25 September 2023
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Q&A Q3 2023 System Demo

Date: 21/09/2023

Location: Online, 09:00 - 13:00 Amsterdam time (CET)

Link: Quarterly system demo – Q3 2023 | European Medicines Agency (europa.eu)

Disclaimer

This document contains a direct record of all questions asked through Slido.com during the System Demo and their written answers.

Questions not asked through Slido.com were not captured. Questions that did not receive written answers below where either responded to verbally or did not receive a response during the System Demo event. Questions asked in the "Plenary" room were generally taken as not addressing specific IT products and are not included below. Where it was clear that a question asked in the "Plenary" room referred to a specific IT product it was moved to the appropriate product room. Wherever this happened, if anywhere, this is indicated in the question text below.

In principle this document will not be updated. Generally, the order of questions answered follows the order in which they were prioritised by the audience using the "thumbs up" feature of Slido.com.

The responses represent the expert view of the development teams at the time of the System Demo and are not official statements by the European Medicines Agency nor its partners.

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Monitoring Value Stream

Critical Medical Device Shortage (CMDS)

Question	Reply
Who is responsible to complete the form - the MAH, or the Notified Body?	Question answered verbally during the demo
Why is it not possible to duplicate or create a template from a closed form?	Question answered verbally during the demo

European Shortages Monitoring Platform (ESMP)

Question	Reply
Will Marketing Status come from IRIS, or from PMS or be re-entered again?	Marketing status for Centrally authorised products is entered in IRIS and the ESMP will use that data. There will be no need to re-enter this information again. For Nationally authorised products in scope of particular crisis reporting the respective MAHs will need to enter information on the Marketing status through the ESMP.
SPOR data has no packaging information for many products (national authorizations). Do you need this as master data? Where will you get them from? From the bulk upload, potentially not in line with SPOR?	In relation to PMS product, please be informed that ESMP will use PMS data including packaging information. The submission of product data in PMS will follow the EU IG Chapter 2 therefore including master data as well as free text field (i.e. packaged medicinal product description).
For ESMP to be fully functional by Feb-2025 (as stated in the Regulation), is it then expected that PMS performs an enrichment of non-CAP data to reflect the packaging level that is needed for ESMP?	The functionalities need to be ready by Feb 2025, the list of Nationally authorised products for which data at the level of packages is needed will depend on a particular crisis (and therefore the scope of medicines monitored in/in anticipation of a particular crisis). For those medicines an enrichment of data will have to be done in order to have information available at the pack size.
If the integration with PMS is not planned to take place currently, will that be the case in the future? If it is, will the marketing status data be used when PMS is enriched with this data in the future?	Intergration with PMS is already taking place and the ESMP is ingesting data on Centrally authorised products which is available in PMS now. Information on Nationally authorised products will be added in the ESMP as soon as it's available in PMS.
Does the ESMP Q4 2023 forecast then expect the enrichment of NAPs in PMS (to reflect the package level) for NAPs?	The data on nationally authorised products will need to be enriched to allow for crisis reporting, however for the needs of the ESMP, that will be required only for a subset of products under close monitoring. Regardless, this would not be required in the following quarter and is something we will be looking into further along in the development stage, together with our PMS colleagues.
Does the ESMP Q4 2023 forecast then expect the enrichment of NAPs in PMS (to reflect the package level) for NAPs?	Yes, PMS will enable the product enrichment functionality to allow users to complete their product data accordingly. These information will be then re-used in other databases including the ESMP product scope.
Doesn't Regulation refer to a fully functional ESMP by Feb-2025?	Indeed it does. The Minimum Viable Product (according to the Agile principles) will have all the needed core functionalities. Based on the feedback received we will

