UPD Release Notes 1.6.13

Veterinary Medicinal Products Regulation: Union Product Database

Release date: 5 December 2022

Version 2

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Table of Contents

Changes made in revised version of release notes:

These two bugs have been resolved in the hotfix release deployed into production on Thursday 15/12/22:

- UPD-11429 Approval of VNRA submission containing more than one automated Variation code
    - VNRA submission that contained more than one automated Variation code and if you approved two or more variations at the same time the updates from only one of the automated variation codes was made in the updated product.
    - Therefore as a workaround we had advised that automated codes should be approved one at a time
    - This issue has been resolved and Approval of two or more automated variation codes in a VNRA Submission may be approved at the same time
- UPD-12584 View VNRA - BVL (German NCA) can't see old VNRA submissions
    - This was an issue since the VNRA datafix that was applied after 1.6.12 deployment
    - In addition they were not able to view new VNRA submission for product under DCP/MRP/SRP where Germany is RMS or CMS and national data has not yet been populated in the product for Germany
    - These issues have been resolved and BVL is now able to view VNRA submissions

The following bugs have been logged since the initial publication of these release notes:

- They have been added into sections 2.3 and Annex 2 Known issues.

UC05 View product	NCA UI & MAH UI	UPD-12758		On the view product screen, documents with language of Norwegian or Icelandic display language as N/A
UC05 View product	NCA UI & MAH UI	UPD-12753		When viewing a product, the hyperlinks in the left hand menu to sections within the product data do not work
UC06 Submit VNRA	MAH UI	UPD_12854		VNRA submission for variation code C.6 fails for products without existing PSMF information
UC07 Submit Volume of Sales	MAH UI	UPD-12755		Submission of Volume of Sales - if any product name or package description contains an embedded quotation mark the submission fails with a validation error "invalid char between encapsulated token and delimiter"
UC25 Update Availability status	MAH UI	UPD-12755		Submission of Availability Status - if any product name or package description contains an embedded quotation mark the submission fails with a validation error "invalid char between encapsulated token and delimiter"
UC25 Update Availability status	MAH UI	UPD-12751		Download fails with a validation error if any product that has been selected to download has Authorisation status of Suspended, Revoked, Surrendered or Expired
UC25 Update Availability status	MAH UI	UPD-12752		Submission of Availability status file: there are validations being applied for some columns of the submission file that shouldn’t happen and cause the submission to fail

1. Overview of functionality and business value

This release is the next iterative version of the Union Product Database, v 1.6.13. The main difference with the previous version, v 1.6.12 released on 12 November 2022, is new functionality as per section 2.1 and resolution of defects as per section 2.2.

This version allows NCAs to submit/enter legacy product information, as per Article 155 of Regulation (EU) 2019/6, compliant with Chapter 4 of the July 2021 version of the Vet EU Implementation Guide (Vet EU IG); and compliant with Chapter 2 of the May 2022 version of the Vet EU IG.

Marketing Authorisation Holders (MAH) are able to view their products, submit Variations not requiring assessment, download and submit Volume of Sales, and update Marketing Authorisation Status.

This version of the UPD allows the creation of products approved under MRP procedure via the Create MRP functionality. The Reference Member State (RMS) uses their Nationally authorised product (NAP) as the basis for this creation, and adds or updates Common data. For example: add Common Product Name, RMS and Concerned Member State(s) (CMS(s)). A new product will be created for CMS with procedure type MRP and the RMS's NAP is updated to procedure type MRP.

The approach for the load of Legacy products under DCP/MRP procedure via the Decentralised procedure may still be used. At the time of creation, the RMS will provide the RMS value 'Decentralised Procedure' for the field 'Procedure type'. According to the Vet EU IG subsequent updates will be made by the CMS as a part of the update of national data, and the procedure type for the CMS product may be updated to MRP if applicable.

In relation to the load of legacy data, for some of the products approved under DCP/MRP, it could be the case that only one RMS, and no CMS(s), is involved in the process. Given that the current implementation of the UPD does not support this scenario, the workaround for recording these products will be as follows: I/the RMS will create the DCP adding as CMS a country belonging to EEA (this country should preferably have very few CMSs and no RMS products); II/ to prevent this product from being available to the general public and to the MAH, the CMS will not update the national part of the product, and finally III/ the CMS product will be nullified by the CMS once UPD allows having these products with only one RMS.

Technical grouping:

Please note that the Technical grouping functionality for VNRAs has been recently delivered to the production environment. This functionality involves a certain complexity, but the learning curve will be less steep if we can rely on the collaboration between all of us, 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 severe delay in processing the VNRA's.

The high-level functionality provided in this release is:

- 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 product with national DCP/MRP/SRP data and documents
    - RMS can update Common data for DCP/MRP/SRP product (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 Nullify product
    - Search/view product (data and documents)
- 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 product with national DCP/MRP data (including documents)
    - RMS can update Common data for DCP/MRP/SRP product (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 Nullify product
    - NCA can Bulk Upload Documents
    - NCA can Transfer Marketing Authorisation
    - Search/view/export product (data and documents)
    - Notifications for Create and Update of products and OPAD actions
    - View Volume of Sales information
    - View and Approve/Reject VNRA submissions
- MAH UI:
    - Search/view/export product (data and documents)
    - Notifications for Create and Update of products and OPAD actions
    - Download, Submit and View Volume of Sales information
    - Submit VNRA and View VNRA submissions
    - Submit updates for Marketing authorisation status (excluding CAP products)
    - Download and Submit updates for Availability status (excluding CAP products)
- Authorisation for NCA & MAH UI:

- Integration with EMA Account Management (EAM) system for CA and Industry (MAH) roles
- CA users may search and view all Vet products
- MAH users may search and view only products under the responsibility of the organisations the user represents

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

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

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

1.1. Functionality not included in this release

The following functionality is not included in this release. Menu items and endpoints should not be used as these are not yet fully implemented.

API:

- none

NCA UI:

- Update CAP products (by EMA or EC staff)
- Transfer Marketing Authorisation for CAP products (by EMA or EC staff)

MAH UI:

- Submit updates for Marketing authorisation status for CAP products
- Submit updates for Availability status for CAP products

2. Changes made compared with 1.6.12

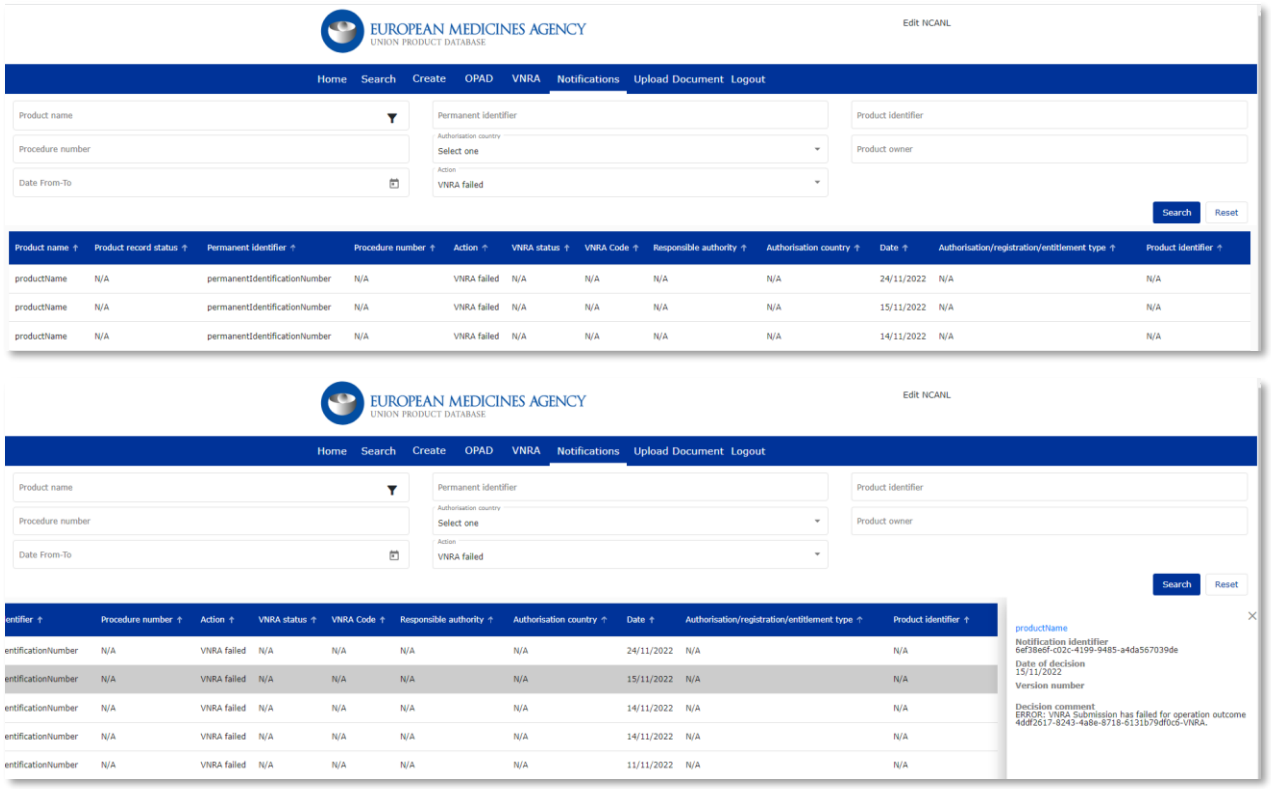
2.1. New functionality

- **UPD-BR-089** Variations not requiring assessment (VNRA) - Management of a VNRA that affects data related to the Pharmacovigilance system master file
  - Variation code C5 and C6
- **UPD-BR-090** Variations not requiring assessment (VNRA) - Management of a VNRA that affects data related to the Qualified person responsible for pharmacovigilance
  - Variation code C1
- Re-released: MAH UI: Submit updates for Availability status (except for CAP products)

- VNRA Submission and new notification
  - A notification with action of "VNRA failed" has been added
  - This is used when there has been some error in successfully saving the VNRA submission after the MAH has submitted the VNRA and received the VNRA Operation Outcome ID
  - One single notification is created for this action irrespective of how many products or variations were included in the submission

- The notifications search grid is not populated with product values from the submission and instead contains values of “productName”, “permanentIdentificationNumber”
- The notification card contains the VNRA Operation Outcome ID of the failed submission
- If this occurs the MAH should log a User Support ticket and provide the VNRA Operation Outcome ID and Notification identifier. The issue for this submission can be investigated and MAH advised how to proceed

Screenshots:



- API Users: example in section 5.5.10. How to use Update National Data DCP/MRP/SRP product endpoint and example bundle
    - The example file names and details of the changes made in the Update payload have been corrected

2.2. Resolved issues

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

This table is ordered by Vet EUIG Chapter 2 section; and then by Use Case number for those items without a specific IG reference.

