Product Management Service (PMS) – Frequently Asked Questions (FAQs)

8 August 2024

Disclaimer

This document contains a direct record of frequently asked questions (FAQs) through Slido.com during the Product Management Service (PMS) events over past months, complementing them. The FAQs are split per topic.

Nothing in this document should be taken as an explicit commitment on behalf of the EMA, or the PMS product team. The responses represent the expert view of the Product team and are not official statements by the European Medicines Agency nor its partners.

For convenience, many technical terms are explained in the table of abbreviations at the beginning of this document.

For general inquiries, please contact the PMS team via the EMA Service Desk. For questions or comments around the content of this FAQ document, please raise a ticket via the EMA Service Desk.

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Acronym key and glossary terms

API	Application Programming Interface
CAP	Centrally Authorised Product
eAF	Electronic Application Form
EMA	European Medicines Agency
ESMP	European Shortage Monitoring Platform
EU IG	EU IDMP Implementation Guide
GTIN	Global Trade Item Number
IAM	EMA Account Management system
MAH	Marketing Authorisation Holder
MFL	Master File Location
MPID	Medicinal Product Identifier
NCA	National Competent Authority
Non-CAP	Non – Centrally Authorised Product
OMS	Organisation Management Service
ORG-ID	Organisation Identifier
PhPID	Pharmaceutical Medicinal Product Identifier
PCID	Packaged Medicinal Product Identifier
PLM	Product Lifecycle Management
PMS	Product Management System
PSMF	Pharmacovigilance System Master File

PUI	Product User Interface
Q&A	Question and Answer
QPPV	Qualified Pharmacovigilance Person
RMS	Referentials Management Service
SMS	Substance Management Service
SPOR	Substance, Product, Organisation, Referentials
XEVMPD	eXtended EudraVigilance Medicinal Product Dictionary
XEVPRM	eXtended EudraVigilance Medicinal Product Report Message

1. Access and registration

1.1. Can I access PMS PUI or PMS API with the same user and password as for RMS, OMS and SMS?

To access the systems, you need to request a dedicated PMS PUI or API role, either as a regular user or a qualified user from the industry. The RMS, OMS and SMS roles, such as super users, are not linked to PMS, so a separate request is necessary.

For more information, please visit the PLM page and click on the PMS guidance section. In particular, please refer to:

- On-boarding of users to Substance, Product, Organisation and Referentials (SPOR) data services;
- EU IG chapter 1 for the registration process.

Although you need a different role type, your user credentials and password can remain the same if you choose to update them in your EMA Account Management platform (IAM).

1.2. If a user is already IRIS / eAF Industry Admin or IRIS / eAF Competent Authority Admin, will the user automatically become IRIS PLM admin?

Please be aware that, in agreement with eAF and ePI team, a name change was applied from "IRIS EAF Industry Admin" and "IRIS EAF Competent Authority Admin" to "IRIS / PLM Industry Admin" or "IRIS / PLM NCA Admin."

This change affects both categories, merging the roles to encompass all products hosted in the PLM portal. Consequently, if you hold roles in eAF and ePI, all privileges are merged.

If user role was granted before the PMS PUI go-live on 31 May 2024, the user will simply see the role name update.

For further information please refer to slides 12 and 13 of the Product Management Service (PMS) Product UI training (access & navigation) (3 June 2024) session.

1.3. Are IRIS / PLM Industry Admin and IRIS / PLM NCA Admin roles sufficient to access PMS?

No, to access PMS PUI and/or API there are additional steps the user should follow. Please refer to **section 3. PMS Registration requirements** of the EU IG chapter 1.

1.4. Is there a specific requirement to request the Industry user role or Industry qualified user role?

As explained in EU IG Chapter 5 and Annex A, Industry users can request one of the two roles available (regular user or qualified user role) based on the type of access they are looking for. The **qualified user role** provides full access to the entire product data set of the authorised medicinal products they are responsible for, while the **regular user role** has limited access to product data, based on the requirements mentioned in Annex A to EU IG Chapter 5.

1.5. What is the difference between NCA user role Nca qualified user role?

There is no difference between the NCA regular user and NCA qualified user roles in terms of accessibility of product data (full data set of authorised medicinal products is accessible with both role). The distinction between these roles is at the level of the **edit functionality**, only granted to qualified user role. However, this role is not yet available for NCA users. The Agency will announce in due time when this last role can be requested.

