UPD Release Notes 1.6.8

Veterinary Medicinal Products Regulation: Union Product Database

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1. Overview of functionality and business value

This release is the next iterative version of the Union Product Database, v 1.6.8. The main difference with the previous version, v 1.6.5 released on 20 June 2022, is new functionality as per section 2.2 and resolution of defects as per section 2.3.

This version allows NCAs to submit/enter legacy product information, as per Art 155 of Reg 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 National Procedure product as the basis for this creation, and adds or updates Common data. For example: add Common Product Name, Reference member state and Concerned member state(s). A new product will be created for each Concerned Member State (CMS) with procedure type MRP and the RMS's NP product 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.

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
    - ~~o~~ NCA can Bulk Upload Documents
    - NCA can Transfer Marketing Authorisation (without documents)
    - 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~~ This functionality which had previously been released should not be used in 1.6.8 due to known issues. It is expected that this will be available for use in release 1.6.10.
- 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:

- Update document

NCA UI:

- Update CAP products (by EMA or EC staff)
- Add, Update or Delete Documents when creating or updating a product

MAH UI:

- Submit updates for Marketing authorisation status for CAP products
- Download or Submit updates for Availability status This has been removed from this release due to bugs for products under DCP/MRP/SRP in both the download file and when submit an update for those products

2. Changes made compared with 1.6.5

2.1. New functionality

- NCA can create & update Parallel Trade products (data and documents) – via API & NCA UI
- Transfer Marketing Authorisation – via NCA UI
    - With limitation that this is not available for updating CAP products
    - Please note: known issue relating to adding/updating documents
- UC34 Bulk Upload Documents – via NCA UI
- UPD-10171 - UC06 - Submission comment limit increased to 4000 characters
- UPD-10067 1.13.1 Manufacturer for Manufacturing Business Operation – via NCA UI
    - In the pop-up dialog when selecting Manufacturer for Manufacturing Business Operation, the drop down menu only showed EEA countries. This has been changed to include all countries
- UPD-BR-092 Variations not requiring assessment (VNRA) - Management of a VNRA that affects data related to the Marketing authorisation holder (variation code A.1.a)
    - MAH now provides the new Product owner at the time they submit variation A.1.a

    - When NCA approves variation A.1.a the system will update the product(s)
- UPD-BR-066 - Variations not requiring assessment (VNRA) - Download VNRA submission data
    - MAH & NCA UI users are now able to download PDF from View VNRA Submissions screen

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
UC01 Create product	NCA UI	UPD-9784	1.8 Veterinary medicinal product name	Create DCP/MRP/SRP - it was not possible to edit the common product name after adding the name and before you submit to create the product. This issue has been resolved.
UC01 Create product UC08 Update product	API	UPD-7160	1.12.2 Reference product identifier	There was no validation error if the provided product reference was an alphanumeric value that contained an embedded space. The create/update was accepted but failed with ERR-1001 when view result using GET OperationOutcome. When referencing one of the dummy products available to use the Permanent Identifier of the corresponding product should be specified. For example in UAT env for “VMP data not provided”: <crossReference> <productReference> <reference value="MedicinalProductDefinition/600000004496" /> Please note that the Permanent Identifier values for these dummy products are not the same in UAT env as in PROD env.

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue that has been resolved
UC01 Create product UC08 Update product	NCA UI	UPD-10067	1.13.1 Manufacturer	In the pop-up dialog when selecting Manufacturer for Manufacturing Business Operation, the drop down menu only showed EEA countries. This has been changed to show all countries.
UC01 Create product	API	UPD-9411	2.2 Authorisation/registration/entitlement number 5.5.1 Marketing authorisation number (package level)	Registered Homeopathic product based on Chapter 2 validation rules: there is now a validation error if submit without any value for Marketing Authorisation Number at either Product or Package level.
UC01 Create product UC08 Update product	API & NCA UI	UPD-5764	2.2 Authorisation/registration/entitlement number 5.5.1 Marketing authorisation number (package level)	UC01 Create UC08 Update – will now reject if Marketing Authorisation Number is populated at both Product and Package Level
UC01 Create product	API	UPD-10176	2.4 Responsible authority	Create Registered Homeopathic - there was a missing validation if Post payload with an invalid LOC-ID for the responsible authority. The payload was accepted but Get OperationOutcome response showed ERR-1002. Validation error will now be displayed when Post.

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue that has been resolved
UC08 Update product	API	UPD-9800	2.4 Responsible authority (organisation)	Update product via API only: when updating the LOC-ID for the Responsible authority, organisation name was not being updated if the RegulatedAuthorization.regulator.display attribute was not included in the Update bundle. This is an optional attribute that should not need to be provided. The organisation name remained as the default of EMA. This issue has been resolved for new updates processed in this release onwards. EMA is applying a data fix to correct the data for existing products so that the correct organisation acronym or name is displayed. It is expected that updates will be completed by 30/09/2022.
UC08 Update product	API	UPD-9800	2.8 Product owner (organisation)	Update product via API only: when updating the LOC-ID for the Product owner, organisation name was not being updated if the RegulatedAuthorization.holder.display attribute is not included in the Update bundle. This is an optional attribute that should not need to be provided. The organisation name remained as the default of EMA. This issue has been resolved for new updates processed in this release onwards. EMA is applying a data fix to correct the data for existing products so that the correct organisation acronym or name is displayed. It is expected that updates will be completed by 30/09/2022.
UC08 Update product	API & NCA UI	UPD-10564	2.12 Concerned member states	Update Common data DCP/MRP/SRP to remove a CMS: the status of the update transaction when checked using Get OperationOutcome shows status remaining as In-Progress. Only the RMS product has been updated and the other CMS products have not been updated. Resolved by the review and redesign of the update workflow used for Update Common Data and Update National Data. This has resolved issues based on the symptoms described in this bug.
UC01 Create product	API	UPD-6561	2.12 Concerned member states	UPD-UC01-AC047 Validation was missing as were able to select non-EU/EEA country as CMS

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue that has been resolved
UC01 Create product	NCA UI	UPD-5908	3 Pharmaceutical Product	Create SRP - Pharmaceutical products section - Labels for 'Edit' and 'Delete' were missing in the table after adding a Pharmaceutical Product
UC05 View product	NCA & MAH UI	UPD-8374	3 Pharmaceutical Product	Pharmaceutical section should list all Ingredients and in previous releases was not.
UC01 Create product	NCA UI	UPD-10580	5 Packaged medicinal product	Create DCP - after adding a package and before clicking the Submit button, it was not possible for the user to edit that package to correct any errors.
UC01 Create product UC08 Update product	NCA UI	UPD-10113	5.2 Pack size	Pack size is to be optional. It was still mandatory for the following procedure types: NP/CAP/Registered Homeopathic.
UC08 Update product	API	UPD-10183	5.5.1 Marketing authorisation number (package level)	Update Registered Homeopathic - change Marketing Authorization number from Product level to Package level failed with an incorrect validation error
UC01 Create product	API	UPD-11374		Create DCP requests were failing during backend processing when the Request “Accept” header was not populated. This issue has been resolved and create now completes if this request header is not populated.
UC01 Create product	API & NCA UI	UPD-10909		UC01 Create DCP/MRP/SRP - Validation related to Marketing Authorisation number was not applicable. This issue has been resolved and now be able to proceed without populating
UC01 Create product	API & NCA UI	UPD-10947		Create MRP - creation of second CMS failed with ERR-1001. However, product was created and showed on Search by Product Identifier but there was no Notification (update to RMS OK and one CMS product created). This issue has been resolved.
UC01 Create product	API & NCA UI	UPD-11423		UC01 Create via API or NCA UI MRP/SRP AC060 CMS country should not be able to be selected more than once within the Concerned Member states list.

