27 June 2025
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Q&A Q2 2025 System Demo

Date: 26 June 2025

Location: Online, 09:00 - 10:45 Amsterdam time (CEST)

Link: https://www.ema.europa.eu/en/events/quarterly-system-demo-q2-2025

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.

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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Product Lifecycle Management Value Stream

You can subscribe to the quarterly PLM Highlights Newsletter at
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Product Management Services (PMS)

Question	**Reply**
Are we still supposed to verify data in PMS and request correction via the service desk? I have a ticket from the service desk (stalled since 29 days) which says that I have to wait until I have full write access to PMS.	*Question answered verbally during the demo*
why tickets takes so long to get a reply? I have tickets of 3 months ago	*Question answered verbally during the demo*
Can you provide an update on PMS API UAT with software vendors and outcome.	*Question answered verbally during the demo*
For the new transfer: was the validation on EMAs side adapted. Until now as MAH and QPPV are connected and you retrieve an error if the QPPV is not matching/allowed for the MAH. Will this error message no longer be received from now?	After confirming with the XEVMPD team, I can confirm that there shouldn't be any error appearing. Please, make sure you are updating the MAH field, not the HQ field. It is the HQ field the one that is connected to the QPPV, not the MAH one.
Add-on: QPPV is mandatory and therefore I cannot remove it. Only for "Nullify" this is possible, but not for "invalidate". Any mandatory field that is missing is also retrieving an error.	*Question answered verbally during the demo*
For “Manufacturing operation start date”, as per Chapter 2 (v 2.3), the conformance of Manufacturing operation start date is “Conditional”, however in PUI, the Manufacturer operation start date conformance is mandatory. Please clarify?	We will review the Chapter and PUI. Thank you
Is possible to see XI products in PMS, if our MAH is in GB? We don't see our XI products for our organization (location in London), ticket opened 4 months ago (RITM[redacted]) with no results. Can you help Marcus?	I have replied to the ticket. Please check SNOW there is an issue with the Organisation

Question	Reply
We have hundreds of duplications in PMS caused by inconsistent "correction" done by EMA in XEVMPD in the past. The ticket INC[redacted] was opened 4 months ago with no results. How you solve this problem in general?	*Question answered verbally during the demo*
What is the est. date for the bulk update for manufacturers to be active?	The target date for the bulk update to be active is in September subject to confirmation following UAT completion.
When will the updated chapters 2 and 3 be available, especially the information related to the enrichment of manufacturers & MBO?	*Question answered verbally during the demo*
When the section 1 of the smpc has 2 lines with line break, is the FULL NAME migrated from XEVMPD in PMS will have 2 lines or 1 line in PMS?	*Question answered verbally during the demo*
Will the PMS public api contain prescription/non-prescription status? AESGP is currently hosting a free tool for this purpose, but maintaining accuracy of the data is a constant challenge. We'd love to be able to integrate the API	*Question answered verbally during the demo*
Is there any news on when Chapters II and III will be updated with the latest information shared during the last Q&A?	*Question answered verbally during the demo*
When there is change from PMS status from nullified to Active. Will the product version changes?	Yes, product version change any time there is a change to the values in the PMS entity.
Please note that the FAQ document is no longer visible in the PMS Guidance Document.	PMS Q&A document is accessible via PLM portal or PMS webpage: https://www.ema.europa.eu/en/documents/other/product-management-service-pms-frequently-asked-questions-faqs_en.pdf
How do you foresee to manage the "pending national phase" in future when XEVMPD is decommissioned?	
match and merge: withdrawn prod. (DCP) are linked to valid natiaonal auth. products because of the same medicinal product name and other match and merge criteria. So DCP and national auth. data is mixed in PMS	A ticket should be raised in SNOW with the provision of details of the case so the team can investigate.