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue that has been resolved
UC09 Approve/Reject VNRA	NCA UI	UPD-11429		Resolved in hotfix release 15/12/22: This issue was listed as a known issue for 1.6.12 release. Repeated here in this section since additional automated VNRA codes have been released. VNRA submission that contains more than one automated Variation code - if you approve two or more variations at the same time the updates from only one of the automated variation codes is made in the updated product. Therefore as a workaround, automated codes should be approved one at a time.
UC28 View VNRA	NCA UI	UPD-12584		Resolved in hotfix release 15/12/22: View VNRA - BVL (German NCA) can't see old VNRA submissions (PROD issue since VNRA datafix applied after 1.6.12 deployment). In addition they can't view new VNRA submission for product under DCP/MRP/SRP where Germany is RMS or CMS and national data has not yet been populated in the product for Germany.
UC05 View product	NCA UI	UPD-11282	1.7.3 ATC Vet code(s) flag	Where product has ATC Vet Code flag = True: a message "code is not available and has been requested" was not displayed
UC01 Create product	API	UPD-8281	2.12 Concerned member states	Create SRP – now receive a validation error if add new CMS for country not in EEA

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue that has been resolved
UC01 Create product	API & NCA UI	UPD-12029	2.12 Concerned member states	Create SRP where under Product Identifier one of the CMS products is Nullified but that CMS has not yet been removed by Update Common Data - the Create SRP Operation did not finish. This issue has been resolved for new Create SRP submissions. Any existing Create SRP that had been affected should be submitted again
UC08 Update product	API & NCA UI	UPD-12060	2.12 Concerned member states	Update Common Data DCP/MRP/SRP : there was a Validation error when the list of Concerned Member States contained the country of a Nullified product. This should not have given a validation error.
UC08 Update product	NCA UI	UPD-8400	5.6 Manufactured item (in Package)	UPD-UC08-AC041 User should not be able to remove a Manufactured Item used in a package
UC08 Update product	NCA UI	UPD-7237	5.7 Availability status	Update DCP/MRP/SRP National data - it was not possible to add or update the Availability status or Availability status date for each package. This issue has been resolved
All UC	NCA UI & MAH UI	UPD-10994		Sometimes there was a "False" expiring session message when using the UI, even although the user was continuously active
All UC	NCA UI & MAH UI	UPD-11886		Users was logged out in less than 30 minutes or while performing an action
UC01 Create product	NCA UI	UPD-11265		Create MRP/SRP: the new CMS product did not have Common document added; and any document deleted by RMS as part of the create had not been removed from existing products
UC01 Create product	NCA UI	UPD-11415		Create MRP/SRP: when search to retrieve product and using search criteria that contains special characters - there were no search results even when matching products do exist. Known to be an issue was '+'. '|' for example was OK.
UC01 Create product	NCA UI	UPD-11850		Create Registered Homeopathic: - The country drop-down list in the manufacturer search didn’t show any countries
UC01 Create Product	NCA UI	UPD-10603		The use of * to label mandatory fields was not always aligned with the Vet EU IG Chapters 2 and 4
UC01 Create product UC08 Update product	NCA UI	UPD-10715		Existing Concerned Member States (CMS) were not always displayed or the same country was listed more than once; and didn’t contain a 'x' (or cross) to allow a CMS to be deleted. This issue only affected a few products
UC03 Search product	NCA UI & MAH UI	UPD-8339		Inconsistencies had existed in Search functionality when paging through search results. This may have only be an issue if Export option has been used and then select to navigate to the next page.
UC06 Submit VNRA	MAH UI	UPD-11483		If the same variation code is selected for a second time, that variation was removed from the submission

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue that has been resolved
UC06 Submit VNRA	MAH UI	UPD-12056		The known root cause of the issues where VNRA were not submitted were resolved in 1.6.12 release. A notification with action of "VNRA failed" has been added This is used when there has been some error in successfully saving the VNRA submission after the MAH has submitted the VNRA and received the VNRA Operation Outcome ID One single notification is created for this action irrespective of how many products or variations were included in the submission
UC08 Update product	API	UPD-7424		When updating a product via the API, the update bundle must include the current version number of the product in the attribute MedicinalProductDefinition.version. This attribute is not listed in Vet EUIG Chapter 2. You will see that it is populated in response to EP304 Get Product Full GET /MedicinalProductDefinition/id/$everything If this attribute is not populated you will now get a meaningful validation error.
UC08 Update product	API & NCA UI	UPD-11816		Update Common Data for product under DCP/MRP/SRP to delete an existing CMS: the system was incorrectly displaying a validation error. CMS may now be deleted
UC08 Update product	NCA UI	UPD-12398		Create Product SRP and as part of the create delete an existing Common Document: the existing CMS are updated with the new CMS but did not have the deleted Common Document removed
UC21 Manage Notifications	NCA UI & MAH UI	UPD-10993		When viewing notifications, the search results table may have had two vertical scroll bars which created a confusing user experience
UC24 Marketing authorisation status	MAH UI	UPD-12445		Submission of update for Marketing Authorisation status was advised as being successful but there was no Notification and Product is not updated (issue in PROD env only). This issue has been resolved and Update Marketing Authorisation Status may be used in this release with the exception of updates for CAP products.
UC25 Update Availability status	NCA UI & MAH UI	UPD-8200		Notification when MAH Updates Availability Status had the wrong Action. The notification had Action of "Update, Upload Document" and it is corrected to "AvS submitted". This change is only effective for new Submissions and there is no update for existing notifications.
UC25 Update Availability status	MAH UI	UPD-8352		Error was not always clearly displayed if there was a failure in the submitted Update Availability status csv file
UC25 Update Availability status	MAH UI	UPD-10684		Submission of Availability status remained In-progress and never completed to either Valid or Failed status. This issue has been resolved (only corrected for new submissions)

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue that has been resolved
UC25 Update Availability status	MAH UI	UPD-10977		When submit file to update Availability Status the screen hung and there was no error displayed to the user. This issue has been resolved.
UC25 Update Availability status	MAH UI	UPD-11216		Submission of Availability Status for products under DCP/MRP/SRP: the RMS product for Product Identifier and not the specified product (Permanent Identifier) in the csv file was being updated. For this reason UC25 had been removed from the previous release. This issue has been resolved and MAH able to Submit Availability status updates
UC25 Update Availability status	MAH UI	UPD-11252		Validation error reviewed: New Availability Status Date cannot be older than previous Availability Status Date. Retested and only receive validation error as expected
UC28 View VNRA	NCA UI & MAH UI	UPD-10400		MAH was advised that submission of VNRA was successful. However, sometime there was no Notification received and when View Submissions it was not listed (for either MAH or NCA). A new notification has been added as documented in section 2.1 with Action of "VNRA failed"
UC28 View VNRA	NCA UI & MAH UI	UPD-12054		BR-093 When view submissions for ATC Vet Code (variation code A4) the current value was not showing all the existing codes on the product and some codes appeared cut off
UC28 View VNRA	NCA UI & MAH UI	UPD-10399		For Pending or Processed VNRA where product has been Nullified after the MAH has submitted the VNRA: instead of displaying product details there is now a message "Product was nullified"
UC34 Bulk Upload for Documents	NCA UI & MAH UI	UPD-10601		The action date for a notification of a bulk upload was displayed as MM/DD/YYY instead of dd/MM/YYYY

2.3. New known issues for functionality in previous release

This table is ordered by Vet EUIG Chapter 2 section; and then by Use Case number for those items without a specific IG reference. 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	Vet EUIG Chapter 2 section	Issue description
UC05 View product	NCA UI & MAH UI	UPD-12758		On the view product screen, documents with language of Norwegian or Icelandic display language as N/A
UC05 View product	NCA UI & MAH UI	UPD-12753		When viewing a product, the hyperlinks in the left hand menu to sections within the product data do not work
UC06 Submit VNRA	MAH UI	UPD_12854		VNRA submission for variation code C.6 fails for products without existing PSMF information
UC07 Submit Volume of Sales	MAH UI	UPD-12755		Submission of Volume of Sales - if any product name or package description contains an embedded quotation mark the submission fails with a validation error "invalid char between encapsulated token and delimiter"
UC25 Update Availability status	MAH UI	UPD-12755		Submission of Availability Status - if any product name or package description contains an embedded quotation mark the submission fails with a validation error "invalid char between encapsulated token and delimiter"
UC25 Update Availability status	MAH UI	UPD-12751		Download fails with a validation error if any product that has been selected to download has Authorisation status of Suspended, Revoked, Surrendered or Expired
UC25 Update Availability status	MAH UI	UPD-12752		Submission of Availability status file: there are validations being applied for some columns of the submission file that shouldn't happen and cause the submission to fail
UC08 Update product	NCA UI	UPD-12602	1.9.4 (PSM) File location	Chapter 4/Legacy products for all procedure types: if no PSM File Location has been populated the edit screen displays a value of "undefined - undefined". If you submit the update like this there will be a validation error. Click the "X" to delete and then you will be able to Submit the update without a validation error
UC18 Manage document	API	UPD-12477	1.11 Attached Document	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.
UC08 Update product	API & NCA UI	UPD-12580	2.4 Responsible Authority 2.8 Product Owner	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
UC01 Create product UC08 Update product	API & NCA UI	UPD-12586		Document of type "Public Assessment Report" is not saved in the created or updated product
UC03 Search product	NCA UI & MAH UI	UPD-12590		If search results require two or more pages, and the last page of search results should contain 51 or more products: the last page of search results is always displaying 100 products

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue description
UC05 View product	NCA UI & MAH UI	UPD-12585		Reference Strength is not being displayed when viewing a product
UC21 Manage Notifications	NCA UI & MAH UI	UPD-12591		VNRA Submitted action: the notification card has incorrect labels. Decision Comment should be Submission Comment. Date of Decision should be Date of Submission. Date of Implementation is not displayed. The correct values of the submission date and submission comment are displayed.
UC25 Update Availability status	MAH UI	UPD-11420		When submit Availability status and the logged on MAH user is not affiliated to the Product owner of the product, an incorrect error message is being displayed. "ERR.05 Package identifier provided doesn't belong to the country selected" is being displayed and it should be "ERR.01: Package Identifier provided doesn't belong to a product under the User's responsibility"
UC28 View VNRA	NCA UI & MAH UI	UPD-12522		The PDF for VNRA for variation Code A4 ATC Vet code is currently displaying the RMS Term code for the current and proposed ATC Vet codes. It should be displaying the RMS Term as displayed on the View VNRA Submission page.
~~UC28 View VNRA~~	~~NCA UI & MAH UI~~	~~UPD-12584~~		Resolved in hotfix release 15/12/22 ~~View VNRA - BVL (German NCA) can't see old VNRA submissions (PROD issue since VNRA datafix applied after 1.6.12 deployment). In addition they can't view new VNRA submission for product under DCP/MRP/SRP where Germany is RMS or CMS and national data has not yet been populated in the product for Germany.~~ ~~We expect to deploy a fix for this issue during the week commencing Monday 5/12/22.~~

2.4. Known issues for new functionality in this release

This table is ordered by Vet EUIG Chapter 2 section; and then by Use Case number for those items without a specific IG reference.