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue that has been resolved
UC01 Create product UC08 Update product	NCA UI	UPD-8985		The system was allowing to create NAP/CAP/DCP/MRP/SRP/Registered Homeopathic products with Documents with the same document type, language and country without any warning message. This issue has been resolved and there will be a validation error. The exception as noted in Vet EU IG is that able to add duplicate EPAR or PuAR for CAP products.
UC03 Search product	NCA UI & MAH UI	UPD-10454		If search with '+' as part pf the product name search criteria the result was that system advised there were no matching products. However, if search with same search criteria but remove the "+" and subsequent characters from the search name the expected products now returned in the search results. Including '|' within the product name search criteria resulted in an error. All special characters that can be populated in a product name should be now be able to be used as part of the search criteria
UC05 View product	NCA UI & MAH UI	UPD-5138		Active substances where manufacturer has been populated were not listed in the Manufacturing business operation section.
UC05 View product	NCA UI & MAH UI	UPD-8061		Under the Manufacturer business operations section, the manufacturer for the active substances detail was missing
UC06 Submit VNRA	MAH UI	UPD-11280		Same VNRA code had been output twice in a submission. There was one example reported to User Support for a VNRA submission where the same VNRA code appears twice for the same CAP product. We have been unable to reproduce this issue in 1.6.8 release. We were also unable to reproduce in PROD under the 1.6.5-6 release. Therefore for now we are closing this issue as it was a one-off instance. If any MAH experiences this issue please log a support ticket.
UC06 Submit VNRA	MAH UI	UPD-10954		UC06 - Maximum length Submission comment was not properly configured. 4,000 characters may now be input for the comment.
UC07 Submit Volume of Sales	MAH UI	UPD-10985		Download Volume of Sales Packages file did not have newly created Registered Homeopathic products (there is 500 Internal server error in the background). This issue has been resolved.

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue that has been resolved
UC07 Submit Volume of Sales	MAH UI	UPD-10588		Download Volume of Sales packages: some users affiliated to more than one organisation were not able to view the downloaded file because of the length of the filename. This issue has been resolved and a different file naming convention is now being used.
UC07 Submit Volume of Sales	MAH UI	UPD-10590		When download packages for Volume of Sales, there was a second empty file vos-download.csv also being downloaded
UC08 Update product	API & NCA UI	UPD-10683		Update Common Data DCP/MRP/SRP - transaction is incomplete with no status to submitter. Status via Get OperationOutcome remains as In-Progress Resolved by the review and redesign of the update workflow used for Update Common Data and Update National Data. This has resolved issues based on the symptoms described in this bug.
UC08 Update product	API & NCA UI	UPD-10680		Update Common Data DCP/MRP/SRP - transaction is incomplete with no status to submitter. Resolved by the review and redesign of the update workflow used for Update Common Data and Update National Data. This has resolved issues based on the symptoms described in this bug.
UC08 Update product	API	UPD-10401		Following an update of a product it may be left in an inconsistent state and cannot be subsequently updated. The GET OperationOutcome of the second/subsequent update shows ERR-1002 without indicating what the underlying issue is. This issue affects only a few products. Resolved by the review and redesign of the update workflow used for Update Common Data and Update National Data. This has resolved issues based on the symptoms described in this bug.

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue that has been resolved
UC08 Update product	API	UPD-10614		POST of update is successful with response code 202 Accepted. In some circumstances when review status using GET OperationOutcome, the response status is 500 with message containing "Unexpected character '{' ". Resolved by the review and redesign of the update workflow used for Update Common Data and Update National Data. This has resolved issues based on the symptoms described in this bug.
UC08 Update product	API	UPD-10457		Update Common Data DCP POST is successful but GET OperationOutcome sometimes shows update does not successfully complete and remains with status of In-Progress. Resolved by the review and redesign of the update workflow used for Update Common Data and Update National Data. This has resolved issues based on the symptoms described in this bug.
UC08 Update product	API & NCA UI	UPD-10970		Update Common Data DCP/MRP/SRP - sometimes the update for CMS product fails with ERR-1003 (as seen using Get OperationOutcome) (intermittent issue). Resolved by the review and redesign of the update workflow used for Update Common Data and Update National Data. This has resolved issues based on the symptoms described in this bug.
UC08 Update product	API & NCA UI	UPD-10681		Update National data DCP/MRP/SRP - remains in status IN_PROGRESS without useful feedback (flavour #2). Resolved by the review and redesign of the update workflow used for Update Common Data and Update National Data. This has resolved issues based on the symptoms described in this bug.
UC08 Update product	API	UPD-10170		Update Common Data DCP/MRP/SRP - via API - there was a missing validation to check that the product version number in update bundle is the latest version for the product that is being used as a basis for the update. Instead the post was accepted and Get OperationOutcome remained with status of In-Progress. This issue has been resolved and there will now be a validation error if MedicinalProductDefinition.version does not have the same value as the current version.

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue that has been resolved
UC08 Update product	API & NCA UI	UPD-10676		Update Common data for DCP/MRP/SRP - sometimes not all CMS products were being updated.
UC08 Update product	API	UPD-9744		Update Registered Homeopathic: if POST a valid update payload there was a validation error of "Not able to validate product: MedicinalProductDefinition/ID".
UC09 Approve/Reject VNRA	NCA UI	UPD-10437		For CAP products only: • for VNRA variation codes A.1.a and C1 only • these are not automated for CAP products and the user will manually update the product in EMA's system on approval of the VNRA there is no automatic update of the product in UPD
UC09 Approve/Reject VNRA	NCA UI	UPD-10542		When viewing a VNRA for products under DCP/MRP/SRP, a user who is a CMS for the product for which the VNRA has been submitted had the Approve/reject checkboxes enabled. If they attempted to approve/reject they were not able to do so as the Submit button was not enabled. This issue has been resolved and the CMS does not have the Approve/reject check boxes enabled.
UC19 Nullify product	NCA UI	UPD-10323		When attempting to nullify a product under DCP/MRP/SRP that did not have national data populated there was an error message displayed and RMS was not able to nullify the product. "Marketing Authorisation Number must be provided either on product level or for all packages." The suggested workaround is no longer required. (first submit an Update National data and populate all mandatory national data including the Marketing authorisation number. Once the update has been successfully completed, view and select to edit the product for a second time and Nullify.)
UC28 View VNRA	NCA UI & MAH UI	UPD-10419		BR-020 When viewing a pending VNRA and there are other pending VNRA for a product in the submission being viewed, the link for the other VNRA did not work. When you clicked on the link, the submission ID in the URL was updated but the selected submission is not displayed. This issue has been resolved and the other VNRA is now displayed.