Question	Reply
	then be releasing further iterations where we learn and prioritise what users want, improving the platform with each iteration.
What if the "bulk uploaded" data fields do NOT match the PMS product data? Will there be a comparison? Or are some data fields populated by bulk upload and some from PMS?	The data present in the bulk download template is coming from PMS. MAHs will be then performing the upload of all the required data for products defined by PMS identifiers, which will be used for validation.
For ESMP, I'm seeing Active Subtance (column 4) & Strength (col 5) in the landing page; how will ESMP display the products containing more active substances?	The data is presented as a single line per product, country of authorisation and pack size. Therefore if the product has multiple active substances, they will be concatenated and shown in a single field.
Will the Excel file for bulk upload be public?	Indeed, this data elements will be public and also explained in the User guides.
Marketing status data coming from IRIS for CAP products in ESMP. How it will be managed for other procedures e.g. MRP/DCP etc.?	Marketing status for Centrally authorised products is entered in IRIS and the ESMP will use that data. There will be no need to re-enter this information again. For Nationally authorised products (including MRP/DCP) in scope of particular crisis reporting the respective MAHs will need to enter information on the Marketing status through the ESMP.
Who is the responsible person for adding the alternative substances?	The person from the Industry performing the submission of data in the ESMP for shortages, and if needed supply and demand, will also need to insert the alternative substances/compositions.
When will a critical medicines list be published?	Lists of critical medicines we refer to in the context of the ESMP are decided on and published by the MSSG when there is a crisis and are crisis-specific.
When is the ESMP foreseen to be the mandatory method for submitting data? Is a transition period foreseen?	Once the features for MAH submission of data are available, we will be gradually releasing them to MAHs to use and test. After this a transition period will be in place and the appropriate communication activities will be done to ensure this is known in advance.
Can you explain the Norwegian graphs in the monitoring dashboard?	The information in the Demo is dummy data and does not reflect the current situation.

Research & Development Value Stream

Priority Medicines (PRIME)

Question	Reply
[No questions received for this product.]	

Real World Metadata Catalogues (RWMC)

Question	Reply
When will this new system be implemented?	The system with launch early 2024.
Does every uploaded study need to be reviewed by EMA? And how long can we expect the reviews to take?	All records inserted will be reviewed before publication. The validation will be to ensure content has been completed as per the guidance that will be provided and we aim to have it completed within few days. The validation process is being fine tuned at the moment.

Clinical Trial Navigator (CTN)

Question	Reply
How IMPs will be reflected in CT Protocols? Still using Development Products in Art57 or moving to SPOR-PMS? Especially if FHIR is used (based on ISO IDMP)?	*(replies to be added when available)*
Is it planed to include only data from CTIS or also older trials from EudraCT?	*(replies to be added when available)*
Research Study is at maturity level 0 so it is understandable that it doesn't meet many of your needs yet. Are you working with the relevant FHIR Work Group to advance the resource maturity through your use case?	*(replies to be added when available)*

Product Lifecycle Management Value Stream

Electronic Application Form (eAF)/PLM Portal

Question	Reply
I have unsolved issues with the helpdesk concerning eAF with high impact. These are stalled since months, and I have no solution. Where can I escalate? How can I get them solved? Whom to contact?	Thank you for sharing your concern. We're sorry to hear about it. As Kristiina mentioned during the demo, we will investigate the queues to see what may have happened to your issue.
If I add a package in PLM, will it also then reflect in Art 57 or must be separately submitted to the Art 57 database?	The existing process of submitting data to Art. 57 remains until all the processes have been transferred to the new tools.
Pack sizes/Packages are just 2 free text fields. When it is planned to have the packaging data enriched in PMS for eAF purposes?	It is planned that the added package will be available in the EMA Procedure Management systems where it will be approved as a part of the variation procedure and subsequently it will be included in PMS. Please note that this initial implementation is simply enabler to use the web eAF for variations adding new packages.
When will the EMA release concrete timelines for eAF variations for NAPs? Previous communication was September, is there a date?	The products available in the eAF are those from PMS. The internal eAF and PMS UAT testing has been performed over summer as planned. Both teams have analysed identified bugs and discussed the most appropriate solution to implement in order to fix the findings identified during this activity. PMS team has been coordinating the identification of bugs with various teams. In the light of the above, we are therefore re loading all data from SIAMED/XEVMPD to PMS UAT environment to re test (second rounds of UAT) whether the implemented solution have successfully fixed the bugs. Once we are certain that the bugs are fixed firm timelines will be communicated for the NAPs release in eAF.
Confidential data beyond what is now structured data and public product data is included in the xml message of the pdf from PLM. Will the confidential data (e.g. manufacturing/ers) be removed until it´s required for application validation?	Yes, we are currently working on a user story to remove the confidential data from the xml export until it can be used. Also, we are planning to show only the relevant confidential data, i.e. what is being changed and not all of it.
What actions should MAH do if they cannot locate product data in PLM?	The PLM Portal eAF currently only has Centrally Authorised Products available. If the CAP product is missing, please raise a ticket through the EMA ServiceNow tool and we will investigate why the product is not available.