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue description
~~UC09 Approve/Reject VNRA~~	~~NCA UI~~	~~UPD-11429~~		Resolved in hotfix release 15/12/22 ~~This issue was listed as a known issue for 1.6.12 release. Repeated here in this section since additional automated VNRA codes have been released.~~ ~~VNRA submission that contains more than one automated Variation code – if you approve two or more variations at the same time the updates from only one of the automated variation codes is made in the updated product. Therefore as a workaround, automated codes should be approved one at a time.~~ ~~We expect to deploy a fix for this issue during the week commencing Monday 5/12/22.~~

3. Veterinary EU Implementation Guide versions for this Release

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

- Chapter 2 May 2022
- Chapter 4 July 2021
- Chapter 6 (Examples for the submission of Legacy data) December 2021
- Chapter 7 (Submission of OPAD data) May 2022
- All other chapters based on 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
    - Scenario 1 Create Product – NAP & Registered Homeopathic – Manual Key In
    - Scenario 2 Create Product – Decentralised Procedure – Manual Key In
    - Scenario 3 Create Product – MRP & SRP
    - Scenario 4 Create Product – Parallel Trade
    - Scenario 5 Cancel Create Product
    - 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
    - Scenario 1 Transfer of ownership
    - Scenario 2 Update a single Product – Common & National data for NP & Registered Homeopathic and National data for DC/MR/SR procedures (data and documents)
    - Scenario 3 Update Common Data for products under DCP/MRP/SRP (data and documents)
    - Scenario 4 Update Parallel Trade
    - Scenario 5 Cancel Update Product
    - Able to update products based on Chapter 4 Legacy or Chapter 2 Validation rules
- UPD UC19 Nullify Product
- UPD UC21 Manage Notifications via UI
    - 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 UC34 Bulk Upload of Documents
- UPD UC27 View Submissions of Volume Sales via Form
    - 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

Other menu items or options should not be used as these are not in scope for this release and are not fully implemented.

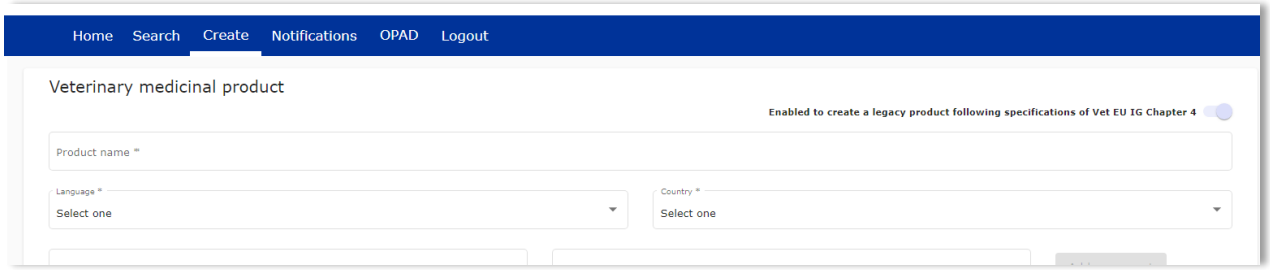
Supported browsers for the NCA UI are Chrome and Edge.

4.2. Apply Chapter 4 Legacy or Chapter 2 Validation rules

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

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

- Log into EAM-Test once registration is complete to Request Access to one of the UPD NCA UI roles
  - select *Request Access for Organizations*. Reference guide: https://register-test.ema.europa.eu/identityiq/help/requestaccess.html
  - choose your country and Organization ID.
  - use "UPD" as a search option to filter available roles
  - select appropriate role:
    - **UPD CA Super User** **(reminder**: **attach document** as evidence of your authority to manage users for your organisation)
    - **UPD CA Edit Search View**
    - **UPD CA Search View**
  - Some UPD-specific screenshots can be found in Annex 1.
  - The request for the first "UPD CA Super User" for your organisation will be approved by EMA. 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:
  - EAM Production 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 EAM Production once registration is complete to Request Access to one of the UPD NCA 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 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.
    - The approved "UPD CA Super User" will manage all other access requests for your organisation.
- Once registered, the UI in PROD can be found at:

  Union product database (upd-portal-prod.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.

5. UPD API

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
    - Edit existing, add new, or delete an existing non-mandatory attribute
    - Add new resources. For example: add an Ingredient or add another Package
    - Delete an existing non-mandatory resource. For example: remove an Ingredient

- Create & Update Parallel trade 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
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 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"

SPOR API Specification v2	API Manager
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
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 UPD 01.03 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	

Type and Procedure	POST Endpoint	Request header Key for validation rules	Additional Request header
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
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
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 Common Data DCP/MRP/SRP

Type and Procedure	POST Endpoint	Request header Key for validation rules	Additional Request header
			• 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/	For NP, DCP, MRP, SRP products: chapter4=true	

Content-Type	Request body

JSON	{
	"permanentId": "*Permanent Identifier*"
	}

	For example:
	{
	"permanentId": "600011984989"
	}

XML	Not supported in this release

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."

In this release the following issues are outstanding UPD-9773:

- Validation that is relevant when updating a product is being applied using the default value of Chapter 2 rules. Therefore, for legacy products that don't comply with Chapter 2 rules there

will be validation errors. If nullification is always submitted with Request header of chapter4=true to apply Legacy validation rules this will workaround this issue

- there is no Content Location with OperationOutcome ID. In a future release this will be changed so that this is provided when POST response is 202 Accepted, and GET OperationOutcome can be used to review the status of the transaction to confirm the update has been successful
- some of the validation errors are not in the format specified in the request Accept header and instead are listed as plain text
- POST in XML format is not supported

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

When POST for Create or Update 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 or update 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 it is the second part with operation-outcome-id that is used for Get OperationOutcome.

POST	Content Location example showing post-operation and format of the operation-outcome-id
Create NP	OperationOutcome/baab996e-8e58-4825-89d1-90a8f30458db
Update NP	OperationOutcome/c2e2275c-141c-4631-a42e-045726d95adb
Create DCP	dcp-operation-outcome/ddb9f96b-10f5-4428-9503-170feb5c58db-DCP
Update Common Data DCP/MRP/SRP	common-data-operation-outcome/f4d76850-358a-48f1-a9bb-3fb4b1615bdb-CD
Update National Data DCP/MRP/SRP	national-data-operation-outcome/b371f2db-dd29-4c60-b6ab-63b0abf95bdb-ND
Create MRP	mrp-operation-outcome/2f89089c-3ad7-4427-9311-7ea491395ddb-MRP

POST	Content Location example showing post-operation and format of the operation-outcome-id
Create SRP	srp-operation-outcome/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

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.

Procedure type	Validation rules	Example file
DCP	Chapter 2	UPD_1.6.5-6_DCP_Chpt2_C2_Mandatory_VetIG.JSON UPD_1.6.5-6_DCP_Chpt2_C2_Mandatory_VetIG.XML UPD_1.6.5-6_DCP_Chpt2_C110_VetEUIG_AllData.JSON UPD_1.6.5-6_DCP_Chpt2_C110_VetEUIG_AllData.XML
DCP	Chapter 4 Legacy	UPD_1.6.5-6_DCP_Legacy_C2_Mandatory_VetIG.JSON UPD_1.6.5-6_DCP_Legacy_C2_Mandatory_VetIG.XML UPD_1.6.5-6_DCP_Legacy_C110_VetEUIG_AllData.JSON

Procedure type	Validation rules	Example file
		UPD_1.6.5-6_DCP_Legacy_C110_VetEUIG_AllData.XML
NAP	Chapter 2	2.2 Authorisation/registration/entitlement number is specified at Product level UPD_1.6.1-4_NAP_Chpt2_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel.JSON UPD_1.6.1-4_NAP_Chpt2_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel.XML UPD_1.5.1-0_NAP_Chpt2_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel.JSON UPD_1.5.1-0_NAP_Chpt2_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel.XML _____ 5.5 Marketing authorisation (package level) UPD_1.5.1-0_NAP_Chpt2_C111_VetEUIG_AllData_MANumber_AtPackageLevel.JSON This example contains 2 packages. There are 3 RegulatedAuthorization resources: • One with subject reference = MedicinalProductDefinition resource; populated with attributes from Section 2 (Vet EUIG Chapter 2), excluding the marketing authorisation number • One with subject reference = 1st PackagedProductDefinition resource; populated with the Marketing authorisation number for Package 1 • One with subject reference = 2nd PackagedProductDefinition resource; populate with the Marketing authorisation number for Package 2
NAP	Chapter 4 Legacy	UPD_1.6.1-4_NAP_Legacy_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel.JSON UPD_1.6.1-4_NAP_Legacy_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel.XML