Question	Reply
Package description button is missing. How could we enter packaging data if is button is missing?	Package description button does not exist in PUI. MAHs can update the package description in XEVMPD directly and structure the pack size data in PUI afterwards.
Is it necessary to use the previous PRD data for all new PRD creations, or can we reference it only in the specific packset /PRD where applicable?	You can just use the previous EV Code in the specific packsets. If after the transfer a new package is authorised, it doesn't need to reflect the previous EV Code. The authorisation status should be valid, and the previous EV Code section should be empty. Nevertheless, the rest of the data should be the same as the other packages, so the pack can be created in the correct Medicinal Product in PMS.
Is the decision for the umbrella terms for manufacturing activity will be reverted or do we have to give granular terms as we have already worked on it and it may be difficult to now change all the terms. Please kindly suggest.	*Question answered verbally during the demo*
When is the new short name feature coming in? As a lot of umbrella terms have been removed. Are we expected to go back and recategorize old MF we have already worked on?	*Question answered verbally during the demo*
There will be another update of ULCM list before end 2025?	PMS team is not responsible to update ULCM list. This question should be raised as ticket to the Shortages team.

Product user interface (PUI)

Question	Reply
Is there any extension expected for the enrichment timelines for ESMP products with the existing issues in PMS UI to select relevant Regulatory agency and High-level terms selection?	This discussion will happen with the ESMP colleagues. The Regulatory Agency is no longer mandatory, we have implemented this change. Additionally, high level terms will be available in Q3.
Dynamic exports take 2 days to sync with PUI, lately.	We will review this comment. We have not experienced any issue with the performance of the dynamic reports.
When will the Regulator LOC-ID list be published?	We are working on it and gathering the information. Still one NCA has not provided the information. As soon as it is available we will publish it. It will happen in Q3.
In spite of being unable to demo the one new BI report, can you kindly share the details regarding which additional PMS structured data elements will be allowed for QC review against xEVMPD/internal RIM data?	*Question answered verbally during the demo*

Question	Reply
Why do we have to go back to Change Detail section instead of saving in the medicinal product section? --> save, refresh etc is greyed out	*Question answered verbally during the demo*
If the user have any of the role for PLM eAF, will the same user be able to view PMS UI products as well? If yes, will they have only read only access as industry user?	*Question answered verbally during the demo*
We did complete the PUI Edit for Manufacturer and CR status is completed(more than 15 days back). Still we dont see that data in PMS front end, but if i download the XML we see that data added. Is it the issue?	Please, open a ticket so we can check what is the issue. It seems that IRIS has not taken the update and therefore is not available in the UI. We need the PMS ID so we can ask IRIS to run the integration.
Is there a possibility to connect subsidiary org ID/LOC ID with parent company org ID so that the Marketing authorisation with parent company MAH in PMS are visible to subsidiary users who have requested access via subsidiary org ID?	Access in PMS works based on ORG IDs. Therefore, if you want to have access to multiple ORG IDs, you just need to request the access in IAM. As soon as the access is approved by the Admin user, you will be able to see all the products for all the ORG IDs you have access to without the need to change your credentials.
Is there a sample xml structure of a full product for API integration.	Yes, please access it via the PMS webpage under Implementation guide section/ Chapter 6: you will find a zip folder with examples.
Several of our tickets for PMS-PUI EMA closed with argument that this is a known issue. However, they were not addressed in the published list of known issues. How can those known issues be included in the published list more frequently?	We are updating the PMS Q&A document periodically. If we have replied that the issue on your products is known, it should be reflected in the Q&A document. I could check with the ticket number what is the issue on your product and make sure it is in the Q&A document.
What is defined numbers of products that can be included in Bulk i.e., 10/50/100? so system works without any issues.	The number of products that can be updated is undefined, you can update as many products as you need. Please just be aware that the more products you update within the same enrichment process the more time PUI may need to reflect the changes to all products ie. 500/1000 etc products
When I will see my manufacturers and packagings as a new version in PMS? Change request completed 16 days ago, however last version is still since 28.1.2025. Pms id [redacted]. Is there some Ema validation waiting for?	EMA does not validate the data submitted in PMS at the moment. If you are experiencing issues please open an incident ticket so the team can investigate. Please detail as much as you can.

