA to query existing Parallel Trade products to identify products that were affected by this issue and then assess how to correct
UC01 Create product	API & NCA UI		151180	CAP : incorrect Availability values have been assigned by the system (according to chapter 2) to a new CAP authorised under the new Regulation 2019/6 at the time of creation
UC01 Create product	NCA UI	UPD-11832	92479	Create MRP : the "Add Package" button remains disabled after entering values for the addition of a package
UC01 Create product	API	UPD-11849	83150	Create NAP via API: if payload contains attributes with CMS information this is accepted and the information stored. These attributes should either give validation error or be ignored as not applicable for this procedure type

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Known Issue Description
UC01 Create product	API	UPD-11277	83042	Create parallel trade product via API: the GET OperationOutcome response is populating in the DCP format and it was expected would use same pattern as NAP
UC01 Create product	NCA UI	UPD-13829	92814	Create SRP where no Pack size specified for a package: when create submitted the page remained with progress contol and product was not created
UC01 Create product	NCA UI		151167	DCP - expected validation error is not displayed if submit Create DCP with same country as RMS and CMS. Submission is not possible with same value for both but there is no error message
UC01 Create product	API & NCA UI		151748	DCP/MRP/SRP : When create a DCP/MRP/SRP the Availability Status value is not displaying "not marketed" as default term
UC01 Create product	NCA UI	UPD-3346	82325	Each ingredient must be selected at least once in one of the manufactured items. This rule is not currently validated. If you don't include an Ingredient in a Manufactured item the product will be created but any Ingredient not referenced may not be saved.
UC01 Create product	NCA UI	UPD-13840	92816	Free text strength values are not displayed when selecting Ingredients to link in Pharmaceutical product and Manufactured item sections
UC01 Create product	API & NCA UI	UPD-10293	82830	If there has been successful rollback in MDM of a transaction when creating a product, there is still a product created (with orphaned entries)
UC01 Create product	API	UPD-4726	82433	MedicinalProductDefinition.name.type used to be an attribute that was required to be populated. This is no longer required to be populated for the create. When you retrieve the product you will find this attribute has been populated with the term code for full name. This will be corrected in a future release.
UC01 Create product	API & NCA UI		152291	NAP: When Create a NAP the Availability Status is not displaying "not marketed" as default term. The default values for Availability status are not populated into each Package
UC01 Create product	API	UPD-4723	82432	PackagedProductDefinition.package.quantity is not an attribute to be populated for a create. When you retrieve the product you will find this attribute has been populated with a value of zero. This will be corrected in a future release.
UC01 Create product	API	UPD-11587	83093	Using $Validate endpoint for Parallel Trade product: the response code is 400 Bad Request and validation errors that are not relevant for Parallel Trade product are displayed.

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Known Issue Description
UC01 Create product	API		144310	Validate endpoint for Create DCP is incorrectly giving a validation error related to missing Marketing authorisation number. When Create DCP payload is posted to the Create endpoint there is no validation error and products are created as expected.
UC01 Create product	API	UPD-2765	82249	Validation in all resources of URN UUID for fullURL attribute: letters allowed are only a to f to form the hexadecimal set from 0 to f pattern of 8-4-4-4-12 The post may not be rejected or may not give an error message that clearly identifies this as being the issue
UC01 Create product UC08 Update product	NCA UI & API		154083	(Marketing authorisation application) Legal basis : Vet EU IG Chapter 2 section 1.7.1 : some terms from the RMS list are missing
UC01 Create product UC08 Update product	API & NCA UI		147296	CA should only be able to add Availability status entry for the same country as the Authorisation country of their product
UC01 Create product UC08 Update product	NCA UI	UPD-7997	82628	Create/Update of a Product - Error Messages need to be more meaningful
UC01 Create product UC08 Update product	NCA UI	UPD-7964	82617	Date field may give an erroneous value when you click on the date picker widget after entering some partial value manually.
UC01 Create product UC08 Update product	API & NCA UI	UPD-5531	82481	Do not select term of "Full name" when entering a name part. It is not an option that should be included as an available option. If used, the created/updated product will have an additional full name rather than the intended name part