Procedure type	Validation rules	Example file
		UPD_1.5.1-0_NAP_Legacy_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel.JSON UPD_1.5.1-0_NAP_Legacy_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel.XML
NAP	Chapter 4 Legacy	UPD_1.5.1-0_NAP_Legacy_Cx_ManyAttributesAndResources_MANumberAtMedicinalProductLevel.XML This example contains: • 2 or more values for those attributes that are repeatable. For example Product name, ATC Vet Code, Manufacturing Business Operation • 2 Packages (PackagedProductDefinition) • 2 Manufactured Items (ManufacturedItemDefinition) • 3 Ingredients (Ingredient)
NAP	Chapter 2	UPD_1.5.1-0_NAP_Chpt2_ExampleForStrengthAsPresentationOrConcentration.XML This example contains Ingredient resources that illustrate how to specify Substance and Reference Strength as either Presentation or Concentration.
Registered Homeopathic	Chapter 2	UPD_1.6.1-4_HOM_Chpt2_C2_Mandatory_VetIG_MANumber_AtMedicinalProductLevel.JSON UPD_1.6.1-4_HOM_Chpt2_C110_VetEUIG_AllData_MANumber_AtMedicinalProductLevel.JSON
Parallel Trade	Chapter 2	UPD_1.6.8-4_PAT_Chpt2_C2_Mandatory_VetIGl.JSON UPD_1.6.8-4_PAT_Chpt2_C110_VetEUIG_AllData.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 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 - Product Owner (this example based on DCP created before RMS populates MAH at time of creation)	Sample XML of Get Everything response used as a starting point: UPD_1.6.13_DCP_UpdateNationalData_600000149645_GetEverything_v2.XML Update bundle prepared: UPD_1.6.13_DCP_UpdateNationalData_600000149645_UpdateBasedOnV2.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: TBC

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. MAH UI

6.1. 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
  - Scenario 1 and 3 – View and Download Volume of Sales as a CA or MAH
  - 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 (excluding CAP products)
- UC25 Download and Submit updates for Availability status (excluding CAP products)
- Other menu items should not be used as these are not in scope for this release and are not fully implemented.

Supported browsers for the MAH UI are Chrome and Edge.

6.2. 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 https://servicedesk.ema.europa.eu/jira/servicedesk/customer/portal/283/group/506.

7. 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.

8. User support

API and UI users may seek support in uploading their legacy data into UPD by contacting the VMP-Reg User Support via https://servicedesk.ema.europa.eu/jira/servicedesk/customer/portal/283/group/506.

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

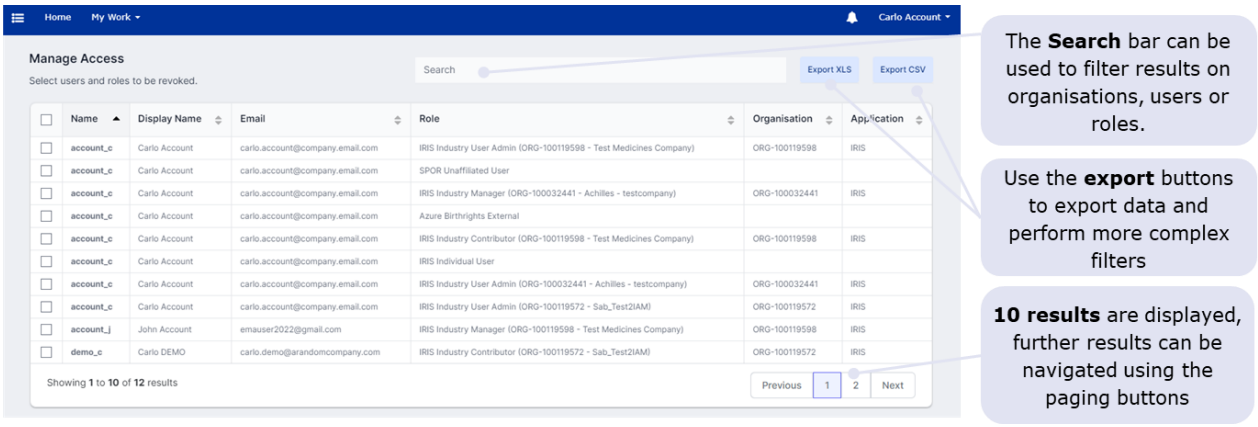
9. References

1. UPD 01.06 Registration Process for UPD API in Production (PDF document)
2. UPD 01.03 Registration Process for UPD API in UAT (PDF document)
3. SPOR API Specification V2_R5 (europa.eu) API specifications for SMS and PMS, based on FHIR
4. HL7 FHIR Release 5 Preview 2: the authoritative source for the FHIR specifications used by EMA to implement SMS and PMS API
5. Referentials Management System
6. Additional information on the Referentials Management System
7. Organisations Management System
8. Additional information on the Organisations Management System
9. UPD_1.6.5_ReleaseNotes_ExampleFilesForAPI (zip file)
10. 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.



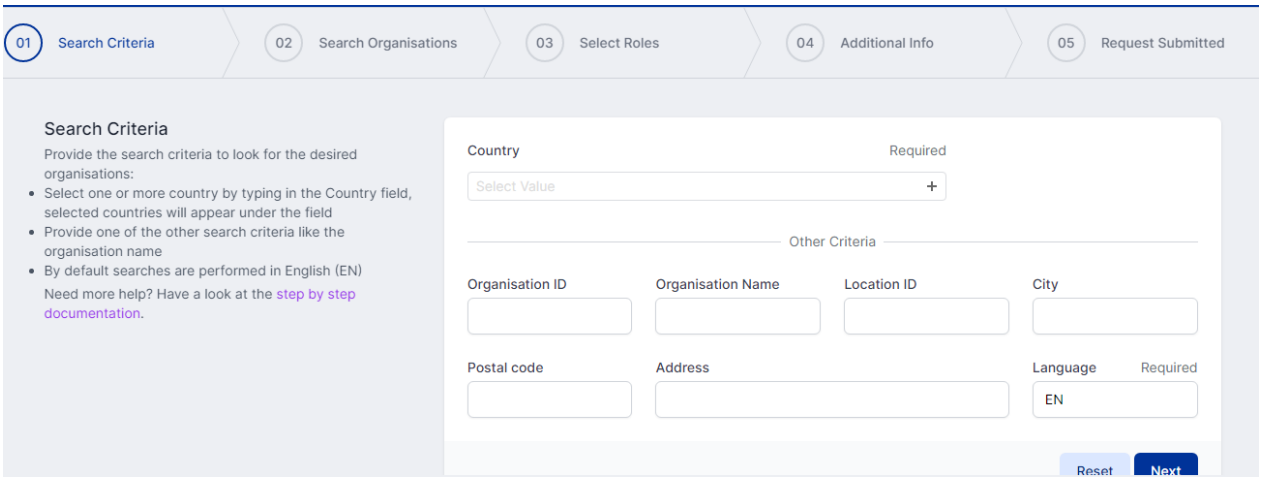
The 'Manage my access' tab, marked in red in the visual below, became obsolete, with all procedures now being managed through the 'Request Access for organisations' tab and the 'Manage Access' tab, marked in green.

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".

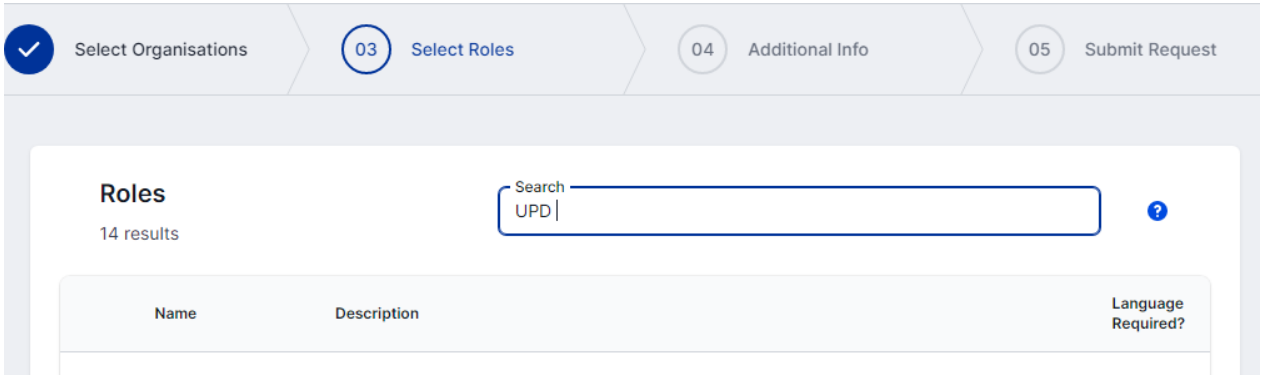
9.1. Request the Super User Role for your Organisation in UAT

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

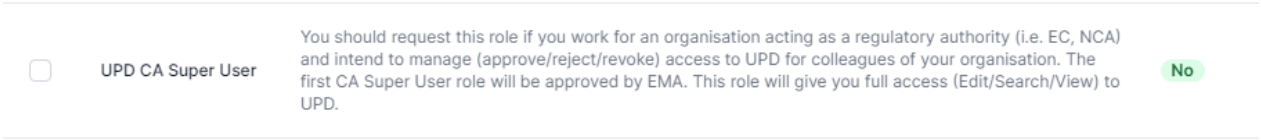
2. Go to "Request Access for Organizations" and search for your country and your ORG ID:



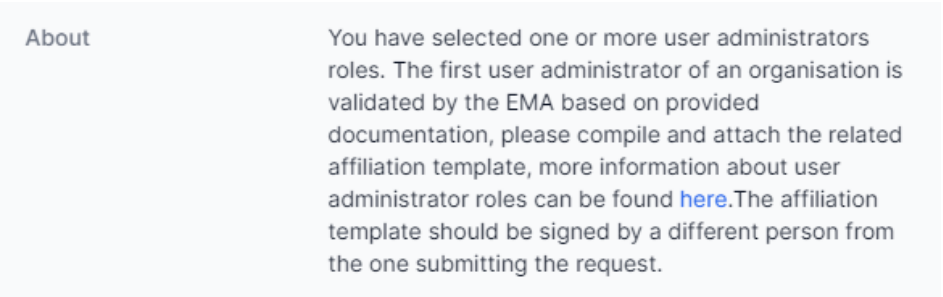
3. Select "UPD" to find the roles:



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)