Question	Reply
When we have change in name of the Organization A to B but ORG ID remain same, should we change operation start date post variation approval or Implementation date post name change?	No, the manufacturer still remains the same organisation and the operation start date is still the same.
When will the package size and package type edit button be available again? Currently this button is not available.	The edit button to update the pack size is available in PUI under package medicinal product section. However the enrichment functionality is not open to update the package type field. If you are experiencing some issue pleas open an incident ticket.
Why MedDRA version numbers in PMS are not reflecting same as XEVMPD? MedDRA code are fine its just MedDRA version are different in PMS	This is explained in the PMS Q&A document. The version in RMS explains when the term was updated. If the MedDRA code didn't changed with the new version of MedDRA, then, the version in RMS will not change. It is OK and no tickets should be opened for this.
Will the former MAH be able to see the Invalidated EVcode with nullified status with this new implementation in PMS?	Only through the PMS API. Not in the UI as nullified packs or products are not shown in the UI.
Will there be a seperate Kick-Off meeting for the PUI Bulk UAT (30.06.?)	The invitation was sent yesterday (25 June) to confirmed testers.

Electronic application form (eAF)

Question	Reply
In the latest slides from PMS info day, it seems that the mandatory use for the variation eAF is foreseen at end of 2026, is that correct?	Currently this indeed seems the most likely timeline for mandatory use. This is mainly dependencies related to other products, namely to PMS product data and the use of organisational data in the dataverse layer. After these issues are fully unblocked we will be able to start the final (UAT) user confirmation to test and confirm that there are no scenario's where the user would be blocked and we can move to decommission the interactive pdf eAF.
For variations for non-CAPS, is a signature in the exported eAF mandatory for the different national agencys? Or do national agencies accept the form without signature?	CMDh is currently reviewing and updating the list of national requirements including the signature requirements. In most cases the signature requirement can be fulfilled by including certified digital signature in the Finalised eAF which contains the integrity stamp or by including the signature in the cover letter or copy of the form in the dossier.
With the new 'Structured Changes' functionality in PLM eAF, it means that there is no need to maintain or enrich the data in PMS separately as the submitted data will be reflecting in the	Replied live. Please, follow the current process to update XEVMPD if the variation is impacting XEVMPD data.

Question	Reply
PMS after variation is approved? Please clarify	
As updates in PMS on NAPs are still ongoing, what is recommendation if data in PMS are not suitable for usage and update via ticket might take some time.	Unfortunately in some of those cases we need to ask you to use the interactive pdf eAF.
CAP: What number to be used for field “Variation Procedure Number” in the eAF? The EU variation procedure number as before ie EMEA/H/C/00xx/ or the new IRIS Case Number? And if IRIS number: by when will variation + eAF guidance updated?	For EU variations that have been allocated the IRIS variation number starting with EMA/VR/xx the IRIS numbering should be used. If for any reason you would need to provide an updated application form for a variation that has started using the old variation numbering, this number should be used. For WS and IG variations, you should include the new high level number from IRIS as provided by EMA. We will update the eAF guidance to reflect this as soon as possible.
How many non-CAP applications have been submitted to the NCAs? Just showing the created applications does not mean that they were finally submitted in eCTD.	This is indeed true, currently, as the non-CAP applications are not submitted to the EMA, we do not have an easy way to find out how many forms have been received by the NCA. A questionnaire was launched to the NCAs to enquire this, however, as we are still in early days of use for non-CAPs, at the time of the questionnaire, the NCAs weren't in a position to confirm numbers.
We are not able to select our UK products in web eAF, because our UK products (sending to XEVMPD with XI code) are not availabble for us in PMS (however they are in public pool). Our MAH is in London (GB). Do other MAHs have the same issue?	Please, raise a ticket in SNOW with some EV Codes that you can't see so we can see what the issue is. If products are submitted to XEMVPD, they are migrated to PMS.
We have an issue with an MAH in PMS, the issue blocks the access to the data, and is already managed from PMS team since months. Will this be an issue if we want to use the eAF?	If you have an issue in PMS UI, it is most likely that this same issue will impact the eAF. Please feel free to 'test' the access in PLM Portal, however, this is one of our most 'critical' known issues and eAF relies on platform level changes in many cases to have these issues fixed.
What is the use of the field "MRP varation no"?	This is the field that is displayed in section 2 of the exported pdf eAF. In this section you can indicate the MRP/DCP number for each medicinal product as per relevant for your application type. We received a request from an NCA to allow inclusion of the MRP number also for the nationally authorised products and this is now also available. Please note that this field is different from the 'high-level' procedure number in the Procedural information section (displayed in section 1 of the exported pdf).
Is it planned to also get Annual Update as selection under type of application?	As per our understanding which was confirmed by the relevant business colleagues, the annual updates should be