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Known Issue Description
UC01 Create product UC08 Update product	NCA UI	UPD-13632	83327	If product contains two or more Pharmaceutical products, the labels are not properly formatted on the View product screen. The case where two or more Pharmaceutical products should link to the same Ingredient to be considered and review documentation. An Ingredient may only be linked to one Pharmaceutical product in this release
UC01 Create product UC08 Update product	API & NCA UI		154001	NAP: It is possible to add duplicate product name for same Country/Language during Create and Update of NAP product. This should give a validation error and not allow the submission of the Create or Update
UC01 Create product UC08 Update product	API & NCA UI	UPD-9338	82761	The Manufactured Item Quantity will be truncated to 2 decimal places. It should be possible to enter greater precision if required of up to 8 decimal places.
UC01 Create product UC08 Update product	NCA UI	UPD-4863	82440	This should not be mandatory for Legacy products. An ingredient must be selected in this release for the create of a NAP product. It is no longer mandatory for a DCP.
UC01 Create product UC08 Update product	API & NCA UI	UPD-7228	82570	UC01 Create & UC08 Update Product - POST should be valid where Reference Strength is populated but there is no Substance Strength; or if specify Substance Strength a Reference Substance and no Reference Substance Strength. Instead there is a validation error and Substance Strength must always be specified
UC01 Create product UC08 Update product	NCA UI	UPD-5114	82452	UC01 UC08 All procedure types - leading and trailing spaces in free-text fields should be removed by the system before validation
UC01 Create product UC08 Update product	NCA UI		151471	When create or update products (NAP/DCP/MRP/SRP) , the button to Retrieve reference product should be activated only for specific options selected in the Legal basis field. Instead it is always activated

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Known Issue Description
UC03 Search product	NCA UI & MAH UI		152113	After updaing a product and have received Notification, the Search results screen and the Search screen product card may take many minutes before it reflects the updates made to a product. The View product screen does show the updated values
UC03 Search product	API		123745	API user not able to search and view products and receives 403 invalid query and 403 Product is NOT in user affiliations response
UC03 Search product	API	UPD-13658	83332	API user only: A search of products using two parameters of _lastUpdated: the second parameter is ignored and only the first is applied
UC03 Search product	API & NCA UI & MAH UI	UPD-5538	82482	Not able to search using marketing authorisation number if has been specified at package level. Affects UI and API
UC03 Search product	NCA UI & MAH UI	UPD-12748	83234	Search limitations due to FHIR limitation or MS FHIR limitation
UC03 Search product	NCA UI & MAH UI		152101	Searching products using product name filter containing Bulgarian Letter (й) does not list product even if it includes that letter in the product name
UC03 Search product	NCA UI & MAH UI		112859	Sometimes the pagination widget in the bottom of the search page displays the total number of results and current range of products being dusplayed on the page overlapping the drop down for the number of products to display per page
UC03 Search product UC05 View product	NCA UI & MAH UI		146968	After Create MRP, the RMS product which was a NAP does not display the Common product name in the Search results table or in the heading at the top of the View product screen
UC05 View product	NCA UI & MAH UI		152389	CAP products only: Surrendered packages are included when View Product in UPD UI and they should have been excluded
UC05 View product	API & NCA UI & MAH UI		156128	CAP product: Authorisation status is not being re-updated to Valid in UPD after it has been changed to Suspended (in error) and then changed again to Valid
UC05 View product	API & NCA UI & MAH UI		156046	Product Owner displays old OMS name in UPD UI after organisation name has been updated in OMS