Question	Reply
As MAH with NAP is it normal that I am not allowed yet to login in PLM ? I assume it will be possible during the scheduled UAT in Q1 2024	If you have already registered to use the PLM Portal eAF in production environment, you should be able to login and to use the 'create new application' function, however, you will not be able to select any products as the system doesn't yet contain any NAPs in production.
When can structured data changes be made using the form?	The structured data changes within the variation eAF form are linked to the Product UI edit pages development. For edit pages and related enabler epics the timelines will be published at a later stage. It is important that the data can be pushed from the eAF back to PMS before we integrate the edit pages into the variation form.
When cloning an application, what is cloned? All data of the eAF, or some fields only? If some, which ones?	When cloning, the applicant 2 different options, the user can clone the full application if they keep the same MAH. In this case all fields and all products will be cloned. Only coordinators who are linked to editing the form will need to be added again. If the MAH is changed, then products need to be added and this means that also further work is required for example in the Present and Proposed section where packages and scopes are linked. Once this feature becomes available in production we will provide user guidance and instructional video on how to use it in different scenarios.
Will the "Add Package" feature be applicable for NAPs as well? In France/Italy where MA Number is at package, or everywhere?	When the NAPs become available in the form, this feature can be used for applications in those NCAs where it is relevant. You could compare this current implementation to the ability of writing the details of new package in the section 2 of the interactive pdf variation form. Regulatory and national requirements are not changed as a result of the implementation of this feature.
Why is it impossible to finalize present and proposed section even when all the data is filled?	Is this an issue you are experiencing in the production environment at this moment? If yes, could you please provide further details (application number and screenshots as well as description of the incident) in a service desk ticket and we will investigate this as soon as possible.
When are homeopathic medicines available in UAT and/or Production enviroment ?	We are still discussing the extension of the eAF to homeopathic medicines internally. Once we have further information, we will provide information through the usual channels.
Regarding homeopathic medicines, the eAF forms are also used for both national registrations and authorisation; depending on the national authority, this is also desired and it also has advantages for the manufacturers.	We are indeed looking into adding the homeopathic products into the web based eAF.

Question	Reply
Will there be an option in the PLM portal to create an eAF manually? Are these scenarios taken into account?	The web eAF is currently inherently linked into SPOR system. Currently there is no plan to implement version that is not connected to PMS, however, if there was a strong enough business case to create a version that is edited with free text for certain business case/certain types of products ...
Guidance available on YouTube [e.g. eAF webforms videos like How to fill in the “Procedural Information”, "Additional information", "Finalization" sections etc.] whether this links will remain unchanged in the future?	Updated guidance will be published as and when improvements, fixes and new features are implemented. We will regularly review the available guidance and out of date guidance will be removed to avoid confusion.

Product Management Services

Question	Reply
Will we have IDs (PMSID, MPID, PCID, PHPID) generated in stages? How will the MAH get the IDs once they are generated or changed? At the time of PLM enforcement, will these IDs be mandatory and checked when validating the application?	Please be informed that PMS related identifiers are automatically generated by the PMS system at the time authorised medicinal products are available in the relevant database. Additionally, please be aware that at the moment PMS (due to the initial data load as explained in EU IG Chapter 7) can generate PMS IDs only. The PCID is not available as several defining element for the automatic generation are not available as value from the source systems (SIAMED/XEVMPD), please refer to EU IG Chapter 7 page 19. This will be achievable when the functionality for performing the data enrichment will be implemented and available for use. Relating to the the PHPID this is not implemented in the EU IG and PMS DM. In relation to the last part of the question (validation of the application) please submit the question to the attention of eAF team.
During the IRIS Webinar 15 Sept: one slide displays what is eligible for IRIS incl.'Submission xEVMPD data'. How does this align with PMS as it becomes the single source of truth for Art 57 in the future? What is the target operating model?	We'll double check that slide. The target operating model has not changed, PMS will become the single source of truth for Article 57 in the future.
When should we expect to have the PLM PMS business process/operating model	I understand you are asking about the roadmap towards the operating model for product lifecycle management. We are looking for an opportunity to share and expose the roadmap and its drivers in a webinar later this year. Please keep an eye on the EMA events page.
Migration is always complex, and the scope of IDMP is larger than XEVMPD. This means that enrichment is required	Enrichments and other processes will be made available through the user interface and API. In order to release all these processes, different enablers should be in place and