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue that has been resolved
UC34 Bulk Upload for Documents	NCA UI	UPD-10973		Advised submission was successful but there was no Notification, product had not been updated and Document had not been added to product. This issue has been resolved and now able to use Bulk Upload functionality.

2.3. New 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. Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue description
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
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" is not displayed

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
UC01 Create product UC08 Update product	NCA UI	UPD-11037	1.11 Attached Document	All procedures: error if add or update documents when creating or updating a product. The transation status as seen via GET OperationOutcome has an error; if product has been created there are no attached documents; no Notification is created. Recommendation is that documents are not added or updated in this release to ensure that create/update is successfully completed.
UC01 Create product UC08 Update product	NCA UI	UPD-11373	1.11.3 (Attached document) type	The drop-down list of document types should not contain an entry for "PI"
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
UC01 Create product	API & NCA UI	UPD-11212	2.12 Concerned member states	Create MRP/SRP: it should not be possible to select the RMS country also as a CMS

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
UC01 Create product UC08 Update product	API & NCA UI	UPD-11220	3.4 Withdrawal period	All procedure types: there should be Validation error if Withdrawal Period 3.4.2 does not have both numeric value and term code; and must have Tissue and Period if specifying Withdrawal period
UC01 Create product UC08 Update product	API & NCA UI	UPD-11250	4.3.2 Strength (quantitative composition)	All procedure types and both Chapter 2/Chapter 4 Legacy validation rules - missing specifications for strengths - zero should be valid value for both numerator or denominator
All UC	NCA UI & MAH UI	UPD-10994		Sometimes there is a "False" expiring session message when using the UI, even although the user has been continously active
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.

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
UC01 Create product	NCA UI	UPD-11265		Create MRP/SRP: the new CMS product does not have Common document added; and any document deleted by RMS as part of the create has 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 are no search results even when matching products do exist. Known to be an issue is '+'. '|' for example is OK.
UC01 Create product	NCA UI	UPD-11380		Create MRP: the National package description that existed in NP for RMS has been removed in the updated RMS MRP product
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 & 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	NCA UI	UPD-10987		When creating SRP, if the RMS removes the existing "QPPV location" and submits there should be a validation error. Instead the submission of the create is successful

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
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	NCA UI	UPD-10715		Existing Concerned Member States (CMS) are not always displayed or the same country is listed more than once; and doesn't contain a 'x' (or cross) to allow a CMS to be deleted. This issue only affects a few products
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

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UC03 Search product	NCA UI & MAH UI	UPD-11058		Only the first 10 Documents are listed in Search notification card and when View Product
UC03 Search product	NCA UI & MAH UI	UPD-11115		Sort of search results by alphabetical order of the product name does not work
UC04 Export	NCA UI & MAH UI	UPD-11199		There is an error when attempting to export all of the products matching the search criteria if the result set contains a large number of products. The known limit is approx. n products. Additional search criteria should be included so that the result set has fewer products and is able to be exported.
UC05 View product	NCA UI & MAH UI	UPD-11749		After viewing an historic version of a product, data values from that previous version may still be displayed on the UI if then select to view a later or current version of that product
UC05 View product	NCA UI & MAH UI	UPD-11058		Only the first 10 Documents are listed in Search notification card and when View Product
UC05 View product	NCA UI & MAH UI	UPD-10956		The strength information is not displayed next to the Susbtance within an Ingredient
UC05 View product	NCA UI	UPD-11474		When viewing product with procedure type SRP, sometime the "Edit National data" button is not displayed

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
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-10943		BR-066 The expected message is not being displayed in the Submission Comment field "MAH is invited to provide all appropriate information on the change(s) applied including the name and e-mail address of the contact person"
UC06 Submit VNRA	MAH UI	UPD-11411		For Variation A.1.a (update Product owner): should not be able to submit if proposed Marketing authorisation holder is empty at variation or product level. There is a validation error but it is not very meaningful. "{"resourceType":"OperationOutcome","issue":[{"severity":"error","code":"processing","diagnostics":"bdl-3: entry.request mandatory for batch/transaction/history, allowed for subscription-notification, otherwise prohibited [entry.all(request.exists() = ((%resource.type = 'batch') or (%resource.type = 'transaction') or (%resource.type = 'history'))) or (type = 'subscription-notification')]","location":["Bundle","Line 1, Col 37"]}]}"
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).

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
UC06 Submit VNRA	MAH UI	UPD-11483		If the same variation code is selected for a second time, that variation is removed from the submission
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-11256		When selecting products, a search by Product Owner doesn't work if used as criteria for second time
UC06 Submit VNRA	MAH UI	UPD-11206		When submitting VNRA, the Responsible authority is not populated with the organisation name and instead is showing "Object, Object" (regression issue)
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-10958		Download list of packages - not all CAP products are included in the csv file
UC07 Submit Volume of Sales	MAH UI	UPD-11433		Download list of Packages: "Pack size_Unit of Presentation" displays value of Manufactured item Unit of presentation instead of the Unit of presentation specified as part of the pack size in the package

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
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-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-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 & NCA UI	UPD-10974		Update Common Data DCP/MRP/SRP - Get OperationOutcome shows just one entry with status In-Progress; the RMS product has been updated and Notification has been created; but there is no update for any CMS products (intermittent issue)
UC08 Update product	API & NCA UI	UPD-11462		Update Common data DCP/MRP/SRP: a product with Authorisation Status of Surrendered is being updated. Common data updates should not be made to product with this status
UC08 Update product	NCA UI	UPD-11477		Update Common data DCP/MRP/SRP: any National package description on RMS product is removed by system in their updated product

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
UC08 Update product	API & NCA UI	UPD-11370		Update Common Data DCP/MRP/SRP: if a new package is added without Common package description with language of English there should be a validation error. Instead the update is accepted but the update transaction remains In-progress and never completes
UC08 Update product	API & NCA UI	UPD-11816		Update Common Data for product under DCP/MRP/SRP to delete an existing CMS: the system is incorrectly displaying a validation error
UC08 Update product	NCA UI	UPD-11191		Update National Data DCP/MRP/SRP - Additional national package descriptions are not saved in the updated product (regression issue)
UC08 Update product	API & NCA UI	UPD-11413		Update National Data DCP/MRP/SRP - Change in procedure type is not saved in 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-11371		Update Product (any procedure type): when adding or updating a Document the update is successfully submited. However, there is an error when processing the update; the product is not updated and there is no Notification

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-10992		NCA is not able to download the VneeS file. There is an error in the background. (intermittent issue)
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
UC09 Approve/Reject VNRA	NCA UI	UPD-11215		VNRA submission for a CAP product can be approved by any NCA and should only be possible for EMA or European Commission staff (regression issue)
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
UC18 Manage document	API	UPD-11362		When submit POST to Update an existing document the Response code is 500 Internal server error
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	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)

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
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
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-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-11063		When changing number of notifications to display on the page, the display of the most recent notifications is not always applied. A new search needs to be submitted after changing the number per page to ensure are viewing the most recent.
UC21 Manage Notifications	NCA UI & MAH UI	UPD-10993		When viewing notifications, the search results table may have two vertical scroll bars which creates a confusing user experience
UC25 Update Availability status	MAH UI	UPD-11208		Download packages for Availability Status - fails to download file with error (405 error seen in background - error seen in UAT) [regression]