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Known Issue Description
UC05 View product	API & NCA UI & MAH UI	UPD-13993	83432	View CAP product - the MAH Organization name displayed may not be the same as seen in SPOR Portal for that LOC ID
UC05 View product	NCA UI & MAH UI	UPD-13125	83259	When View product QPPV displays as N/A even although the product does have a LOC-ID populated. This affects only some products and may be due to some Data Quality issue in the affected products
UC05 View product	NCA UI & MAH UI	UPD-12279	83197	When view product, dates are different according to browser timezone
UC05 View product	NCA UI & MAH UI	UPD-10185	82822	When view product, there has been an example where Marketing authorisation date shows differently for MAH and NCA user. Issue is still being investigated but is thought to occur infrequently and examples have differed by 1 day
UC06 Submit VNRA	MAH UI		104507	An intermittent issue affecting some users when attempting to Submit VNRA. Error message advises of VNRA Creation error and that VNeeS file cound not be uploaded.
UC06 Submit VNRA	MAH UI	UPD-11632	83112	If submit an automated variation that will update National Data, for example A.1.a to update MAH, for products under DCP/MRP/SRP where National Data has not been populated: the submission fails with a Validation error that the Marketing Authorisation Number has not been populated. The MAH should be able to submit a variation even if the RMS/CMS has not populated national data. As a workaround for this release the NCA will need to populate national data before the MAH can submit the VNRA
UC06 Submit VNRA	MAH UI		152295	It is not possible to submit a VNRA if the Date of implementation at Submission information level is not filled in
UC06 Submit VNRA	MAH UI	UPD-8440	82652	Overall Date of submission shows red outline if it had been populated, then value removed and individual values added for each variation for each product
UC06 Submit VNRA	MAH UI		143619	When submitting a VNRA for Automated codes C1 QPPV and C5 C6 PSMF the labels on the screen for the current and proposed values are not as expected and not aligned with the mock-up.
UC06 Submit VNRA	MAH UI	UPD-13125	83259	When View product QPPV displays as N/A even although the product does have a LOC-ID populated. This affects only some products and may be due to some Data Quality issue in the affected products

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Known Issue Description
UC07 Submit Volume of Sales	MAH UI	UPD-9868	92026	Download Packages - some users receive the following error and download file is not created: "ERROR Resource(s) not found for User Id: Y and Organisation Id: X" (from release 1.5.4)
UC07 Submit Volume of Sales	MAH UI		144183	There appears to be two duplicate validation errors for the Species %. ER.27 and ERR.15. ER.27 is displayed. Validation errors will be reviewed
UC08 Update product	API & NCA UI	UPD-12949	92687	Able to submit update but does not complete successfully where product has Data Quality issue. OperationOutcome result displays ERR-1003. This is due to incomplete and orphan records for product names in the underpinning PMS MDM database. Affects about 56 products
UC08 Update product	NCA UI	UPD-7996	82627	Add button in Package medicinal product section needs to have more meaningful caption
UC08 Update product	API & NCA UI	UPD-12580	79977	All procedure types: if product does not contain any existing value for Responsible Authority or Product Owner, when an update is submitted the new LOC-ID is not saved
UC08 Update product	API & NCA UI		152242	CAP product only - after updating product in UPD there is a duplicated Pack size attribute. This duplicate attribute is only seen view Retrieve product via API. Subsequent updates via UPD for affected products are successful
UC08 Update product	NCA UI		156132	CAP product: Not able to update CAP product that has packages with Authorization status values of both Valid and Surrendered. The update page never finishes loading
UC08 Update product	API	UPD-4812	82437	Change to procedure number not saved if existing inline attribute id is not included in the request body
UC08 Update product	API	UPD-4811	82436	Change to Responsible authority or Product Owner is not saved if existing inline attribute id is not included in the request body
UC08 Update product	NCA UI & MAH UI	UPD-11819	83142	For CAP products: there are examples where two products have been created and expected just one. This may occur when a new package has been added or package information has been updated. The cause of the issue will be resolved and affected products corrected
UC08 Update product	NCA UI		156077	If Strength (free text) or Reference Strength (free text) is present, deleting or editing the free text disables the 'Edit Ingredient' button
UC08 Update product	API & NCA UI		109885	Products that had previously been affected by Bug 89511 (replacing Pharmaceutical product removed the Ingredients) cannot be further updated. EMA to investigate whether it is possible for NCA to update products to correct this issue so that products can be updated

