Product Management Service (PMS) Product UI training (access & navigation) (3 June 2024) – Questions & Answers

Date: 03/06/2024

Location: Online, 10:00 – 11:30 Amsterdam time (CEST)

Link: https://www.ema.europa.eu/en/events/product-management-service-pms-info-day

Disclaimer

This document contains a direct record of questions asked & answered through Slido.com during the Product Management Service (PMS) Product UI training (access & navigation).

In principle this document will not be updated.

The responses represent the expert view of the Product team at the time of the webinar and are not official statements by the European Medicines Agency nor its partners.

Acronym key and glossary terms

API	Application Programming Interface
CAP	Centrally Authorised Product
eAF	electronic Application Form
EMA	European Medicines Agency
ePI	electronic Product Information
ESMP	European Shortages Monitoring Platform
EU	European Union
EU IG	EU IDMP Implementation Guide (EU IG)
EV Code	EudraVigilance Code
IAM	Identity Access Management
MAH	Marketing Authorisation Holder
MPID	Medicinal Product Identifier
NAP	Nationally Authorised Product
NCA	National Competent Authority
OMS	Organisation Management Service
PMS	Product Management Service
PLM	Product Lifecycle Management
PUI	Product Management Service
RMS	Referentials Management System
SIAMED	Sistema de Información Automatizada sobre Medicamentos
SPOR	Substance, Product, Organisation and Referential
UAT	User Acceptance Testing
UPD	Union Product Database
XCOMP	external compliance testing environment
XEVMPD	Extended EudraVigilance medicinal product dictionary

#	Question	Reply
1	Are PowerBI reports available for download of CAPs data from PMS PUI?	Yes, they are. This was explained during this webinar as well.
2	Are PRD EV Codes loaded by EMA for CAPs and available for read-only from PMS PUI?	Yes, if the match and merge is performed the EV codes are available in the Product UI.
3	Are there any time estimations of when will MAHs be required to enrich the PMS data to fill the currently empty data fields?	The Agency will announce in due time when the enrichment functionality will be made available for users. For the moment, as announced at the PMS info day meeting held on 16 April, the edit functionality will be made available at the end of 2024 for a limited

		subset of PMS information to support ESMP project. Overall, the entire edit process will be released in a phased approach.
4	As a service provider, IAM states we should request the PUI Industry User. However, if we need full management for the product data, why is not Qualified user more suitable? What kind of data is restricted to us?	This is just a suggestion. If you need to manage all the data from your customer, you should request the Qualified Industry role. The Admin role of the organisation will receive the request and check if you really need access to all the data (Qualified user) or to only public data (normal user). For the moment, the data difference is on manufacturers and strength of the excipients as this is the only confidential data we have.
5	As MAHs that only have NAPs are currently not able to see any product in PMS, will there also be "Q&A clinics" after the go-live for NAPs in July?	Yes, as soon as new data is released in PUI, we will provide new webinars/trainings and Q&A sessions.
6	Can it be explained in detail what the differences will be between the PMS PUI and API from a data view/write access perspective as well as functionalities? A comparison table would be helpful.	Thank you for this suggestion. We have taken it onboard.
7	Could there be one location where info on downtime and new functionality for all EMA systems, like PMS, IRIS and UPD is published?	This information is shown in the Service Desk Portal. This way, users wanting to raise a ticket due to these downtimes would know that this is a known issue.
8	Currently, in XEVMPD pack sizes are included in a text field as a description. If we have to submit all the pack sizes at this level, will they be transposed in structured fields in PMS? What is the aim of this enrichment now?	CAPs pack sizes are already in PMS with structure data but not NAPs. The idea is that with XEVMPD you will be providing the pack size as such and with the enrichment you will provide the structure data of the pack size.
9	Did we understand correct that the pack size has to maintained in the PMS UI and not in XEVMPD? From when will editing be possible?	No, products data are to be submitted in XEVMPD. PUI edit functionality is not yet available.
10	Do we still have to fill in XEVMPD for new medicinal products (or updates through variations) and how these data are transferred to PLM?	Please, check chapter 9 of the EU IG where the deltas from XEVMPD to PMS are explained. In a nutshell, XEVMPD must be maintained and any change performed in XEVMPD will be propagated to PMS.
11	Do you expect MAHs to use controlled vocabulary for Pack Sizes in XEVMPD without having a drop-down menu to add this information?	No. In XEVMPD it is still free text. It is advisable for MAHs to use simple terms and text that can be used to identify the pack size. However, controlled vocabulary (IDs) cannot be used.
12	Does the delay on API availability also postpone the submission of data on ESMP?	No. Access to the read API does not interfere with the submission of data to XEVMPD. Therefore, the delay on the access to the PMS API does not impact the submission of data to XEVMPD.
13	eAF Coordinator\ Manager can request PUI User role?	By default, the eAF Manager/Coordinator users already have PUI access. However, there is no default access to the reports. To access the reports, you will need to request additional PUI user role.
14	Is the access to the reports available already?	If you have eAF access, you automatically have access to PUI to view your product(s) details, but without the access to the reports. In order to access the reports, you will need to request further PUI access as detailed in the