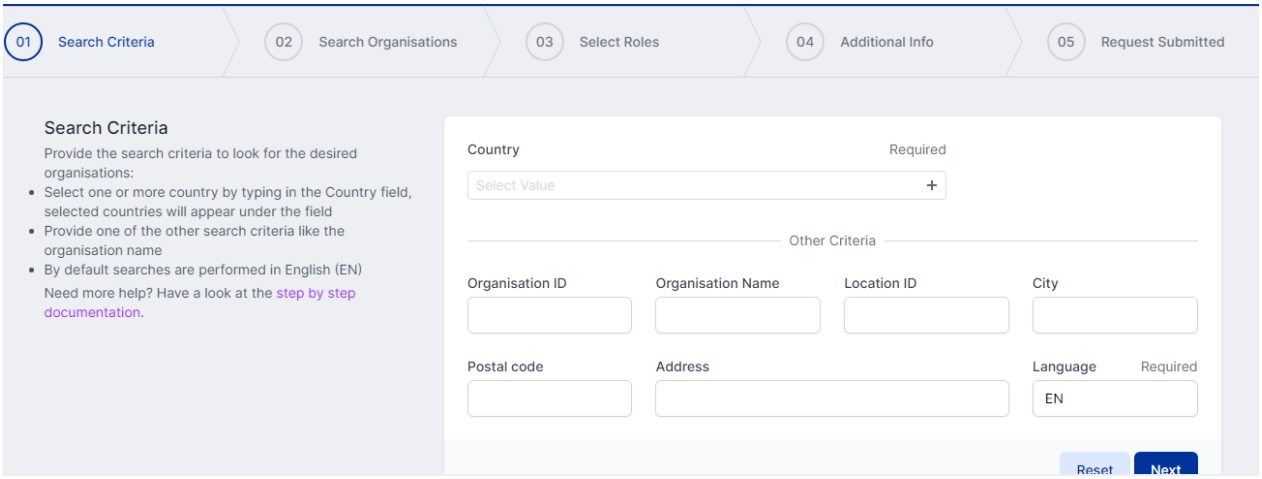
6. Click "Submit"

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

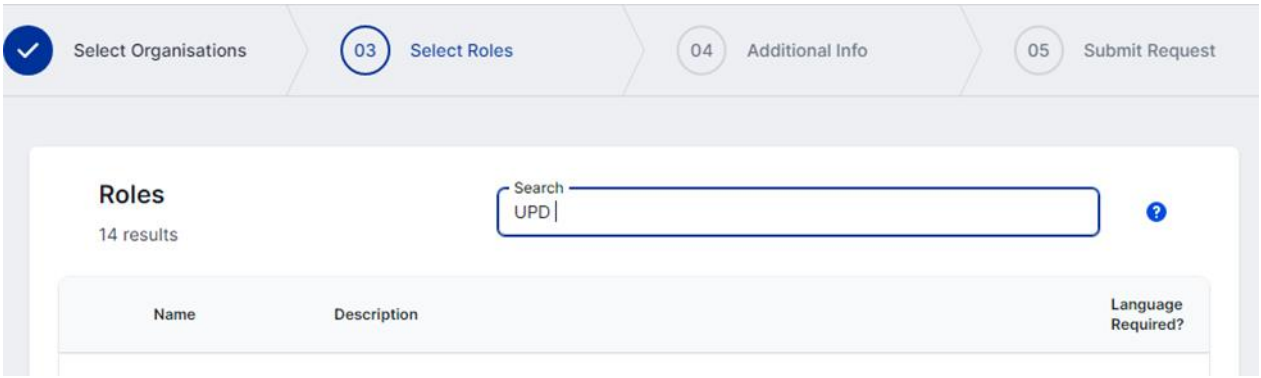
9.2. Request a Member User Role for your Organisation and Affiliate to your Organisation in UAT

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.

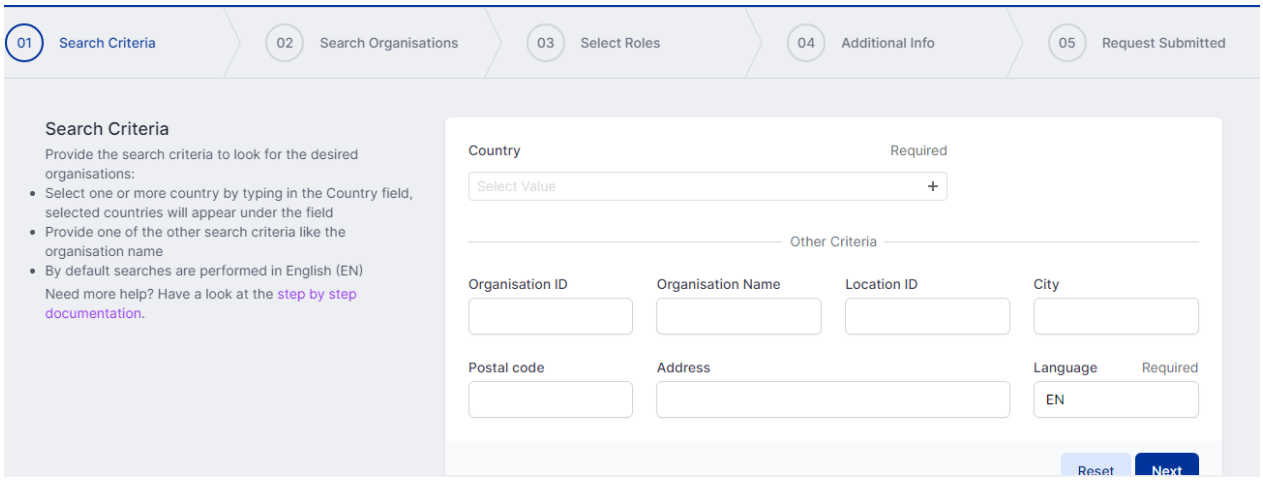
5. Submit.

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

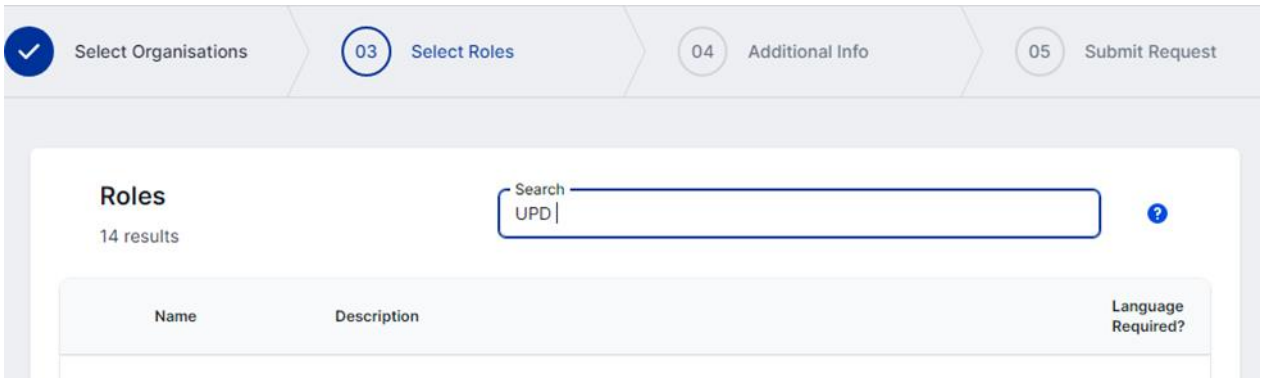
Note: This is at this point only relevant for UI usage. The model for the API accounts remains as per section 5.3. and the document referred to in section 9. .

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

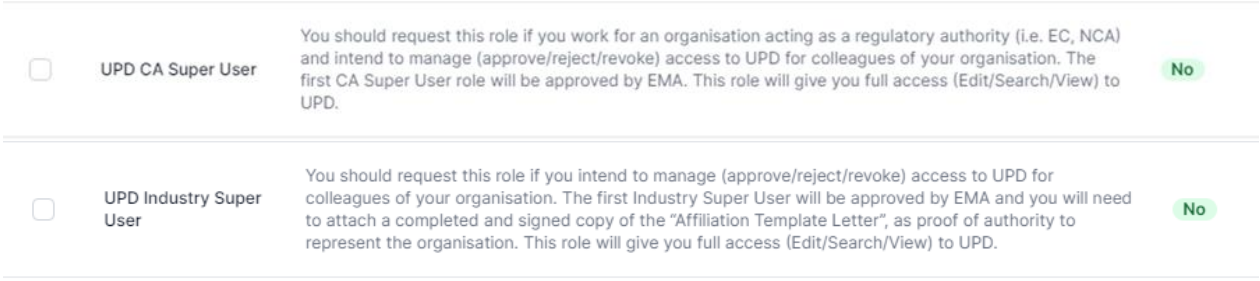
2. Go to "Request Access for Organizations" and search for your country and your ORG ID:



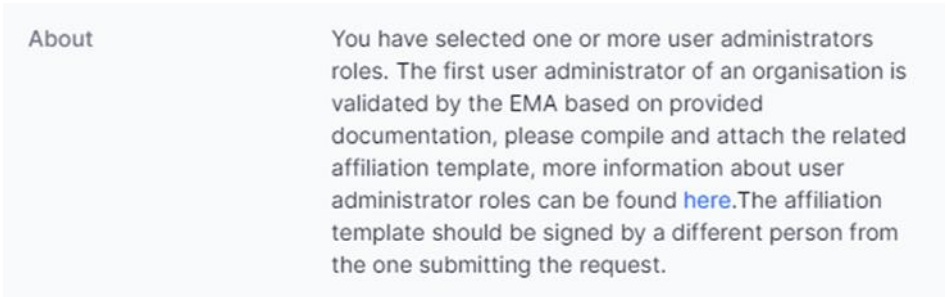
3. Select "UPD" to find the roles:



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



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.

9.4. 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 9. .

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

See the screenshots in section 9.2. 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 Vet EUIG Chapter 2 section; and then by Use Case number for those items without a specific IG reference.