Question	Reply
(cf. discussions on ESMP). By when would that be allowed? By when to be complete? How? Product UI? APIs?	therefore, we are not in a position now to define accurate timelines for this. Please, keep an eye to our webinars, system demos, and news to be up to date.
When should we expect the Nationally Authorised products to start appearing in PLM?	All authorised medicinal products including Nationally Authorised products will be available in PLM as soon as the rounds of UATs involving PMS, IRIS and eAF are fully successful. Please refer to the previous question for getting updates on PMS UAT rounds.
As the NPs are released in PMS, how will the operating model/business process work on its maintenance? As additional NP data (not in xEVMPD) is submitted to PMS, how will this additional data be governed?	Please be informed that the PMS team is writing EU IG Chapter 9 to explain how data are maintained in PMS.
Confidential data beyond what is now structured data and public product data is included in the xml message of the pdf from PLM. Will the confidential data (e.g. manufacturing/ers) be removed until it´s required for application validation?	However this is an eAF related question. Please submit this question to the attention of eAF team who are the most appropriate experts to reply.
What do the terms "Not Marketed," "never Marketed," "No Data Provided," and "Temporarily unavailable" mean? According to the RMS definition Not marketed is The product has a marketing authorization granted and is not placed on the market.	Please note that the EMA PMS and ESMP teams are reviewing the definition of the available terms in the RMS list named Marketing Status (RMS id 100000072052). Additionally, the terms without description will be updated with the relevant information to clarify the use and applicability of each term. Please note that this activity is ongoing and as soon as the text is approved it will be released in the relevant RMS list.
(authorization status) Valid-Renewed term in IDMP is intended an MA that is being renewed, meanwhile in xEVMPD the term is used when following a MA renewal the MA number has changed. What is the advice meanwhile the 2 DB are coexisting?	Please be informed that the definition of the RMS term Valid - Renewed/Varied (RMS ID: 200000017708) in the RMS list Regulatory Entitlement Status (RMS ID 100000072049) reflects such situation. Thus the is 1:1 match with the XEVMPD terms. In RMS portal you can see the relevant mapping points to the XEVMPD term (8) Valid – Renewed/Varied Marketing Authorisation.
Have corrective actions been implemented related to issues: 1. multi lingual member states (NP) product migration from xEVMPD to PMS (business rules used for the migration) 2. security in accessing Transferred MA (non-CAP) products in PMs	Yes, you can find more details in the presentation.
Is the internal PMS UAT testing completed? Can we have a quick feedback?	Yes, the internal PMS UAT testing has been performed over summer as planned. The PMS team has analysed the identified bugs and discussed the most appropriate solution

Question	Reply
	to implement in order to fix the findings identified during this activity. PMS team has performed such activity in coordination also with Core Team to streamline the identification of bugs. In the light of the above, we are therefore re loading all data from SIAMED/XEVMPD to PMS UAT environment to re test (second rounds of UAT) whether the implemented solution have successfully fixed the bugs.
Is there an update on the availability of the remaining 'mandatory' functionality to support non-CAPs products/WS procedures? e.g. an update on the development progress with all the key mandatory functionality required for a complete UAT?	Could you please provide me more details on the PMS mandatory activity mentioned above so I can provide you the most adequate answer.
Is it the new grouping criteria for Belgium included in Chapter 7 of the EU IG?	Yes, the new grouping criteria for Belgium are reported in the updated version of the EU IG Chapter 7. Please note that this is not yet available on te EMA website. The publication date will be announced as soon as possible.
Can we anticipate more fields in future versions? IG version 3.0 or 2.1.2	The PMS team in coordination with NPO and SMEs are updating the EU IG Chapter 2 to indeed reflect the latest updates in terms of additional fields agreed to be added to the PMS data model. Overall there will be updates to: a) the references of the manufacturer and manufacturing business operation data across the entire PMS data model; b) to additional information to be provided in relation to the legal status of supply when medicinal products are not subject to medical prescription Please note that the date for the next EU IG release are not yet available however we will announce it as soon as possible and in advance.
When the EU IG Chapter 3 new version is planned?	Please be informed that the publication of EU IG chapter 3 is linked to the answer provided in question "When should we expect to have the PLM PMS business process/operating model".
Will distinct PMSIDs be defined for the same CAP Medicinal Product for EU VS EEA countries (IS/NO/LI) re MA 2.6, 2.10.x?	Yes, in case of CAP product 4 records will have to be created in PMS and therefore 4 different ID will be generated by the system. Please refer to EU IG chapter 2 section named Submission of medicinal products authorised in EEA countries outside the EU.