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Known Issue Description
UC08 Update product	NCA UI	UPD-12399	83206	The edit screen freezes and does not successfully load if the selected product has an invalid LOC-ID for the Product owner. This situation was possible in a previous release due to a bug.
UC08 Update product	NCA UI	UPD-9023	82735	The quantity and units of presentation are not shown in package table for Manufactured Item. The values are displayed if the package is edited. This is only issue with display of information on the UI and no data has been lost from the product
UC08 Update product	API	UPD-7148	82569	UC08 Update SC2 NAP - should reject update with validation error message if MedicinalProductDefinition.id is not populated
UC08 Update product	API	UPD-10607	82865	Update Common Data DCP/MRP/SRP by API only - not all expected Validation errors are displayed if Mandatory attributes are not populated in POST for Update Common
UC08 Update product	API & NCA UI		144350	Update Common Data DCP/MRP/SRP to remove the last remaining country from the list of Concerned MS fails with Validation error when submitting via NCA UI. There is no validation error if submitted via API. Acceptance criteria and validation required to be reviewed so that API and NCA UI are aligned.
UC08 Update product	API & NCA UI		147984	Update National Data DCP/MRP/SRP - Availability status is not updated to "Not marketed" when Authorisation status is updated to Suspended or Revoked if Product has no existing record for Availability status from when product was created. Under 111377 in the 1.6.37 release we had thought the issue was resolved for all procedure types, however it now appears as if issue was only resolved for NAP. Issue remains for other procedure types.
UC08 Update product	API & NCA UI	UPD-13296	83276	Update of product fails leaving product in Pending state and this blocks and subsequent update
UC08 Update product	API & NCA UI	UPD-12385	83203	Update of product fails with error in GET OperationOutcome of ERR-1003. An error from previous failed update with an incorrect payload prevents a subsequent update
UC08 Update product	API & NCA UI		100337	Update of product has not completed sucessfully and Operation Outcomce states remains In-Progress. The error seen in logs is OSB-382510. Only 7 instances observed for this over the past year but does mean that update did not complete and also blocks any subsequent update.
UC08 Update product	API & NCA UI	UPD-12396	83205	Update product - error regarding buffer space for connections occurs on server but flag is not set to error preventing further updates and advising user that existing transaction needs to be completed before they submit another

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Known Issue Description
UC08 Update product	API & NCA UI		147083	Update product for any procedure type: The error message when updating product that has a non-current Substance is not the correct error message and is different across the procedure types. Error message is to be amended for all to the same expected wording
UC09 Approve/Reject VNRA	NCA UI		151292	Automated C1/C5/C6: Where MAH has populated new values at product level only and left fields at VNRA level empty when VNRA was submitted: when view VNRA submission the fields on the VNRA level are populated with the values of the first product card
UC09 Approve/Reject VNRA	NCA UI		84163	CMS NCA is able to select Approve/Reject checkbox when viewing a VNRA, although the Submit button correctly remains disabled
UC18 Manage document	API	UPD-12477	83213	Add or Update document via API: if payload is invalid and does not conform to the JSON/XML format (for example there is an extra comma or other formatting control after an attribute) this returns a Response of 500 Internal Server error. Instead it should return Response of 400 Bad Request with details of the error.
UC18 Manage document	API		148970	EP401 Search document endpoint - error is returned if value greater than 100 is used for the page size parameter "_count". If the FHIR server has implemented a maximum for number of records to return within a search result it should not give an error. Instead it should silently ignore the parameter value. In all cases for any search, you should expect and check that pagination may be applied
UC19 Nullify product	API	UPD-11471	83064	Any procedure type: After product has been nullified, able to submit a subsequent update product which is accepted and processed. There should be a Validation error
UC19 Nullify product	API	UPD-10057	82811	API Manager Nullification endpoint: when Try It option is selected the Content-Type request header defaults to application/json and it should be application/fhir+json. Using the default value will give an error
UC19 Nullify product	API		132758	Nullify Product via API - OperationOutcome ID now has suffix of "-Patch" which is not expected and is potentially a breaking change for API users. When submitting GET OperationOutcome/ID the response code is 499 Client Closed Request. Therefore it is not possible to nullify a product via the API in this release and NCA UI will need to be used
UC19 Nullify product	NCA UI	UPD-9830	82796	When you nullify a product, the confirmation message does not include the Permanent Identifier