		guidance.
15	What type of access should be requested for read-only access?	As explained during the webinar, only read access is granted for the moment. They type of access requested depends on the data that they should see. Normal Industry role cannot see confidential data (manufacturers for example) while Qualified Industry user can access all the data.
16	For an organisation, can there be Admin user with a Qualified user role and user with Qualified user role alone?	Yes, this is possible.
17	For those data missing from SIAMED, should we raise a ticket to enrich? For those missing in XEVMPD, we can update directly there.	If there is data missing, it is because we do not have it either in SIAMED or in XEVMPD. For example, storage conditions. There is no field in XEVMPD to populate this information and there is no field in SIAMED either. Therefore, this enrichment will be done in PMS in the future.
18	For UPD, an Azure interface was available for testing API calls. Will this be the case as well for PMS API?	We are discussing with the SMEs what is needed to test and connect to the PMS API so we can deliver all these documents/ information.
19	How is possible to enter into SIAMED?	It is not possible for external users to access and edit SIAMED. If MAHs notice that product information in one of the data element originating from SIAMED (as per EU IG Chapter 7) is not correct, they should submit a ticket in EMA Service Desk. In the training presentation, we have explained which category to select in Service DESK.
20	How is possible to verify who is the IRIS/PLM Industry Admin for a Company if it already exists?	You can check within your Organisation or submit a question in EMA Service Desk to seek this information.
21	How many people can register as PUI user qualifier in a single MAH?	There is no limit of users.
22	How to request access for PMS API? Are these API's available in both test and prod environments? What are the roles available to read API? Is it possible to extend the roles to existing users available for other integration like RMS?	PMS API access is not available yet. For the moment, we only have a production environment but we are also working to provide access to a test environment. There will be no roles for the API, just one role to request access. MAHs will need to manage how they grant access to the API to the rest of the users.
23	How should be packages added in PMS?	As for the moment, only CAPs from PMS can be seen and data for CAPs is coming from SIAMED you need to log a ticket with the information so we can check which pack sizes are missing and why.
24	Can a user with PLM eAF coordinator role request Qualified User role?	Yes.
25	Can EMA account credentials be used to request access to IRIS/PLM Industry Admin?	You will have access to the data under the organisation you are registered.
26	If an eAF Coordinator\Manager requests a User Role and not a Qualifier Role, which would be the impacts on the permissions for the eAF management in PLM?	The impact is only on PUI access: with the eAF coordinator/ manager role, you will be accessing the full PUI data set without restrictions established for the Industry level 2b - regular users as per EU IG Chapter 5. There is no impact of eAF use. This is because eAF coordinator/manager privileges are equal to PUI Qualified role privileges.