Product User Interface

Question	Reply
What is the strategy for the data enrichment? Will there be a phased	The strategy for enrichments, corrections, etc are still under discussion. Once it has been agreed with the

Question	Reply
approach and what are the highest priority data areas for consideration? When will this be communicated if the development is not yet at the right maturity level?	Network we will provide this information. It is important to understand that in order to allow users to submit data to PMS, other enablers should be in place.
I appreciate the effort being placed on improved UI and ability to Edit, but I already hold and maintain most of this data in my RIMS. When will a two-way API be available so we can transmit data straight from my RIMS?	The PMS API is also being developed. EMA has always said that both API and User Interface will be made available so users can decide which way they prefer to access their data. Therefore, as soon as user interface read access is granted, PMS API read access will be granted as well.
Is the dependency with ESMP (package level for all products) recognized by the Product UI Team to support the enrichment before Feb-2025?	Yes, PMS team is aware of the dependency ESMP has with our data. Discussions are happening to understand how we can support them.
When will the 'export' (download) functionality release take place? Is it planned for the first phase?	Product UI will allow different levels of export as well as different formats (XML, Excel). The download functionality will be release in different phases: from simple reports to more complex ones.
What about "corrections/3rd ACK" on NAPs. If a 3rdACk requests a correction for a data field, are NCAs copying/synchronizing this change into their national databases? How shall this quality process look like for MRP/DCP/NAPs?	Changes performed as part of the data quality review in XEVMPD will be propagated to PMS. There is no strategy yet in place to know how NCAs will use PMS data and we will discuss with them this process. More information will be provided in due course.
If the Edit feature is linked to the process, when the process will be discussed within the Product Team? PMS Team or PLM Team?	Process will be discussed from Q4 2023 onwards. They will also be discussed with the eAF team in case the process impacts them. SMEs will also be involved in these discussions.
When a PMS API will be available for testing?	In Q4 an alpha UAT will be performed by the SMEs. We will discuss if a beta UAT is needed in Q1 2024 based on the feedback we will receive from them.
In the search field, is the MA Holder field a free text or a pick list?	Free text field
I understand that subparts of the product data are possible to export. Is a full product being exportable in an xml or Excel format? Or maybe my search results that I looked for in the UI?	There will be a possibility to export all data from your products. We will try to demo the export of product data in XML format next quarter. For Excel export we are still working on it.
Has all of the functionality to support NAPs and worksharing procedures been developed or still in progress? Is there an update on when UAT including all functionality will take place?	This question should be raised to the eAF team. PMS is not responsible of worksharing or any other variation process.

Question	Reply
Is it confirmed that once PMS is enriched, the submissions via Art57 will stop?	No, this is not confirmed yet. EMA is discussing this internally. More information will be provided in due course.
As MAH, I presume I can only see the products of my organization, once the UI is available for industry users?!	Users will be able to see a list of all products authorised. Nevertheless, full data set will only be available for products of your organisation.
If the Medicinal Product Full Name changes, will the PMS ID and MPID change?	PMS ID is a stable ID that will never change. MPID on the other hand might change if the defining elements change. You can find more information on that in Chapter 2 of the EU IG.
When will you start discussing proposed process with SMEs? Will it be 2024? If so should we assume that it won't actually be possible to submit until 2025, 2026?	We will start discussing the processes in Q4 2023 with SMEs. Nevertheless, timelines to implement those processes are not clear yet. More information on timelines will be provided in due course.
For search criteria MA Holder, all the products filtered are specific to that MAH or I can see the products of other organisations as well?	Users will be able to see a list of all products authorised. Nevertheless, full data set will only be available for products of your organisation.
For 'Manufacturers' information, what will be the source of truth considered for CAPS and NAPS?	As stated in Chapter 7 of the EU IG, manufacturers are migrated from SIAMED II for CAPs. For NAPs, we don't have this information and it will have to be provided by MAHs once the capability to submit data to PMS is available.
[Moved from eAF room] Will the added package be available in the PMS UI for enrichment ?	It is planned that the added package will be available in the Regulatory Procedure Management system where it will be approved as a part of the variation procedure and subsequently it will be included in PMS. Please note that this initial implementation is simply enabler to use the web eAF for variations adding new packages.
When searching for terms in edit screens, is it possible to enter the term-id? In the demo only term names/values were used.	Yes, IDs can also be used to look for terms.