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Known Issue Description
UC21 Manage Notifications	NCA UI & MAH UI	UPD-13049	83254	Date format inconsistent between different actions
UC21 Manage Notifications	NCA UI	UPD-8340	82641	For an update National Data for DCP/MRP/SRP UPD-UC08-AC018, the CMS should only see notifications for their own product. At present they also see notifications for RMS & other CMS products
UC21 Manage Notifications	NCA UI & MAH UI		83114	For CAP products, no Notification generated on successful creation or update of products from SIAMED
UC21 Manage Notifications	NCA UI	UPD-13811	83359	Notification for VNRA actions Submitted/Approved/Rejected for a NAP product should not be visible for an NCA who is not the Responsible Authority
UC21 Manage Notifications	NCA UI & MAH UI		146700	Notifications for PET products show "null" in the field "Procedure Number" instead of "N/A"
UC21 Manage Notifications	NCA UI & MAH UI		131608	Responsible Authority displays the Organisation full name in Notification search results and it should display only the Acronym
UC21 Manage Notifications	NCA UI & MAH UI		156686	Upload document notification is not generated after the creation of a NAP product where documents were provided
UC25 Update Availability status	MAH UI		149382	After downloading Availability status for one or more products and clicking Reset button, then selecting other product(s), the downloaded file contains products previously download
UC25 Update Availability status	MAH UI	UPD-13995	83433	Download Product data file : the 'Availability Status' column may have zero for the RMS Term code if no default Availability status value has been populated at the time the product or package was created
UC25 Update Availability status	MAH UI	UPD-7980	82625	Not able to select all products to download in the one csv file if product search results are over two or more pages
UC25 Update Availability status	MAH UI		131136	Submission of Availability status - example where products submitted in the file have not been updated. Further analysis is required before further details can be provided of affected products but appears to be some DCP/MRP/SRP products where availability status entries for countries other than the Authorisation country were incorrectly added into some products.
UC25 Update Availability status	MAH UI		149816	When select to download a second time after previously selecting a product and then deselecting one or more products - the download file still contains the deselected products

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Known Issue Description
UC26 Manage draft Products	NCA UI		139405	Drafts are not discarded after 30 days from creation/last update. As a workaround, it is possible to retrieve an old draft that is no longer required and use Discard draft option to delete
UC28 View VNRA	NCA UI		154201	Approve/Reject VNRA: When CMS enters decision for their product and before they submit, the summary table may incorrectly update the user name and decision date for some other CMS product as well as the CMS product; or may incorrectly only populate the Decision maker field on the CMS product. After decision has been submitted the status table is correctly updated and redisplayed showing updates only for the CMS variations where decision was submitted
UC28 View VNRA	NCA UI		152323	DCP/MRP/SRP products only: The VNRA card is not always highlighted for the decision maker user
UC28 View VNRA	NCA UI		152369	DCP/MRP/SRP products only: Where there is a submission for two or more variations where one variation the CA cannot approve and one variation the CA can approve: both variations are highlighted. Only the variation that the logged on CA can approved (based on their role as RMS/CMS) should be highlighted
UC28 View VNRA	NCA UI	UPD-13717	83344	For a VNRA submitted for a product where the Responsible Authority is not correctly populated (for example may have incorrectly been populated with MAH LOC-ID): an NCA User for that Authorisation country is not able to view the VNRA Submission even after the Responsible Authority has been corrected in the product(s) included in the submission
UC28 View VNRA	NCA UI	UPD-12886	83242	NCA Germany only for DCP/MRP/SRP where National Data has been populated with Responsible Authority of either PEI or BVL. Where VNRA Submission made for product: Both PEI and BVL can view and approve the submission and they should only be able to view those submissions where they are the Responsible authority. Only where National Data has not been populated and Responsible Authority is the default value of EMA both PEI and BVL should be able to view a VNRA submission.