Use Case	Affects API and/or UI user	Issue reference	Vet EUIG Chapter 2 section	Issue Description
UC08 Update product	API	UPD-7273	1.2 Product Record Status	UC08 Update SC2 Update National - API - UPD-UC08-AC016 - Missing Validation error when update Product Status from Current to Provisional & product has been updated
UC08 Update product	NCA UI	UPD-8246	1.3 Product identifier	Update SRP National data - The Product identifier is displaying [object Object], [object Object]
UC08 Update product	API	UPD-7148	1.4 Permanent identifier	UC08 Update SC2 NAP - should reject update with validation error message if MedicinalProductDefinition.id is not populated
UC08 Update product	API	UPD-9031	1.6 Legal status of supply 5.4 Legal status of supply	If Legal status of supply had been specified at Package level and submit an update to populate at Product level and remove from the package : the updated product still has the previous value at Package as well as the new value at Product level
UC08 Update product	API	UPD-5192	1.6 Legal status of supply 5.4 Legal status of supply	When updating product to change from specifying Legal status of supply at product level to package level, when you retrieve the updated product the previous value is still populated at the product level.
UC08 Update product	API & NCA UI	UPD-11476	1.6 Legal Status 5.4 Legal status of supply	Update National Data DCP/MRP/SRP: if product does not have Legal status of supply populated at either product or package level there should be a validation error. Instead the update is accepted and product is updated
UC01 Create product	API	UPD-4726	1.8.1 Veterinary medicinal product name	MedicinalProductDefinition.name.type used to be an attribute that was required to be populated. This is no longer required to be populated for the create. When you retrieve the product you will find this attribute has been populated with the term code for full name. This will be corrected in a future release.
UC01 Create product UC08 Update product	API & NCA UI	UPD-5531	1.8.2.1 Name type	Do not select term of "Full name" when entering a name part. It is not an option that should be included as an available option. If used, the created/updated product will have an additional full name rather than the intended name part

UC01 Create product	NCA UI	UPD-12284	1.11 Attached Document	Create DCP and Create MRP, the RMS is able to successfully attach National documents during the DCP/MRP product creation and they are saved on the RMS and CMS products. Any national documents should be ignored or Create rejected
UC01 Create product	NCA UI	UPD-10750	1.11 Attached Document	Create DCP UPD-UC01-AC202 - Only Common Documents where country is European Union (EU) and language is English should be output to the created products and any other documents should be ignored
UC08 Update product	NCA UI	UPD-12141	1.11 Attached Document	Update National Data DCP/MRP/SRP: User is able to delete a Common Data document from their product (common document is not removed from other products under that Product Identifier). The delete button should be disabled for common documents.
UC18 Manage document	API	UPD-12477	1.11 Attached Document	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.
UC01 Create product UC08 Update product	NCA UI	UPD-7971	1.11.5 (Attached document) content type	System allows Word .doc/.docx type document to be attached and this should not be valid
UC01 Create product	NCA UI	UPD-10714	1.13 Manufacturing Business Operation	Create Homeopathic - Manufacturing business operation - the "Add" button is always enabled even if no Manufacturer and Activity have been entered
UC08 Update product	NCA UI	UPD-12602	1.9.4 (PSM) File location	Chapter 4/Legacy products for all procedure types: if no PSM File Location has been populated the edit screen displays a value of "undefined - undefined". If you submit the update like this there will be a validation error. Click the "X" to delete and then you will be able to Submit the update without a validation error
UC01 Create product UC08 Update product	NCA UI	UPD-6910	1.9.4 (PSM) File location 1.10.3 QPPV Location	The Validate button doesn't highlight PSMF or QPPV Location as missing mandatory fields if the code/contact value s populated but no location selected (PSMF for Chapter 2 only)
UC08 Update product	API & NCA UI	UPD-12580	2.4 Responsible Authority 2.8 Product Owner	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	UPD-4811	2.4 Responsible authority (organisation) 2.8 Product Owner (organisation)	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	API & NCA UI	UPD-6927	2.5 Authorisation status	Update Common Data - when a CMS is removed from the list the Acceptance criteria has been updated and there should no longer be any update of the authorisation status in the removed CMS product
UC08 Update product	API	UPD-11235	2.6 Date of authorisation status change	Update National Data DCP/MRP/SRP or Update NP/Registered Homeopathic/Parallel Trade - if no Date of Authorisation status change attribute populated in payload getting validation error based on Legacy/Chapter 4 rules. It should be optional for Legacy
UC05 View product	NCA UI & MAH UI	UPD-10185	2.7 Marketing authorisation date	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
UC03 Search product	MAH UI	UPD-9253	2.8 Product Owner (organisation)	MAH is not able to search and view product where they are the Product Owner if the OMS Location selected by the NCA is the non-surviving location as a result of a merge in OMS
UC01 Create product	API	UPD-12240	2.12 Concerned member states	Create NAP/MRP/SRP via API - able to create product with old country code 100000000556 (United Kingdom of Great Britain and Northern Ireland) as CMS and this should reject with validation error
UC08 Update product	API	UPD-4812	2.13.1 Procedure number	Change to procedure number not saved if existing inline attribute id is not included in the request body
UC08 Update product	NCA UI	UPD-8399	3.1 Ingredient	Update product that has more then one Pharmaceutical product. There will be a validation error when update is submitted if one of the Pharmaceutical Product has no linked Ingredients. Workaround is to ensure at least one Ingredient is linked for each Pharmaceutical Product
UC08 Update product	API	UPD-4734	4.2 Manufacturer	Change of manufacturer in an Ingredient results in no manufacturer being populated in the updated product for that Ingredient
UC01 Create product UC08 Update product	API & NCA UI	UPD-7228	4.3.2.1 & 4.3.2.2	UC01 Create & UC08 Update Product - POST should be valid where Reference Strength is populated but there is no Substance Strength; 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

UC08 Update product	API	UPD-5384	5.1 Package description	New Package description added to product is output in main package description attribute and not as a translation as expected
UC01 Create product	API & NCA UI	UPD-12261	5.5 Marketing authorisation number	Create SRP where one or more existing RMS or a CMS has specified Marketing Authorisation number at Package level: after the Create SRP the Marketing Authorisation number at package level has been deleted from the existing products
UC08 Update product	NCA UI	UPD-9023	5.6 Manufactured item (in Package)	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
UC01 Create product UC08 Update product	API & NCA UI	UPD-9338	5.6.2 Manufactured item quantity	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	NCA UI	UPD-3346	5.6.4 Ingredient (in Manufactured item)	Each ingredient must be selected at least once in one of the manufactured items. This rule is not currently validated. 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 UC08 Update product	NCA UI	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 the create of a NAP product. It is no longer mandatory for a DCP.
All UC	MAH UI	UPD-9896		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-9862		All search result tables/grids - sorting search results should apply the sort across all entries matching the search criteria and not just sort the current page of search results
All UC	NCA UI & MAH UI	UPD-12055		Retrieve Product dialog: enter search criteria and Submit. Sometimes the dialog hangs and remains showing the progress control. No error message is returned to the user. The only workaround is to refresh the screen which will refresh the screen where were attempting to retrieve a product. Therefore

			any data that had been input in that calling screen will have been lost. For example issue has been observed for MAH Submit VNRA; and for NCA in Create MRP when retrieving the NAP product. This is an intermittent issue and we believe the occurrance will be infrequent
All UC	NCA UI & MAH UI	UPD-12400	Search and View product screens and others: the Country term code sometimes displays the expected short name and sometimes the full term name (e.g. Spain vs. Kingdom of Spain)
All UC	NCA UI & MAH UI	UPD-12084	There should be consistent display of the Marketing Authorisation Holder information across UPD screens with all address details displayed (street address, city, postcode, country). Some screens only display the organisation name or organisation name and street address
API Manager	API	UPD-10952	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
UC01 Create product	API & NCA UI	UPD-11038	Create DCP: submission is successful but when check transaction status using GET OperationOutcome there is an error "Failed to generate snapshot". The product is not created and there is no Notification. This is an intermittent issue that infrequently occurs.
UC01 Create product	NCA UI	UPD-9013	Create MRP - when Retrieving Product Information in the search dialog, if the enter key is clicked after entering some search criteria the screen changes to be main Search product screen and user is no longer in Create MRP screen. Do not use the Enter key when searching for product
UC01 Create product	NCA UI	UPD-11832	Create MRP : the "Add Package" button remains disabled after entering values for the addition of a package
UC01 Create product	API	UPD-11849	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
UC01 Create product	API	UPD-11277	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	API	UPD-12272	Create Parallel Trade via API where referenced product has Authorisation status that is not equal to "Valid" : the response code is Error 500 with no meaningful validation error message

UC01 Create product	API & NCA UI	UPD-10475	Create SRP based on selecting one of the existing CMS products should not be possible. The RMS should select their own product as a basis for the Create SRP
UC01 Create product	API & NCA UI	UPD-10293	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-4723	PackagedProductDefinition.package.quantity is not an attribute to be populated for a create. When you retrieve the product you will find this attribute has been populated with a value of zero. This will be corrected in a future release.
UC01 Create product	API	UPD-10136	POST Create bundle for DCP where URI starts with https and not http - this should be rejected with a validation error. Instead the post is accepted and product is created
UC01 Create product	API	UPD-10673	Post to the EP318 Validate end point for Create DCP displays an incorrect validation error relating to Marketing Authorisation Number "Marketing Authorisation Number must be provided either on product level or for all packages.". If this is the only validation error, the POST of the create to the EP309 Endpoint will be successful
UC01 Create product	API & NCA UI	UPD-11798	Products are created even though the transaction has failed and Operation Outcome shows there has been a timeout error. No Notification will have been created. This is expected to be an infrequent occurrence
UC01 Create product	API	UPD-11587	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.
UC01 Create product	API	UPD-2765	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 UC03 Search product UC05 View product	NCA UI	UPD-11879	The preferred name should be displayed for a Substance

UC08 Update product			
UC01 Create product UC08 Update product	API & NCA UI	UPD-10716	All procedure types: ATC Vet code fields are conditional. Either an ATC Vet code or ATC Vet Code pending flag should be populated when create or update a product. There should be a validation error if neither is populated. At present able to create/update without providing either value.
UC01 Create product UC08 Update product	NCA UI	UPD-11419	CAP procedure type: create or update with Document of type EPAR is able to be submitted. There is an exception when processing and the document is not saved on the product
UC01 Create product UC08 Update product	API	UPD-10145	Create or Update Registered Homeopathic product via API - POST is rejected with validation error if any attributes that are not applicable for this procedure type are populated. Instead the post should be accepted without validation error and all of the not applicable attributes should be silently ignored and data values not output into the product
UC01 Create product UC08 Update product	API	UPD-11621	For any product where Reference Strength Denominator has a term from Unit of Measurement list with List ID specified as Unit of Presentation, or vice-versa, there should be a validation error
UC01 Create product UC08 Update product	NCA UI	UPD-9857	Parallel Trade product: the Authorised pharmaceutical form has been implemented as single drop-down list and not two like Create/Update screens for other procedures. In a future release this will be aligned across all of the create/update screens so that they are the same.
UC01 Create product UC08 Update product	API	UPD-10133	POST Create or Update bundle for NP where URI starts with https and not http - this should be rejected with a validation error. Instead the post is accepted and product is created
UC01 Create product UC08 Update product	NCA UI	UPD-7997	Create/Update of a Product - Error Messages need to be more meaningful
UC01 Create product	NCA UI	UPD-7964	Date field may give an erroneous value when you click on the date picker widget after entering some partial value manually.