Electronic Product Information (ePI)

Question	Reply
Is there any intention to include hyperlinks between ePI and PMS records?	For the moment, the ePI display web pages from the pilot will not have hyperlinks. However, in future epics, optimal display of ePI including relevant links will be considered.

Question	Reply
There was an ePI FHIR standard recently published by the HL7 Vulcan project. Is this something which can be used to generate an EU ePI?	The ePI standard published by HL7 Vulcan is indeed fully aligned with the EU ePI Common Standard. In order to create a compliant EU ePI we would suggest following the ePI type 1 guide as defined in the HL7/Vulcan Implementation guide: http://hl7.org/fhir/uv/emedicinal-product-info/STU1/steps-to-create-epi1.html
Is a FHIR profile (StructureDefinition) also published for the ePI Composition?	We have not published a FHIR profile for ePI composition. However, in the coming weeks there will be live ePIs (including the composition resource) available via the API.

Regulatory Procedure Management (RPM)

Question	Reply
Can you clarify the interdependencies between RPM (using IRIS) and PMS as the process for CAPs will trigger use of two platforms: first the PLM platform (eAF, PMS data enrichment, etc.) and then IRIS for tracking cases for CAPs.	PLM is for CAPS and NAPS forms and PMS data enrichment as you say. IRIS is for procedures in EMA's remit, CAPs and EMA managed procedures. However they have a shared dataverse.
Is RPM restricted to CAPs only or will it be rolled-out to NAps as well?	RPM on IRIS is for EMA managed procedures. That will as a rule be CAPs.
In the 15-Sep Webinar, we saw that IRIS would include a feature for XEVMPD - could you expand the intention? Replacement of EV Web or something else?	We noted the same question came up in the PMS demo. We'll double check that slide and clarify.
Are there plans to grant roles in IRIS for procedure management on a product (I.e. marketing authorisation) basis, and not on a case basis? A similar request has also been raised for UPD and web-based eAF	We are indeed planning (on a longer term) to provide possibility for the MAH to update the product contacts direcly in IRIS. Currently, the default case contact will be the case manager and the product contact. A case manager will be able to add case managers/contributors and change the case. Other suggestions are welcome. Have a nice day!
Will there be a course/webinar for NCA assessors? This demo was quite technical and not comprehensible for assessors confronted with it first time for variations in the very near future.	Yes there certainly will be training for NCA staff that will need to work with IRIS. Please note that the system demo is not intended as training, so I appreciate it appears unsuited in that regard! The system demo is a development progress report and an opportunity to get your feedback.

Question	Reply
not having to manage contributors and managers for each and every case, but once for a given product: can we record this as a new business requirement?	Currently, the default case contact will be the case manager and the product contact. A case manager will be able to add case managers/contributors and change the case contact. Is not mandatory to manage the contributors/managers/contact, but is possible, in case additional/different users need to be involved. Currently we are limited to one contact as per the Agency`s rules. If the requirement is to have more default managers/contributors as default, to all cases of a given product, we can look into this in the future when we will be working on managing product contacts/roles in IRIS.
Background to 3rd [previous] question: not having to manage contributors and managers for each and every case, but once for a given product	In practice both should be possible. Currently the default case contact will be the case manager and the product contact. A case manager will be able to add case managers/contributors and change the case.

Union Product Database (UPD)

Question	Reply
Can you demo the VoS and VNRA API?	The VoS and VNRA API will not be DEMO during today's session. Information related to the use of those two functionalities can be found in the release notes of the version 1.6.34.
Are draft products shared within the same NCA or are they personal, linked to the login?	Dear user, the user must have the necessary affiliation to match the draft product's organisation identifier.
Validate VoS csv upload file: is this in the UPD itself or somewhere else. If somewhere else, is the link given in chapter 7?	The link to the test environment for VoS can be found in the latest version of the release notes for version 1.6.34.
Can the link to the validation platform for VoS ba added to chapter 7 please	The link will be added to Chapter 7 at the next revision. For your convenience the link is https://upd-portal-prod-validation.azurewebsites.net/updwebui/home

Improved regulatory user journey for EMA stakeholders

Question	Reply
[No questions received for this product.]	