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Known Issue Description
UC28 View VNRA	NCA UI & MAH UI	UPD-13814	92808	Search results will not be correct if new search is submitted after viewing second or subsequent page of search results from previous search. In the following sequence of actions: User submits search that results in 2 or more pages of search results, navigates to second or subsequent page, enters new search criteria for results found on page 1 or previous page (with or without clicking Reset button) then the search results will not include results from page 1 or previous pages. The page number that user was on from the previous search is still being applied to the new search. Thus new search results are not correct. After navigating to the next page, please reselect the search option from the menu to correctly reset the page counter and clear previous search results
UC28 View VNRA	NCA UI & MAH UI	UPD-11574	83091	Sometimes when selecting to view a submission the display is incomplete (empty boxes for combination of VNRA code & product). Viewing the submission at another time is successful. Potentially only an issue when also experience issues searching products due to timeouts in the UI
UC28 View VNRA	NCA UI		145289	View VNRA submissions screen sometimes shows highlighted VNRA incorrectly to CA who is not the decision maker
UC28 View VNRA	MAH UI		150814	When MAH user views submission the decision maker field is fill in with MAH user Organisation name
UC31 Manage VNRA Submissions via API	API		139691	Retrieve VNRA submissions by Permanent identifier - Retrieves all VNRAs including VNRAs not related to query parameter "permanent identifier"
UC31 Manage VNRA Submissions via API	API		142804	All of the endpoints for VNRA API https://spor.azure-api.net/upd/api/vnra/v3/vnra-submission fail with 404 Resource Not Found
UC33 Manage Third Country Product Names	MAH UI		150127	Download file for Third Country Product Names contains an extra column at the end of each row for a product with value of "null". If submission file based on the download file contains this extra column the submission will fail with an error. As a workaround, this extra column in the data should be removed from the Submission file.
UC33 Manage Third Country Product Names	MAH UI		150681	Download Third Country Product Names file: the Delete column is filled with "null " values and new column added with no header and with "null" values. As a workaround to use the download file for a submission: remove the additional column that has been added in the file; and delete the "null" values in the Delete column.

Use Case	Affects user	Issue reference (Old JIRA)	Issue reference (New ADO)	Known Issue Description
UC33 Manage Third Country Product Names	MAH UI		142332	User affiliated to two or more Organisations is not seeing data values added by another MAH user who is only affiliated to one of those Organisations. Issue affects both Third country product names and Products Grouping
UC33 Manage Third Country Product Names UC38 Products Grouping	MAH UI		151721	If the logged on MAH has more than 10,000 products, the download files for Third Country Product Names and Products Grouping only contain the first 10,000 products
UC34 Bulk Upload for Documents	NCA UI		140303	Submitting a file for a Registered Homeopathic product fails with an error "ERROR: Your organization is not the Responsible Authority of this/these product(s)."
UC38 Products Grouping	MAH UI		142332	User affiliated to two or more Organisations is not seeing data values added by another MAH user who is only affiliated to one of those Organisations. Issue affects both Third country product names and Products Grouping

Annex 3: Release Schedule

Environment	From	To	Description
UAT	10 January 2024	12 January 2024	Upgrade of UPD to 1.6.42
PROD	17 January 2024	19 January 2024	Upgrade of UPD to 1.6.42
UAT	7 February 2024	7 February 2024	Upgrade of UPD to 1.6.42-5 Please note, this update contains only a hot fix affecting the product information bulk upload feature and will not include other bug fixes nor new features.
PROD	12 February 2024	12 February 2024	Upgrade of UPD to 1.6.42-5 Please note, this update contains only a hot fix affecting the product information bulk upload feature and will not include other bug fixes nor new features.
UAT	(TBC)	(TBC)	Upgrade of UPD to 1.7.2413
PROD	(TBC)	(TBC)	Upgrade of UPD to 1.7.2413
UAT	(TBC)	(TBC)	Upgrade of UPD to 1.7.241x related to rearchitecting (aka decoupling FHIR from MDM)
PROD	(TBC)	(TBC)	Upgrade of UPD to 1.7.241x related to rearchitecting (aka decoupling FHIR from MDM)