27	Can Admin for several ORG ID visualse products for all ORGs or the access will be segregated per ORG?	If you are Admin, you cannot access product data. Admin role is for granting/revoking other PMS users' requests. To read PMS data, you need to request the regular role or Qualified role. If you have this role for multiple ORG ID in PUI, you can log in with your credentials and you will see all the products directly in PUI. To facilitate the view, you can filter them per ORG ID, if needed.
28	If MAHs update the OMS or other SPOR sections, will this also be transferred to XEVMPD by EMA?	No. XEVMPD needs to be updated and maintained separately from SPOR.
29	If XEVMPD data is updated, what is the frequency of data sync between latest version of XEVMPD and its load into PMS? Last updated date in PMS UI refers to last product data load from XEVMPD or product load from SIAMED?	Data from SIAMED/XEVMPD are loaded to PMS live. In case of huge queues, this might occur in max 15 min.
30	Is an update of Chapter 3.II XEVPRM User Guidance planned regarding the enrichment process of pack sizes in XEVMPD? E.g. Update of the first product entry with the first pack size. Duplication and submit inserts of the following pack sizes?	Yes, this document update is in progress and will be published as soon as possible. Nevertheless, take into account that in Chapter 3.II this is already explained. The udpdate will just improve the already available explanation.
31	Is it possible to adapt the columns in the "Report section" of PMS PUI as desired? Or is this pre-defined?	The reports are pre-defined.
32	Is the package description coming from SIAMED or XEVMPD for the data in PMS?	For CAPs, it is coming from SIAMED and for NAPs is coming from XEVMPD.
33	Is there a specific requirement to request the Industry user or Industry Qualified user?	The differences between the two roles is that the Qualified one can have access to confidential data. Therefore, it depends what data you should access. The Admin role will approve the request anyway, checking if the user should have access to this data or not.
34	Could it be possible to have a different label for the info that are not present at all in SIAMED\XEVMPD from those that are missing and need to be enriched in those systems? This would help Companies quality check.	The elements having "-" (for data elements) and "Data are not available in SIAMED/XEVMPD and not loaded. Users are encouraged to provide it when applicable." (for full data class) mean that no data were available from SIAMED/XEVMPD for migration purposes. We will highlight in future the elements that will be due to enrichment.
35	Is it possible to have a legend on the PLM Portal of i.e. for MAH, PUI…?	We will investigate this and improve the system if possible.
36	Could you please give the PMS Data Model in higher resolution in readable version?	We will try to include improved graphic. Please note you can also find this diagram in Chapter 2 of the EU IG.
37	Must existing eAF contributors request PMS roles, or are PMS roles assigned automatically?	eAF contributor user should request it their PMS role to access PUI properly.
38	Could you please confirm the level of access needed to access Reports?	Both Industry users and Qualified Industry users have access to the reports. The normal user will not get access to manufacturers information as it is confidential.
39	Regarding parallel imports (covered by issued national licences) - will these	Only if they are included in XEVMPD.

	be entered into and shown in the system?	
40	Should the MAH request the PMS API access now or wait until July?	The role is not available in IAM, so you would not be able to request access yet. We will make it visible in IAM as soon as the access can be granted.
41	Is creating as many entries in XEVMPD as pack sizes only a recommendation, meaning that there is no need to have 1 EV Code per pack size?	It is a recommendation for most of your portfolio, but it is a requirement for those products under the union list of critical medicines. This was explained during the PMS Info Day. You can find the information on the event page.
42	Some colleagues will only work with the eAFs in PLM. Will they also need a PMS PUI role in order to create/ edit eAFs? Or is that optional?	No, PMS PUI roles are only used to read product data via PUI.
43	If a user is unable to view PMS PUI, is there any specific date to read data on SPOR PMS?	From Friday 31st of May, the PMS PUI is available. You need to request a role first in IAM to access PUI.
44	Can existing EMA user account used to connect via API to RMS and OMS also be used to connect via API to PMS?	No. The access to the PMS API shall be registered using a different role in IAM. Moreover, PMS API access is not granted for the moment.
45	What do you mean when you refer to structured pack size data?	It is the quantity and the units of measurement. The reference is Section 4.4 of Chapter 2 of the EU IG. One thing is the pack size as an entity, another is the package description (free text) and another is structure data of the pack size (saying 2 vials or 14 tablets with controlled vocabulary).
46	What does mean data carrier identifier?	Please check Chapter 2 of the EU IG.
47	What happens when MAHs do not update the data in XEVMPD? Will the eAF not work? Will there be other consequences?	Pharmacovigilance legislation states in Art. 57 that MAHs are responsible of submitting medicinal product data to XEVMPD and keep it up to date. In case this data is not updated, eAF might not get the products or, when submitting, the variation might be rejected by competent authorities. Moreover, XEVMPD is monitored by EMA. In case discrepancies are found, these are shared with the NCAs PV inspectors that will deal with the MAH.
48	What is the data carrier?	Please, check Ch 2 of the EU IG.
49	When is the EMA planning to populate MPIDs? What is the cardinality between PRD EV Code and the PMS ID, and between PMS ID and MPID? E.g., 1 PMS ID may correspond to 3 PRD EV codes	For the moment, we are not in a position to create and maintain MPDIs and that is why we are still working on this. 1 PMS ID might be related to multiple EV Codes (the PMS ID is one per medicinal product but the EV Code is one per pack size) 1 PMS ID is linked to 1 MPID but the MPID can change. Please, check chapter 2 of the EU IG for more information related to the IDs.
50	When is the next release planned for PMS API?	As explained in the webinar, it is expected by beginning of July 2024.
51	When requesting the Admin role for a company which for example has more than 40 MAHs, do you need to request the Admin role per MAH in IAM one by one or is there an easier way?	No, in IAM, users can request multiple roles in one single request.
52	When should the MAH start splitting	MAHs can start doing this now. The most important ones