Question	Reply
	submitted as Type IA variations and it is not foreseen that any changes are needed in the eAF.
I remember on the eAF roadmap slide there was a mention of a 6 month transition timeline. Would this 6 months start from the date of strongly recommended use of web base eAF? or is this not correct?	The 6 months transitional period will start from an announcement following a successful UAT. It does not start from the Strongly Recommended Use. The strongly recommended use means that all applicants should aim to use the new eAF where possible, i.e. there are no technical blocking issues for the use of the PLM Portal use. This will help all users/stakeholders to familiarise with the new form and also gives us extremely valuable feedback on any issues that might be found. The earlier we identify any issues/need for change/improvement, the better as this will give us guarantee that we will not find blocking issues during the final UAT or during the transitional period.
In the PMS info slides (pg 155), MRP number was not mentioned as one of the PMS data element needed for eAF. Is that correct or was it a typo in the slides?	MRP number is an important part of the procedural data and it can also help to find the product in the PLM Portal. In case the MRP number is missing, the product can still be selected and the eAF allows to indicate the number using the MRP number field functionality. If your MRP/DCP number is missing in PMS, please, first make sure the data is correctly reported in XEVMPD and if this is the case, please, raise a ticket so we can check where the issue is.
Is 'MRP number' critical for eAF use? In tabular list 'PMS data needed for eAF' PMS InfoDay slide 155/201 it was unlisted. It would be very helpful you help us understanding, informing internal PMS Data Quality KPI specific to eAF. Thankyou	MRP number is an important part of the procedural data and it can also help to find the product in the PLM Portal. In case the MRP number is missing, the product can still be selected and the eAF allows to indicate the number using the MRP number field functionality. If your MRP/DCP number is missing in PMS, please, first make sure the data is correctly reported in XEVMPD and if this is the case, please, raise a ticket so we can check where the issue is.
There are differences in the order of presents and proposed between the EAF Web Form and the PDF Export. Could you please explain ? Is it an issue ?	Ideally there should be no difference between the UI and the pdf export. If this is happening, it may indeed be regression bug. We will investigate and would appreciate if you could raise a service desk ticket with the application ID so that we can check from the back end what has happened. Normally, the sections should appear in the order they were added/edited and the user can order the sections as needed.

Electronic product information (ePI)

Question	Reply
We already have a QR code on our boxes to permit users to scan it and see the leaflet in their phones for example. What would be the difference between our current Qr leaflet and ePI?	Please view the reflection paper, where this topic is outlined: https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/product-information-requirements/electronic-product-information-epi#patient-access-to-epi-public-consultation-75438
When do you expect to communicate the roadmap/timelines for voluntary use of ePI for products?	As soon as we have reasonable certainty on the outcomes of the ongoing development, testing and consultation, we will communicate timelines.
In addition to the timeline, when will the requested data/information also be published?	More information on what data/information the questioner is referring to is needed to reply to the question.
Is there any limitation foreseen to the ePI app, if the applicant does not have an API access to PLM (no internal tool connected to PLM with FHIR messages, use only of the PUI for example) ?	There is currently no API for ePI upload. ePI is created/uploaded via the PLM portal user interface. Any applicant can create ePI and submit it to the regulator using the editor and tooling provided at the PLM portal.
The QR codes in use today are widespread - has there been any reports or evidence of confusion in codes? We have not seen that in use - patients are scanning the QR for access.	It would be particularly useful to know more about examples, data or testing you may have or be aware of on user experience with these QR codes. Please provide this and any other feedback you may have to the Reflection paper: https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/product-information-requirements/electronic-product-information-epi#patient-access-to-epi-public-consultation-75438
What vendors are involved in testing?	We are not publishing UAT participant organisation names.
will there also be an app with the PL of all medicines for patients?	Please view the reflection paper, where this topic is outlined: https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/product-information-requirements/electronic-product-information-epi#patient-access-to-epi-public-consultation-75438