UC08 Update product			
UC01 Create product UC08 Update product	API & NCA UI	UPD-12586	Document of type "Public Assessment Report" is not saved in the created or updated product
UC01 Create product UC08 Update product	NCA UI	UPD-5114	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	API & NCA UI	UPD-12406	When processing a Create or Update to product an error occurs on one of the servers "No buffer space available". This results in the create or update being Queued and is never subsequently processed
UC03 Search product	NCA UI & MAH UI	UPD-12278	Active substance and strength column in Search table shows N/a instead of zero for products having substance strength or reference strength values as zero
UC03 Search product	NCA UI & MAH UI	UPD-12590	If search results require two or more pages, and the last page of search results should contain 51 or more products: the last page of search results is always displaying 100 products
UC03 Search product	API & NCA UI & MAH UI	UPD-5538	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-10219	Reset button does not clear existing search criteria from "Authorisation Country"
UC03 Search product	API & NCA UI & MAH UI	UPD-1024	Search should be accent insensitive when using the exact modifier and it is not
UC03 Search product	NCA UI & MAH UI	UPD-11115	Sort of search results by alphabetical order of the product name does not work
UC03 Search product	API & NCA UI & MAH UI	UPD-140	Sort of search results does not work

UC03 Search product	NCA UI & MAH UI	UPD-10666	When searching for products may receive an error message "There has been a glitch". In most cases a resubmission of the search will be successful and return products matching the submitted criteria.
UC04 Export	NCA UI & MAH UI	UPD-9861	The downloaded csv file should contain all products matching the search criteria. The file only contains those displayed on the current page
UC05 View product	NCA UI & MAH UI	UPD-12585	Reference Strength is not being displayed when viewing a product
UC05 View product	NCA UI & MAH UI	UPD-10956	The strength information is not displayed next to the Substance within an Ingredient
UC05 View product	NCA UI & MAH UI	UPD-12279	When view product, dates are different according to browser timezone
UC05 View product	NCA UI	UPD-11474	When viewing product with procedure type SRP, sometime the "Edit National data" button is not displayed
UC06 Submit VNRA	MAH UI	UPD-10901	After successful submission of VNRA, if click on the Cancel button the screen should be ready to input another submission. Instead the screen becomes unusable with grey background and MAH needs to refresh the browser page
UC06 Submit VNRA	MAH UI	UPD-11617	For UPD-BR-092 Automated A.1.a for update to MAH : only allow MAH to select LOC-ID for an Organisation that they have affiliation to
UC06 Submit VNRA	MAH UI	UPD-12246	If MAH is affiliated with many Organisations, when they Submit a VNRA the Notifications for MAH are generated based on affiliations that the logged on MAH has and should be based on Products in the Submission. This means MAH user only affiliated to some of the organisations may see a Notification but they will not be able to view the Submission and will not be able to view any products where they are not the MAH for all products in that submission
UC06 Submit VNRA	MAH UI	UPD-11596	If Submission Comment exceeds limit of 4000 a meaningful error message is displayed. Instead it displays an error of "undefined" in the banner (with red background).
UC06 Submit VNRA	MAH UI	UPD-11632	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	NCA UI	UPD-11278	Issue affects EMA/EC users only: When VNRA is submitted, the VNeeS files is not reaching the Common Repository for some submissions
UC06 Submit VNRA	MAH UI	UPD-8440	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	UPD-7960	Submit VNRA: No search results displayed when the 'Retrieve product' search dialog is opened a second time
UC06 Submit VNRA	MAH UI	UPD-12062	The System is displaying Homeopathic products as available to select in VNRA submission and they should not be included in search results
UC06 Submit VNRA	MAH UI	UPD-12277	VNRA submission fails where product with Liechtenstein as CMS is included
UC06 Submit VNRA	MAH UI	UPD-11256	When selecting products, a search by Product Owner doesn't work if used as criteria for second time
UC06 Submit VNRA UC28 View VNRA	NCA UI & MAH UI	UPD-10184	Accented and special characters for all EU languages are not correctly displayed for Product Name and Package description. Some are OK but others aren't
UC07 Submit Volume of Sales	MAH UI	UPD-11489	Download list of packages - example from Create DCP where one of the new products is not included in the csv file. The MAH is able to search and view all products under that Product Identifier. This does not happen in all cases and believe is when the create DCP transaction did not complete successfully
UC07 Submit Volume of Sales	MAH UI	UPD-9868	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	UPD-7992	Volume of Sales: Error incorrectly triggered by the system in the error file after the submission of VoS
UC08 Update product	API & NCA UI	UPD-10288	A Product stuck in 'pending' state from a previously failed update transaction cannot be updated
UC08 Update product	NCA UI	UPD-7996	Add button in Package medicinal product section needs to have more meaningful caption
UC08 Update product	NCA UI	UPD-12096	Bulk Transfer of Ownership screen: not able to update existing document
UC08 Update product	NCA UI & MAH UI	UPD-11819	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	UPD-9483	For product under DCP/MRP/SRP procedure, an NCA who is not the RMS or CMS is able to select to edit a product under the procedure. Only the RMS should be able to Update Common Data or Update National Data; and only CMS should be able to update National Data for their product
UC08 Update product	API	UPD-4714	If there are duplicate inline attribute IDs within a resource, the request will be rejected. The validation message will say that the resource is not included and is mandatory, with no other validation errors in the response. As a workaround, remove the existing inline ID from one attribute so there is no longer duplicate values. This may occur and most frequently affects: - MedicinalProductDefinition.contact - MedicinalProductDefinition.masterFile - AdministrableProductDefinition.routeOfAdministration - AdministrableProductDefinition.routeOfAdministration.targetSpecies - AdministrableProductDefinition.routeOfAdministration.targetSpecies .withdrawalPeriod
UC08 Update product	NCA UI	UPD-11559	On View product screen, the edit product buttons are not correctly enabled or disabled. An NCA is able to edit a product that they shouldn't be able to; and in some cases may not have edit button enabled when it should be
UC08 Update product	NCA UI	UPD-10894	Registered Homeopathic product can't be updated as there are a number of unexpected validation errors (regression issue)
UC08 Update product	NCA UI	UPD-12399	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-7247	UC08 - Update DCP SC2 National data - Able to add a new Pharmaceutical Product which is a Common data; advised successful but Get OperationOutcome has Validation error
UC08 Update product	API & NCA UI	UPD-6961	UC08 - Update DCP SC2 National data UPD-UC08-AC041 - Able to delete Manufactured item from package and submit update and should get validation error

UC08 Update product	API	UPD-6882	UC08 Update SC2 Update National Data for DCP/MRP/SRP. The Content location in the response is in the format: national-data-operation-outcome/e915f652-d3b9-4cca-8c4d-23f0aae5a19a-ND. The id value should be used with a GET OperationOutcome/id.
UC08 Update product	NCA UI	UPD-11218	Update National data and after entering what is believed to be all national data, the Update button is not enabled (Package data is not displayed which is likely to be the underlying issue) (intermittent issue)
UC08 Update product	API	UPD-9709	Update Common Data - the response to Get OperationOutcome in some circumstances does not contain the status of the POST and instead has "Failed to parse JSON encoded FHIR content: Content does not appear to be FHIR JSON, first non-whitespace character was: '<' (must be '{')". This issue only arises for some instances where there has been a failure processing the update. It is not expected that this will occur frequently.
UC08 Update product	API	UPD-12224	Update Common Data DCP/MRP/SRP where RMS product does not have National data populated: POST has response code of 500 Internal server error. If Authorisation status and Date of Authorisation status change date attributes are populated the POST is successful. This is a regression issue and update common data should not require these attributes to be populated if RMS has not populated national data for their product.
UC08 Update product	NCA UI	UPD-12393	Update Common Data MRP/DCP/SRP - Delete Common Document only deletes the document from RMS product and does not delete from CMS products
UC08 Update product	NCA UI	UPD-12239	Update NAP - deletion of existing Pharmaceutical product and addition of a new Pharmaceutical product removed the existing Ingredients from the updated product
UC08 Update product	NCA UI	UPD-11292	Update National Data DCP/MRP/SRP: User cannot edit or delete an existing or new national name before submitting the update
UC08 Update product	NCA UI	UPD-10287	Update National DCP/MRP/SRP - the confirmation modal message lists all RMS and CMS countries, and should just be the authorisation country from the product that is being updated
UC08 Update product	API	UPD-12286	Update Parallel Trade via API fails with validation error messages relating to RMS and CMS (regression issue from previous release)
UC08 Update product	API & NCA UI	UPD-12396	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
UC08 Update product	NCA UI	UPD-12260	When updating product and managing document: the Size of existing documents is not displayed; and when add new document the Country and Language is not displayed in documents grid. However, the update of the product and documents is successful. This is a display issue in the edit screen.
UC09 Approve/Reject VNRA	NCA UI	UPD-9866	If an NCA is affiliated with two or more Organisations, they should only be able to view and approve/reject VNRA for submissions of NP products where they are the Responsible Authority; or DCP/MRP/SRP where they are RMS/CMS
UC09 Approve/Reject VNRA	NCA UI	UPD-12464	Products under DCP/MRP/SRP should be grouped by Product Identifier. In this release they are not listed by sub-group within the Variation code and instead each product is listed under its own Product Identifier heading. This means that selecting Approve or Reject check-box for one product under a Product Identifier is not selecting the same checkbox for all of the other products under that Product Identifier
UC09 Approve/Reject VNRA	NCA UI	UPD-12231	Submission and variation level checkboxes are not enabled as expected when submission contains products for many NCA
UC09 Approve/Reject VNRA	NCA UI	UPD-11052	UC09 Approve/Reject VNRA NCA - When the user views a Pending submission and clicks on Cancel button empty blank cards are showing on the screen
UC18 Manage document	API	UPD-12249	Create or Update of Document via API - infrequently the POST fails with response code 500 Internal server error. This is an intermittent issue as POST of the same payload is subsequently successful. This is an issue only observed in PROD environment
UC18 Manage document	API	UPD-11460	EP403 Create Document for CAP with document type of EPAR: get a validation error even although payload is valid
UC19 Nullify product	API & NCA UI	UPD-12048	A product with a Data Quality issue can't be nullified