	the pack sizes in XEVMPD?	are the ones related to products under the union list of critical medicines.
53	Why is the box for ingredients blue for the PhProduct, but partially blue for Manufactured Item? At least, for solid forms it is identical and should be referenced and not entered again, as this might cause issues due to manual errors.	The color is the same. It is repeated because these are different sections. Ingredients will be the same, but they have to be in both section as might be used by different processes.
54	Will all the 180 fields be compulsory to be completed?	The approach to get all the PMS data elements is under discussion. It will be an iterative approach and for the moment only manufacturers data are requested for NAPs.
55	Will External Organisation Admin role be capable to approve IRIS/PLM Admin role or this is changed now?	IRIS/PLM Admin role can approve/reject any IRIS/PLM Admin role request for the same organisation.
56	Will NCA users having an eAF Competent Authority User role have problems to access the PMS UI properly when having at same time a PUI NCA User role (as it was the case during UAT testing)? Should these users remove their eAF role?	No, this issue has been fixed. NCA can see all data in PUI with the PUI NCA user roles even when having the eAF Competent Authority user role.
57	Will PMS also be accessible through the SPOR UI interface?	PMS is only accessible though the PLM Portal. We might create a link in the SPOR UI to the PLM Portal.
58	Will PMS UI also contain NAPs at a later point in time or will PMS API (from July on) be the only interface to view NAPs data?	Product UI will contain NAPs in July 2024.
59	Will the API Connection be the only way to read data about our NAPs? Will it be possibile to check data about NAPs from PUI?	NAPs will be made available in the product UI in July 2024.
60	Will the External Organisation Administrator role be able to approve requests for the first API Industry roles? Or does the first role always have to be approved by EMA? Are current Admins for eAF/ePI/IRIS able to approve new users?	External Organisation Administrator role can approve any API Industry roles. EMA only approves the very first Admin role for that Organisation. Yes, current admins for eAF/ePI/IRIS are able to approve new user.
61	Will there be training videos published by the EMA for the Qualified User (like for xEVMPD)? Will there be an EMA certification to obtain? If so, when will it be available?	As explained in EU IG chapter 1 no certification is needed to read PMS data. More training material will be released in future and every Thursday, from 15:00 to 15:30 until the end of the end of the month we will be hosting Q&A clinic session.
62	Will this training be available as a recording? Will additional training materials be available e.g. via YouTube?	Yes, the recording is usually made available in a week time on EMA YouTube Channel and event web page. There will also be more recordings made available as training material. Additionally, we will also host Q&A Clinics on Product Management Service (PMS) Product User Interface meeting every Thursday from 15:00-15:30, until the end of June 2024.
63	Will we have access to a test environment for PMS (like we have XCOMP for XEVMPD)?	Not for the view capability. As soon as we open the edit capability, we will have UAT environment so users can practice and test the system.
64	Will you kindly confirm whether users	Product UI does not follow the EV structure. Therefore,

	must register for the PMS roles under 1) as many times as the amount of MAH ORGs associated to their products in PMS and 2) there is no generic mother ORG similar to EudraVigilance mother ORG account?	you need to register to as many ORG IDs you need to have access to. Please, take into account the registration is done at ORG ID, not LOC ID.
65	Will you kindly remind when the NAPs (non-CAPs) data will be made available for read-only from the PMS PUI?	As it will be explained in this meeting, the idea is to include them in July 2024.
66	Will you kindly share when is the EMA planning the release of the updated EU IG Chapter 2?	EU IG Chapter 2 update is planned in July 2024.