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
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-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 is being updated. For this reason UC25 has been removed from this release
UC25 Update Availability status	MAH UI	UPD-10977		When submit file to update Availability Status the screen hangs and there is no error displayed to the user
UC28 View VNRA	MAH UI	UPD-11575		For products under DCP/MRP/SRP where there are unrelated MAH: MAH may be able to view a pending submission if the other unrelated MAH has submitted a variation for a product under that procedure. The unrelated MAH is not able to view the submission details or any of the products
UC28 View VNRA	NCA UI	UPD-10992		NCA is not able to download the VneeS file. There is an error in the background. (intermittent issue)
UC28 View VNRA	NCA UI	UPD-11823		Some NCA cannot view VNRA submission details. This issue does not affect all NCA. Potentially is the same issue as UPD-11604

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
UC28 View VNRA	NCA UI	UPD-11604		Some RMS & CMS are not able to view a submission for product under DCP/MRP/SRP. This issue does not affect all NCA
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	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
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-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-11193		Using Bulk Upload, unable to submit files with language = is (Iceland) and no (Norwegian)

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
UC01 Create product	API	UPD-10278		Create Parallel Trade: if the product that is referenced as either the Source or Destination product has Authorisation status that is not "Valid", there should be a validation error. Instead the payload is accepted but there is a 500 Internal server error
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 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.
UC05 View product	NCA UI & MAH UI	UPD-11589		Parallel Trade product: the Authorisation country should be displayed before the Date of Authorisation status change
UC05 View product	NCA UI & MAH UI	UPD-11588		Parallel Trade product: the product names for the Reference Product in the Source and Destination Member State are meant to be hyperlinks. Just the product name of the reference product is displayed, therefore as a workaround will need to copy the product name and then search products using that name in order to view the reference product

Use Case	Affects API and/or UI	Issue reference	Vet EUIG Chapter 2 section	Issue description
UC05 View product	NCA UI & MAH UI	UPD-11056		View Parallel Trade: when view older version of the product the page layout changes to that of the other procedure types. The page layout should always be the cut-down view for Parallel trade products.
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-11754		If submit an automated variation (A.1.a to update MAH) where product has been created using Legacy rules without PSMF populated, there will be a validation error and the VNRA submission will fail. As part of the submission process, the system is checking that an update to the product will be successful and for this check it is applying Chapter 2 rules. Instead the system should be applying Legacy Chapter 4 rules.
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
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

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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	No and not able to resolve as this is a FHIR	Report as substance

	Amoxicillin	500 mg/tablet				requirement to always have substance specified	
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.

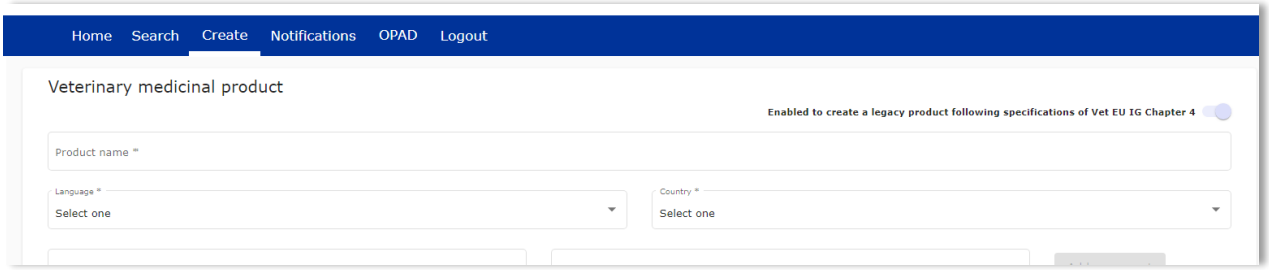
Supported browsers for the NCA UI are Chrome and Edge.

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 *Manage My Access* Reference guide: https://register-test.ema.europa.eu/identityiq/help/requestaccess.html
  - 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 *Manage My Access* Reference guide: https://register.ema.europa.eu/identityiq/help/requestaccess.html
- 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"
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

SPOR API Specification v2	API Manager
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

Value	Validation rules applied
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
Create SRP	srp-operation-outcome/cf7af9a9-b34d-4db9-a551-89d40c077306-SRP

POST	Content Location example showing post-operation and format of the operation-outcome-id
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 UPD_1.6.5-6_DCP_Legacy_C110_VetEUIG_AllData.XML

Procedure type	Validation rules	Example file
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_AllDa

		ta_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 response 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

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.	Sample XML of Get Everything response used as a starting point: UPD_1.5.1-0_EP311_UpdateProduct_GetEverything_version1.XML

	Edit the response e.g. - modify product name - add another ATC Vet code - add another ManufacturedItemDefinition including this into the existing PackagedProductDefinition	Update bundle prepared: UPD_1.5.1-0_EP311_UpdateProduct_RequestBundle.XML
Update product via API	POST Bundle with request headers to /upd/api/v1/national-data-bundle/ • "is_update=true" • "chapter4" = true or false for the validation rules to apply	
Check operation outcome	MSG_CREATED message expected containing Permanent identifier	
EP304 Get Product Full	Check the response for modifications	Sample XML of GET everything after update: UPD_1.5.1-0_EP311_UpdateProduct_GetEverything_version2.XML

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

EP304 Get Product Full	Prepare update bundle based on the response by updating Bundle.type to transaction and adding Bundle.entry.request.method for each resource. Edit the response 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
- The endpoints to use for the Document service have been clarified or corrected in this section with the full url. There has been some confusion whether to use v2 or v3. It is v2 to be used.

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) – functionality to download removed in this release due to UPD-11066 & UPD-10984; and to submit removed due

to UPD-10977 This functionality which had previously been released should not be used in 1.6.8 due to known issues. It is expected that this will be available for use in release 1.6.10.

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 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 EMA-Test once registration is complete to Request Access to one of the UPD MAH UI roles
    - select *Manage My Access* Reference guide: https://register-test.ema.europa.eu/identityiq/help/requestaccess.html
    - 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 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.

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6.3. 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 *Manage My Access* Reference guide: https://register.ema.europa.eu/identityiq/help/requestaccess.html
    - 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.

6.4. Change to csv file for Volume of Sales in this release

Bug UPD-7968 documents a change that has been made to the column heading for the Volume of Sales csv file. The existing column heading of "Month/Year" is changed to "Year-Month". The column heading will therefore match the format that the data is to be provided in and avoid any possible confusion. **This change was included in release 1.6.4** and applies now that Download Volume of Sales has been re-released.

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.