UC19 Nullify product	API	UPD-11471	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	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	UPD-9773	Implementation of endpoint to nullify a product is not as expected: didn't expect to have to specify which Validation rules to apply; there is no Content Location with OperationOutcome ID; format of errors when POST are not in the format specified in request Accept header; does not support request in XML format
UC19 Nullify product	API	UPD-10115	Nullify Parallel Trade product via API is giving an error with response code of 500 Internal server error
UC19 Nullify product	NCA UI	UPD-10910	Nullify Registered Homeopathic - not able to nullify as get error when submit "there was an error when trying to nullificate the product" (regression)
UC19 Nullify product	API	UPD-11204	Response when submit POST to nullify a product is to be reviewed: there is no message returned in response body; consider aligning the nullify endpoint with other create/update endpoints and provide an OperationOutcome ID that can be used to query outcome
UC19 Nullify product	NCA UI	UPD-9830	When you nullify a product, the confirmation message does not include the Permanent Identifier
UC21 Manage Notifications	NCA UI & MAH UI	UPD-10184	Accented and special characters for all EU languages are not correctly displayed for Product Name and Package description. Some are OK but others aren't
UC21 Manage Notifications	NCA UI	UPD-8340	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	UPD-11827	Not able to search notifications using Procedure number
UC21 Manage Notifications	NCA UI & MAH UI	UPD-12454	Notifications are sometimes missing for some actions. For example Create DCP - only notifications received for some CMS even although transaction has been completed successfully and products have been created

UC21 Manage Notifications	NCA UI & MAH UI	UPD-12405	Returning to search results in the notifications screen displays the previously selected search criteria. But the notifications displayed are the default to display when first selecting notifications from the menu and has not applied the selected search criteria. As a workaround need to Search again.
UC21 Manage Notifications	NCA UI & MAH UI	UPD-12591	VNRA Submitted action: the notification card has incorrect labels. Decision Comment should be Submission Comment. Date of Decision should be Date of Submission. Date of Implementation is not displayed. The correct values of the submission date and submission comment are displayed.
UC21 Manage Notifications	NCA UI & MAH UI	UPD-11200	When approving VNRA for product under DCP/MRP/SRP, duplicate notification records have been generated for some CMS products
UC21 Manage Notifications	NCA UI & MAH UI	UPD-12091	When select to view notifications from the Menu, the search results and total count also shows only those notifications for the past month. If user searches again the total count then displays the correct total of all notifications. When user selects from the menu the total should be for all notifications.
UC24 Marketing authorisation status	MAH UI	UPD-10751	Availability status is not updated to "Not marketed" when Authorisation status updated to Suspended or Revoked
UC24 Marketing authorisation status	MAH UI	UPD-12092	When MAH selects to update a product that has some data quality issue, the screen hangs on submission due to a validation error. This validation error is not shown to the user. The submission should fail with validation error displayed to the user.
UC25 Update Availability status	MAH UI	UPD-11130	If there are errors when submitting file for Availability status updates, the Error report file has incorrect values for "Pack size_Unit of presentation identifier" and Marketing Authorisation Number
UC25 Update Availability status	MAH UI	UPD-7980	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	UPD-11420	When submit Availability status and the logged on MAH is not affiliated to the Product owner of the product, an incorrect error message is being displayed. "ERR.05 Package identifier provided doesn't belong to the country

			selected" is being displayed and it should be "ERR.01: Package Identifier provided doesn't belong to a product under the User's responsibility".
UC27 View Volume of Sales	MAH UI	UPD-12423	View Volume of Sales for a Product that has had Volume of sales successfully submitted. After selecting product and sales period and submit this fails with an error 499 (issue in PROD env only)
UC28 View VNRA	NCA UI	UPD-12208	Datafix for existing VNRA. Following the resolution of the root-cause under UPD-11604 in release 1.6.10, a datafix was required for existing VNRA submitted prior to that release so that NCA able to view. This datafix has now been applied. Therefore, NCA should now be able to view VNRA submissions as expected
UC28 View VNRA	NCA UI	UPD-9866	If an NCA is affiliated with two or more Organisations, they should only be able to view and approve/reject VNRA for submissions of NP products where they are the Responsible Authority; or DCP/MRP/SRP where they are RMS/CMS
UC28 View VNRA	NCA UI & MAH UI	UPD-12464	Products under DCP/MRP/SRP should be grouped by Product Identifier. In this release they are not listed by sub-group within the Variation code and instead each product is listed under its own Product Identifier heading
UC28 View VNRA	NCA UI & MAH UI	UPD-11574	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 & MAH UI	UPD-12522	The PDF for VNRA for variation Code A4 ATC Vet code is currently displaying the RMS Term code for the current and proposed ATC Vet codes. It should be displaying the RMS Term as displayed on the View VNRA Submission page.
UC28 View VNRA	NCA UI & MAH UI	UPD-11633	UPD-BR-066 VNRA Submission PDF: date format is yyyy-mm-dd and should be dd-mm-yyyy
UC28 View VNRA	MAH UI	UPD-10911	View partially approved VNRA and message is displayed "System error: try again in a few minutes". Waiting some time and retrying will not work and it will always fail to display
UC28 View VNRA	NCA UI & MAH UI	UPD-11888	View VNRA submission: Empty VneeS file viewing submission when MAH has attached a zip file that contains file(s) while submitting the VNRA. This infrequently occurs.

UC28 View VNRA	NCA UI & MAH UI	UPD-12047	VNRA PDF: the existing MAH is listed as for all variation codes and data value is only printed for A.1.a; Current and proposed values for MAH should only be printed for A.1.a
UC28 View VNRA	NCA UI & MAH UI	UPD-11890	VNRA submission for CAP products is present in Notifications but is not listed as pending submission on View VNRA Submissions screen. We believe this is the same issue as resolved under UPD-11604 but are waiting to confirm.
UC28 View VNRA	NCA UI & MAH UI	UPD-11936	When selecting to view a VNRA Submission, on the view submission screen it displays "System error: Try again in few seconds". This usually only occurs for the first submission you try after logging on. The workaround is to refresh the screen using the F5 function button. The selected VNRA submission will now be displayed.
UC34 Bulk Upload for Documents	NCA UI	UPD-12223	Advised submission of files is successful but there is no Notification and document is not added to product
UC34 Bulk Upload for Documents	NCA UI & MAH UI	UPD-10698	After successful Bulk Upload of one or more documents, 'Date of Action' and 'Version number' are not populated in Notification card when viewing Notification
UC34 Bulk Upload for Documents	NCA UI	UPD-11885	Bulk upload: sometimes the file is not uploaded to product(s). Potentially this issue is when filename contains characters other than lower case characters a-z, digits 0-9 or a hyphen. This is the guidance in Vet EU IG Chapter 2 Annex 2 and there may be missing validation to enforce this. Example that contains an underscore appears to not load
UC34 Bulk Upload for Documents	NCA UI	UPD-11418	Document uploaded with Type = "epar" is being wrongly saved as "puar"
UC34 Bulk Upload for Documents	NCA UI	UPD-10699	For CAP products - EPAR document type is not available and it should be possible to add multiple EPAR documents for a CAP product
UC34 Bulk Upload for Documents	NCA UI	UPD-11376	For CAP products only: review document types that can be loaded as only expected PuAR, EPAR and Combined to be valid
UC34 Bulk Upload for Documents	NCA UI	UPD-12226	Not all documents added in one submit are loaded to the product

UC34 Bulk Upload for Documents	NCA UI	UPD-12182	Notifications are not all generated after uploading multiple documents using the bulk upload functionality (files have been added to the product)
UC34 Bulk Upload for Documents	NCA UI	UPD-12218	Trying to update an existing document sometimes results in an addition of a duplicate document for combination of country/document type/language
UC05 View product	NCA UI & MAH UI	UPD-12758	On the view product screen, documents with language of Norwegian or Icelandic display language as N/A
UC05 View product	NCA UI & MAH UI	UPD-12753	When viewing a product, the hyperlinks in the left hand menu to sections within the product data do not work
UC06 Submit VNRA	MAH UI	UPD_12854	VNRA submission for variation code C.6 fails for products without existing PSMF information
UC07 Submit Volume of Sales	MAH UI	UPD-12755	Submission of Volume of Sales - if any product name or package description contains an embedded quotation mark the submission fails with a validation error "invalid char between encapsulated token and delimiter"
UC25 Update Availability status	MAH UI	UPD-12755	Submission of Availability Status - if any product name or package description contains an embedded quotation mark the submission fails with a validation error "invalid char between encapsulated token and delimiter"
UC25 Update Availability status	MAH UI	UPD-12751	Download fails with a validation error if any product that has been selected to download has Authorisation status of Suspended, Revoked, Surrendered or Expired
UC25 Update Availability status	MAH UI	UPD-12752	Submission of Availability status file: there are validations being applied for some columns of the submission file that shouldn't happen and cause the submission to fail

Annex 3: Release Schedule

#	Environment	Date From	Date Till	Description

35	UAT	~~01 Dec 22~~ 14 Nov 22	~~02 Dec 22~~ 15 Nov 22	Upgrade of UPD to 1.6.13 Deployment rescheduled
36	PROD	~~08 Dec 22~~ 01 Dec 22	~~09 Dec 22~~ 02 Dec 22	Upgrade of UPD to 1.6.13 Deployment was rescheduled
37	PROD		13 Jan 23	Upgrade of UPD to 1.6.16