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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

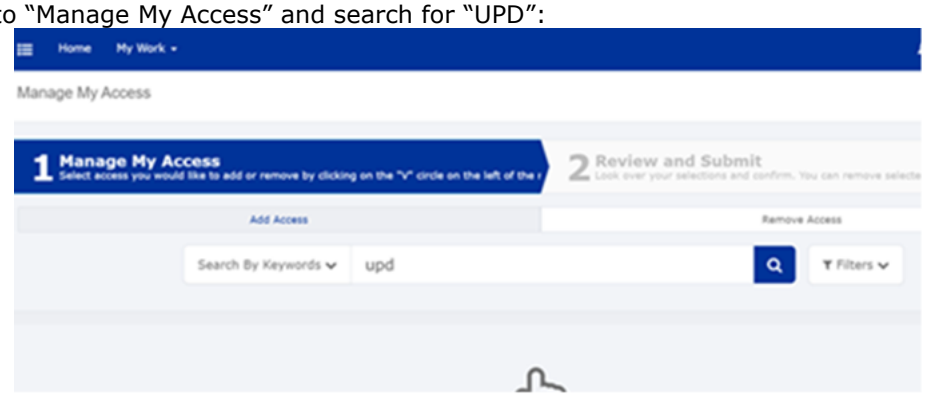
9. References

1. UPD 01.03 Registration Process for UPD API in Production (PDF document)
2. UPD 01.03 Registration Process for UPD API in UAT (PDF document)
3. SPOR API Specification V2 R5 (europa.eu) API specifications for SMS and PMS, based on FHIR
4. HL7 FHIR Release 5 Preview 2: the authoritative source for the FHIR specifications used by EMA to implement SMS and PMS API
5. Referentials Management System
6. Additional information on the Referentials Management System
7. Organisations Management System
8. Additional information on the Organisations Management System
9. UPD_1.6.5_ReleaseNotes_ExampleFilesForAPI (zip file)
10. Nomination letter for EAM CA Super user role

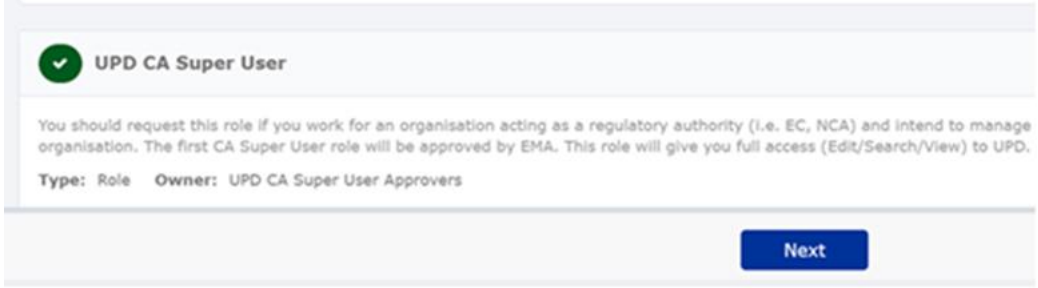
Annex 1: UPD-Specific Screenshots for Registration for an Account for the UI

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 "Manage My Access" and search for "UPD":

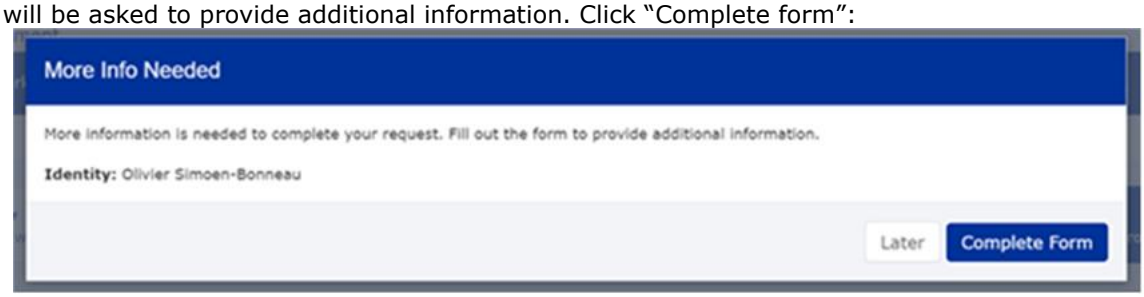


3. Select "UPD Super User"

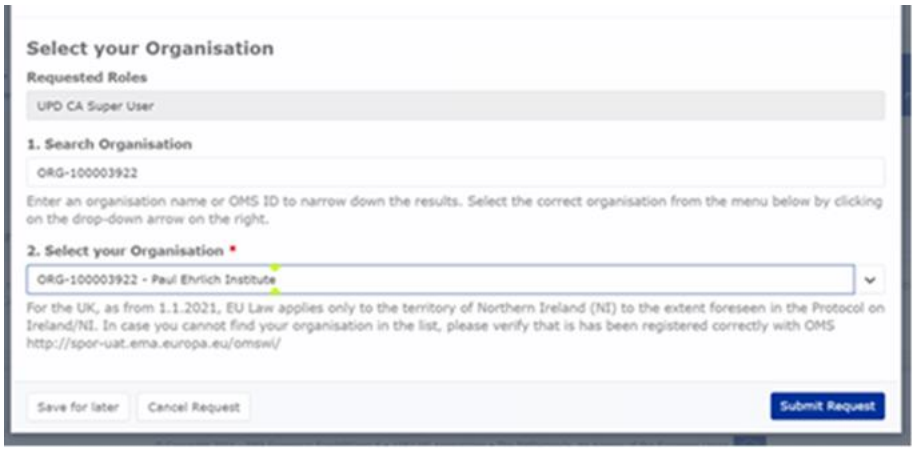


4.Upload a document (see paperclip button to the right) to show your affiliation to your organisation. For now, just upload any document (We'll need the formal document later and will also need this for production)

5. Click "Next"
4. Click "Submit"
5. You will be asked to provide additional information. Click "Complete form":



6. Search and Select your organisation:

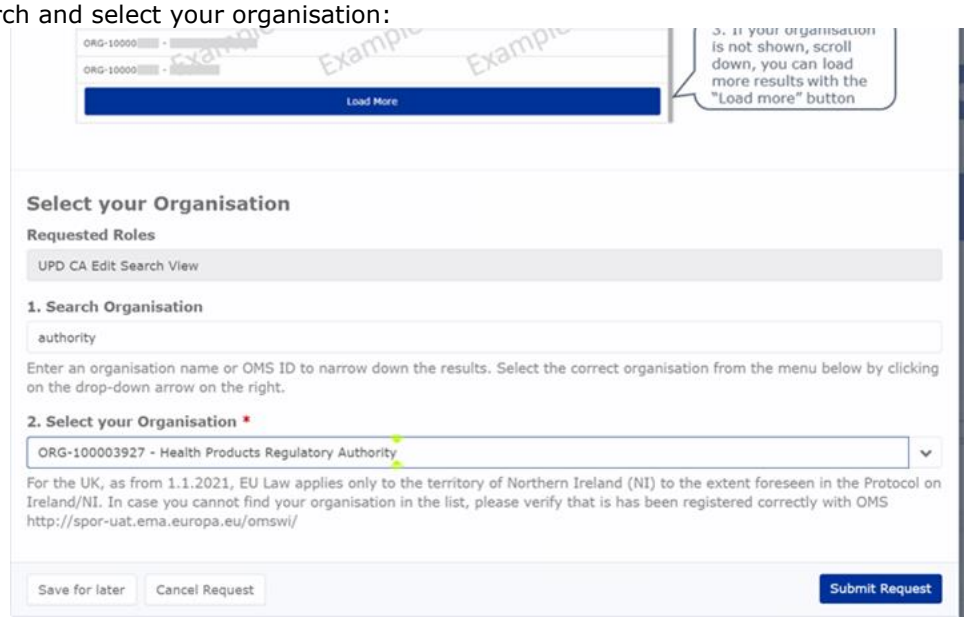


7. "Submit Request"

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 "Manage My Access" and search for "UPD"
3. Select "UPD CA Edit Search View" (read/write) or "UPD CA Search View" (read-only)

3. On the next screen, click "Submit"
4. On the next screen, click "Complete Form"
5. Search and select your organisation:



6. Click "Submit Request"
7. The super user of your organisation will then get a request to approve this.

9.3. Request the NCA 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 "Manage My Access" and search for "UPD":

3. Select "UPD CA Super User"

4.Upload the Nomination Letter (see paperclip button to the right). You can find the template below.

5. Click "Next"

4. Click "Submit"

5. You will be asked to provide additional information. Click "Complete form":

6. Search and Select your organisation. Contact @UPD-Registration if in doubt on which the correct organisation ID is for your organisation.

7. "Submit Request"

8. 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-4810	1.5 (Authorised) pharmaceutical form	Change to Authorised pharmaceutical form results in both old and new value in updated product if existing inline attribute id is not included in the request body
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
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" is not displayed
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
UC08 Update product	API	UPD-4796	1.10.1 QPPV Name	Change to QPPV name is not saved if existing inline attribute id is not included in the request body
UC08 Update product	API	UPD-4732	1.10.3 QPPV Location	Change to QPPV File location is not saved (whether existing inline attribute id is included or not in the request body)
UC08 Update product	API & NCA UI	UPD-7246	1.10.3 QPPV Location	Update Common Data - updates to QPPV Location is not saved in the updated version of the product and the old value remains
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
UC01 Create product UC08 Update product	NCA UI	UPD-10754	1.11 Attached Document	[Regression] When create or update product, not able to add 3 or more documents and get error message "specified Bloc already exists"
UC01 Create product UC08 Update product	NCA UI	UPD-11037	1.11 Attached Document	All procedures: error if add or update documents when creating or updating a product. The transaction status as seen via GET OperationOutcome has an error; if product has been created there are no attached documents; no Notification is created. Recommendation is that documents are not added or updated in this release to ensure that create/update is successfully completed.
UC03 Search product	NCA UI & MAH UI	UPD-9428	1.11 Attached Document	There is an error if attempt to view a document using the link on the Search notification card. Documents may be viewed from the View product screen.
UC08 Update product	API & NCA UI	UPD-9448	1.11 Attached Document	Delete of a document does not work, even although receive message back to the UI that submission of the update has been successful. When product is viewed, the deleted document remains. There is no API endpoint available to delete a document. The requirements and resolution for this option are being reviewed.

UC01 Create product UC08 Update product	NCA UI	UPD-11373	1.11.3 (Attached document) type	The drop-down list of document types should not contain an entry for "PI"
UC18 Manage document	API	UPD-9748	1.11.4 (Attached document) country	There is a validation error if attempt to populate country code for any of the three EEA countries: Iceland, Liechtenstein, Norway. These three countries should be valid and should not result in a validation 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 UC08 Update product	NCA UI	UPD-7654	1.11.8 (Attached document) title	UC01 Create MRP/SRP and UC08 Update for any procedure type: the document name for existing documents is displayed as HTML code. In this release you are not able to Update any documents. Submission of the update with the document name displayed like this is successful.
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	API	UPD-4733	1.9.4 (PSM) File location	Change to PSMF File location is not saved if existing inline attribute id is not included in the request body
UC08 Update product	API & NCA UI	UPD-7246	1.9.4 (PSM) File location	Update Common Data - updates to PSMF Location is not saved in the updated version of the product and the old value remains
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	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-8044	2.5 Authorisation status 2.6 Date of authorisation	Update National Data - there is missing validation if the following mandatory attributes are not populated when updating national Data for DCP/MRP/SRP

			status change 2.7 Marketing authorisation date	procedure product 2.5 Authorisation status 2.6 Date of authorisation status change 2.7 Marketing authorisation date
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
UC08 Update product	NCA UI	UPD-10582	2.8 Product owner	When updating national data, if the existing Product owner value is deleted and a new location not selected the submit of the update is accepted. This should be rejected with a validation error since Product owner is mandatory. However, the update will be successful and the existing Product owner value has been retained
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
UC08 Update product	API & NCA UI	UPD-7147	2.11 Reference member state	Update Common Data - the validation error when attempt to switch CMS of United Kingdom (Northern Ireland) to be the RMS is not clear enough that this is the issue
UC08 Update product	API & NCA UI	UPD-6986	2.11 Reference member state	Update Common Data - United Kingdom (Northern Ireland) is able to be the RMS. This should result in a validation error
UC01 Create product	API & NCA UI	UPD-11212	2.12 Concerned member states	Create MRP/SRP: it should not be possible to select the RMS country also as a CMS
UC01 Create product	API	UPD-8281	2.12 Concerned member states	Create SRP - should receive a validation error if add new CMS for country not in EEA
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	API & NCA UI	UPD-9068	3 Pharmaceutical Product	Update NP - Addition of multiple pharmaceutical products corrupts the product data and referenced Ingredient is not populated in the new

				Pharmaceutical product. This results in a validation error when attempt to submit a subsequent update
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
UC01 Create product UC08 Update product	API & NCA UI	UPD-11220	3.4 Withdrawal period	All procedure types: there should be Validation error if Withdrawal Period 3.4.2 does not have both numeric value and term code; and must have Tissue and Period if specifying Withdrawal period
UC01 Create product	NCA UI	UPD-6432	4.2 Manufacturer	Create MRP - existing Manufacturer of an Ingredient is not being retained when create is submitted. Manufacturer is no longer populated in the RMS product and is not populated in the new products for the CMS
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-11250	4.3.2 Strength (quantitative composition)	All procedure types and both Chapter 2/Chapter 4 Legacy validation rules - missing specifications for strengths - zero should be valid value for both numerator or denominator
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 & NCA UI	UPD-10392	4.3.3 Reference strength	When update National Procedure or Registered Homeopathic product that has Reference strength populated for an Ingredient, the updated product no longer contains any of the reference strength data
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
UC08 Update product	API	UPD-7198	5.3 Package identifier	UC08 Update SC2 NAP - API only - should reject update with valid error message if Package Identifier in PackageProductDefinition.identifier is missing
UC08 Update product	API	UPD-10537	5.3 Package identifier	UC08 When updating a product the user is able to change the Package Identifier and the new value provided is saved in the updated product. As

				this is a system generated identifier, any update to this value by the user should not be made
UC01 Create product	NCA UI	UPD-7511	5.6 Manufactured item (in Package)	Create SRP - when click on button to 'Edit Manufactured Item', the manufactured item is deleted. If update is required to Manufactured item this should be completed in two steps: first Create SRP; and then Update Common Data
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
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
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.
UC08 Update product	NCA UI	UPD-9505	5.7 Availability status	National procedure and Registered Homeopathic product: any updates to Availability status are not saved in the updated product. The product is updated with a new version, however the value input in the NCA UI is ignored, and the existing value is always overwritten with the value "Not marketed" and todays date.
UC08 Update product	NCA UI	UPD-7237	5.7 Availability status	Update DCP/MRP/SRP National data - it is not possible to add or update the Availability status or Availability status date for each package. The update will be successful without this populated.

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-10994	Sometimes there is a "False" expiring session message when using the UI, even although the user has been continually active
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	UPD-9731	Create DCP - duplicate products are being created for some CMS. This is an intermittent issue and we do not have any indication at this time how frequently this is occurring. Analysis is ongoing to identify the root cause and also to identify existing procedures that have been affected by this issue
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-11265	Create MRP/SRP: the new CMS product does not have Common document added; and any document deleted by RMS as part of the create has 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 are no search results even when matching products do exist. Known to be an issue is '+'. '|' for example is OK.
UC01 Create product	NCA UI	UPD-11380	Create MRP: the National package description that existed in NP for RMS has been removed in the updated RMS MRP product

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-10278	Create Parallel Trade: if the product that is referenced as either the Source or Destination product has Authorisation status that is not "Valid", there should be a validation error. Instead the payload is accepted but there is a 500 Internal server error
UC01 Create product	API & NCA UI	UPD-10719	Create SRP - transaction status remains IN PROGRESS when review using Get OperationOutcome
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	UPD-10207	Create SRP via API - Post of payload is accepted but Get OperationOutcome shows status of In-Progress and new CMS products not created
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	NCA UI	UPD-10603	The use of * to label mandatory fields is not always aligned with the Vet EU IG Chapters 2 and 4

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	NCA UI	UPD-10987	When creating SRP, if the RMS removes the existing "QPPV location" and submits there should be a validation error. Instead the submission of the create is successful
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	NCA UI	UPD-10715	Existing Concerned Member States (CMS) are not always displayed or the same country is listed more than once; and doesn't contain a 'x' (or cross) to allow a CMS to be deleted. This issue only affects a few products
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	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

UC08 Update product			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	API	UPD-9771	Create or Update via API: the request remains in status QUEUED for an abnormally long time. There has been an error during the processing of the request but this is not displayed when reviewing status with Get OperationOutcome and the status always remains as QUEUED.
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 UC08 Update 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.
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
UC03 Search product	NCA UI & MAH UI	UPD-8339	Inconsistencies found in Search functionality when paging through search results. This may only be an issue if Export option has been used and then select to navigate to the next page.
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-11058	Only the first 10 Documents are listed in Search notification card and when View Product
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-7970	User unable to Search products though after clearing cache it worked again (intermittent issue)
UC03 Search product	NCA UI & MAH UI	UPD-10463	When attempting to view the product card on the search results screen, for certain products UPD freezes and the product card is not populated. Therefore are not able to view those products, and the NCA is not able to update via NCA UI
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
UC04 Export	NCA UI & MAH UI	UPD-11199	There is an error when attempting to export all of the products matching the search criteria if the result set contains a large number of products. The known limit is approx. n products. Additional search criteria should be included so that the result set has fewer products and is able to be exported.
UC05 View product	NCA UI & MAH UI	UPD-11749	After viewing an historic version of a product, data values from that previous version may still be displayed on the UI if then select to view a later or current version of that product
UC05 View product	NCA UI & MAH UI	UPD-11058	Only the first 10 Documents are listed in Search notification card and when View Product
UC05 View product	NCA UI & MAH UI	UPD-11589	Parallel Trade product: the Authorisation country should be displayed before the Date of Authorisation status change
UC05 View product	NCA UI & MAH UI	UPD-11588	Parallel Trade product: the product names for the Reference Product in the Source and Destination Member State are meant to be hyperlinks. Just the product name of the reference product is displayed, therefore as a

			workaround will need to copy the product name and then search products using that name in order to view the reference 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-11056	View Parallel Trade: when view older version of the product the page layout changes to that of the other procedure types. The page layout should always be the cut-down view for Parallel trade products.
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-10689	After submitting a VNRA you can not select any menu item other that logout, therefore have to log out & log in to continue
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-10943	BR-066 The expected message is not being displayed in the Submission Comment field "MAH is invited to provide all appropriate information on the change(s) applied including the name and e-mail address of the contact person"
UC06 Submit VNRA	MAH UI	UPD-9076	CAP products may not have Authorisation County populated with value of EEA, and may display "European Union" or blank
UC06 Submit VNRA	MAH UI	UPD-8572	Change request: When submitting a VNRA, the conformance will be changed from Mandatory to Optional for the Vnees zip file. As a workaround for a VNRA that has no impact on UPD data or documents, the MAH may attach a zip file does not contain any document with a filename of empty.zip. The NCA will ignore any VNees of this name when approving/rejecting the VNRA.
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-11411	For Variation A.1.a (update Product owner): should not be able to submit if proposed Marketing authorisation holder is empty at variation or product level. There is a validation error but it is not very meaningful. "{"resourceType":"OperationOutcome","issue":[{"severity":"error","code":"processing","diagnostics":"bdl-3: entry.request mandatory for batch/transaction/history, allowed for subscription-notification, otherwise

			prohibited [entry.all(request.exists() = ((%resource.type = 'batch') or (%resource.type = 'transaction') or (%resource.type = 'history'))) or (type = 'subscription-notification')]","location":["Bundle","Line 1, Col 37"]}]}"
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-11754	If submit an automated variation (A.1.a to update MAH) where product has been created using Legacy rules without PSMF populated, there will be a validation error and the VNRA submission will fail. As part of the submission process, the system is checking that an update to the product will be successful and for this check it is applying Chapter 2 rules. Instead the system should be applying Legacy Chapter 4 rules.
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	MAH UI	UPD-11483	If the same variation code is selected for a second time, that variation is removed from the submission
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-11256	When selecting products, a search by Product Owner doesn't work if used as criteria for second time
UC06 Submit VNRA	MAH UI	UPD-11206	When submitting VNRA, the Responsible authority is not populated with the organisation name and instead is showing "Object, Object" (regression issue)

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-10958	Download list of packages - not all CAP products are included in the csv file
UC07 Submit Volume of Sales	MAH UI	UPD-11433	Download list of Packages: "Pack size_Unit of Presentation" displays value of Manufactured item Unit of presentation instead of the Unit of presentation specified as part of the pack size in the package
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 & 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-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-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	NCA UI	UPD-7011	UC08 Update SC2 SC3 SC5 - pop-up dialogs to confirm Update or to confirm Cancellation refer to "create" and not "update"
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 & NCA UI	UPD-10974	Update Common Data DCP/MRP/SRP - Get OperationOutcome shows just one entry with status In-Progress; the RMS product has been updated and Notification has been created; but there is no update for any CMS products (intermittent issue)
UC08 Update product	API & NCA UI	UPD-11462	Update Common data DCP/MRP/SRP: a product with Authorisation Status of Surrendered is being updated. Common data updates should not be made to product with this status
UC08 Update product	NCA UI	UPD-11477	Update Common data DCP/MRP/SRP: any National package description on RMS product is removed by system in their updated product
UC08 Update product	API & NCA UI	UPD-11370	Update Common Data DCP/MRP/SRP: if a new package is added without Common package description with language of English there should be a validation error. Instead the update is accepted but the update transaction remains In-progress and never completes
UC08 Update product	API & NCA UI	UPD-11816	Update Common Data for product under DCP/MRP/SRP to delete an existing CMS: the system is incorrectly displaying a validation error
UC08 Update product	NCA UI	UPD-11191	Update National Data DCP/MRP/SRP - Additional national package descriptions are not saved in the updated product (regression issue)
UC08 Update product	API & NCA UI	UPD-11413	Update National Data DCP/MRP/SRP - Change in procedure type is not saved in 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	NCA UI	UPD-11371	Update Product (any procedure type): when adding or updating a Document the update is successfully submitted. However, there is an error when processing the update; the product is not updated and there is no Notification
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 get a validation error. From the error message it is not clear what is missing. Validation error is:
			{
			"resourceType": "OperationOutcome",
			"issue": [{
			"severity": "error",
			"code": "business-rule",
			"diagnostics": "Not able to validate product: MedicinalProductDefinition/600000073934",
			"location": ["MedicinalProductDefinition"]
			}
			]
			}

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-10992	NCA is not able to download the VneeS file. There is an error in the background. (intermittent issue)
UC09 Approve/Reject VNRA	NCA UI	UPD-11475	UC09 Approve/Reject VNRA for DCP/MRP/SRP - Selecting the Approve/Reject checkbox for a specific product selects same checkbox for all other products
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
UC09 Approve/Reject VNRA	NCA UI	UPD-11215	VNRA submission for a CAP product can be approved by any NCA and should only be possible for EMA or European Commission staff (regression issue)
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

UC18 Manage document	API	UPD-11362	When submit POST to Update an existing document the Response code is 500 Internal server error
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	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-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-11063	When changing number of notifications to display on the page, the display of the most recent notifications is not always applied. A new search needs to be submitted after changing the number per page to ensure are viewing the most recent.
UC21 Manage Notifications	NCA UI & MAH UI	UPD-10993	When viewing notifications, the search results table may have two vertical scroll bars which creates a confusing user experience
UC24 Marketing authorisation status	MAH UI	UPD-10751	Availability status is not updated to "Not marketed" when Authorisation status updated to Suspended or Revoked
UC25 Update Availability status	MAH UI	UPD-10985	Download Availability Status files - not able to download for newly created Registered Homeopathic products (there is 500 Internal server error in the background)
UC25 Update Availability status	MAH UI	UPD-10604	Accented characters in the product name are not always handled correctly
UC25 Update Availability status	MAH UI	UPD-11006	Download for Availability Status - additional rows are incorrectly included in the downloaded csv for products under DCP/MRP/SRP. Instead of one row for the Authorisation country for that product, rows are also included for the other RMS and CMS countries. For this reason UC25 has been removed from this release
UC25 Update Availability status	MAH UI	UPD-11208	Download packages for Availability Status - fails to download file with error (405 error seen in background - error seen in UAT) [regression]
UC25 Update Availability status	MAH UI	UPD-10945	Download Product data for Availability Status - getting 'Resource not found(404)' error. This only appears to be an issue for some MAH and in particular those affiliated to many organisations (3+)
UC25 Update Availability status	MAH UI	UPD-8352	Error is not always clearly displayed if there is a failure in the submitted Update Availability status csv file
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	NCA UI & MAH UI	UPD-8200	Notification when MAH Updates Availability Status has the wrong Action. The notification has Action of "Update, Upload Document" and it should be "AvS submitted"
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 is being updated. For this reason UC25 has been removed from this release
UC25 Update Availability status	MAH UI	UPD-10684	Submission of Availability status remains In-progress and never completes to either Valid or Failed status. Further analysis is required to understand whether this only occurs when the update for one of the products included in the upload fails due to data quality issues or other bugs that prevent an update
UC25 Update Availability status	MAH UI	UPD-10105	The Authorisation status and Availability status are not correctly populated in the product search results table
UC25 Update Availability status	MAH UI	UPD-8198	The download csv file has incorrect Creation Date for product
UC25 Update Availability status	MAH UI	UPD-10418	When attempting to download file for availability status there is a limitation where only up to 200 products can be included in the file. After 200 products a limitation is reached in how the list of selected products is being prepared for the download.
UC25 Update Availability status	MAH UI	UPD-10417	When attempting to download file with 600+ products selected an error message is displayed "500 internal server error"
UC25 Update Availability status	MAH UI	UPD-10977	When submit file to update Availability Status the screen hangs and there is no error displayed to the user
UC28 View VNRA	MAH UI	UPD-11575	For products under DCP/MRP/SRP where there are unrelated MAH: MAH may be able to view a pending submission if the other unrelated MAH has

			submitted a variation for a product under that procedure. The unrelated MAH is not able to view the submission details or any of the products
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-10400	MAH has been advised that submission of VNRA was successful. However, sometime there is no Notification received and when View Submissions it is not listed (for either MAH or NCA)
UC28 View VNRA	NCA UI	UPD-10992	NCA is not able to download the VneeS file. There is an error in the background. (intermittent issue)
UC28 View VNRA	NCA UI	UPD-11823	Some NCA cannot view VNRA submission details. This issue does not affect all NCA. Potentially is the same issue as UPD-11604
UC28 View VNRA	NCA UI	UPD-11604	Some RMS & CMS are not able to view a submission for product under DCP/MRP/SRP. This issue does not affect all NCA
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-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
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-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 & MAH UI	UPD-10601	The action date for a notification of a bulk upload is displayed as MM/DD/YYY instead of dd/MM/YYYY
UC34 Bulk Upload for Documents	NCA UI	UPD-11193	Using Bulk Upload, unable to submit files with language = is (Iceland) and no (Norwegian)

Annex 3: Release Schedule

#	Environment	Date From	Date Till	Description
22	~~PROD~~	~~06 Jul 2022 18:00~~	~~08 Jul 2022~~	~~Upgrade of UPD to 1.6.6~~ Deployment was cancelled
23	~~UAT (TBC)~~	~~21 Jul 2022~~	~~22 Jul 2022~~	~~Upgrade of UPD to 1.6.7~~ Deployment was cancelled
24	~~PROD (TBC)~~	~~28 Jul 2022~~	~~29 Jul 2022~~	~~Upgrade of UPD to 1.6.7~~ Deployment was cancelled
25	UAT	~~11 Aug 2022~~ 10 Aug 2022	~~12 Aug 2022~~ 06 Sep 2022	Upgrade of UPD to 1.6.8
26	PROD	08 Sep 22	09 Sep 22	Upgrade of UPD to 1.6.8
27	UAT (TBC)	~~01 Sep 22~~ 14 Sep 22	~~02 Sep 22~~ 15 Sep 22	Upgrade of UPD to 1.6.9
28	~~PROD (TBC)~~	~~08 Sep 22~~	~~09 Sep 22~~	~~Upgrade of UPD to 1.6.9~~ Deployment cancelled

29	UAT (TBC)	22 Sep 22	23 Sep 22	Upgrade of UPD to 1.6.10
30	PROD (TBC)	29 Sep 22	30 Sep 22	Upgrade of UPD to 1.6.10