1.6. How is it possible to verify who is the IRIS/PLM Industry Admin for a Company if it already exists?

It is good practice that each Organisation has at least two IRIS/PLM Admin user and these are known internally. In case this is unknown, please submit a request to EMA service desk.

1.7. If I need to access products data in PMS on behalf of more than one ORG ID, shall I submit separate requests in IAM?

No, as announced at the SPOR status update webinar on 10 April 2024, users can submit in a single request the multiple ORG ID access in IAM.

When requesting access to EMA services, users can add organisations to a shopping cart and keep searching for other organisations with different criteria.

1.8. How can software vendors get access to PMS API?

Software vendors can access Marketing Authorisation Holder's product data thought PMS API by using the API secret credential assigned to the relevant IRIS/PLM Admin user of a specific organisation.

1.9. Is PMS API publicly available to read product data?

No, at the moment PMS API is only accessible upon registration to EMA Account Management portal. User can select the most applicable user role type as mentioned in EU IG Chapter 1.

Moreover, the Agency is working to developing a public PMS API whose release will be communicated in due time.

Currently, a public report of medicinal products is accessible through the Product Lifecyle Management (PLM) portal.

1.10. How can product data from PMS can be exported and in which formats?

User can export authorised product data from PMS through:

- **PMS PUI:** product data can be exported in **XML format** upon acceptance of the Data Protection Disclaimer from each of the product PUI pages. Alternatively, consolidated product data can be exported in **excel file** from the private Dynamic Product Report focused on specific elements such as the full list of authorised products, manufacturers, ingredients, pack sizes, ATC codes etc.

In PMS PUI single report, consolidating all product-related information for download is not available due to the large amount of data available in PMS. Additional Dynamic Product Report types will be delivered based on a specific use case.

- **PMS API:** full products dataset can be exported in **JSON, XML, HTML, Text, Auto formats**. The export is product-based.

2. Data model

2.1. When will PMS database contain all PMS data fields reported in EU IG Chapter 2?

The implementation of all PMS data elements as reported in EU IG chapter 2 will occur. At the moment the attributes implemented in PMS are the ones used to enable the product data load from XEVMPD/SIAMED to PMS.

More data elements will be implemented in due time based on the agreed priorities. The same activity will be performed in PLM PUI portal.

2.2. When will the updated version of EU IG Chapter 2 be released?

The European Union IDMP Implementation Guide (EU IG) Chapter 2 is under review. A new version should be released in September 2024.

2.3. Will the 'PMS' section in the SPOR portal be updated?

Access to PMS is hosted under the PLM portal only. This is due to the connections with other databases such as the eAF and ePI portals.

2.4. Are MAHs required to check their authorised product data in PMS as result of the XEVMPD data load?

Yes, upon registration being completed, MAHs is recommended to check their authorised product data in PMS thought API and/or PUI. It is in MAH's interest to ensure the accuracy of their products data.

For further information on how to access and navigate through PMS API and PUI, please refer to the following training sections and Q&A clinic sessions:

- Product Management Service (PMS) Product UI training (access & navigation) hosted on 3 June 2024;
- Product Management Service (PMS) Application Programming Interface (API) training session hosted on 8 July 2024;
- Series of Q&A clinic on Product Management Service (PMS) hosted since the PMS Go-Live and available at this Link.

2.5. How is the Master File Location (MFL) created in PMS?

As stated in the EU IG Chapter 2, Master File Location (MFL) are currently created in XEVMPD and loaded into PMS as per migration rules reported in EU IG Chapter 7.

As initial temporary process, registration of the PSMF location will us two systems XEVMPD and PMS and will be performed in two steps:

1. At the time of the marketing authorisation application, the applicant should submit electronically the PSMF location information using the agreed format as referred to in chapter IV, Article 26 of the Commission Implementing Regulation (EU) No 520/2012 using the XEVMPD database and

XEVPRM format. This will generate a unique PSMF location reference number/identifier, which is the unique code assigned by the EMA to the master file.

2. Subsequently, the PSMF location reference number/identifier generated in XEVMPD database should be linked to the medicinal product during the submission of product data in PMS.

This process will be revised in future to make use of a central repository for Master File information using SPOR capabilities.

2.6. An authorised medicinal product can have more than one packaged medicinal product each of them can have different authorisation status. How is this managed in PMS?

As stated in sections Authorisation status available at both medicinal and packaged medicinal product level in EU IG Chapter 2 in case of different authorisation status at package level of the same authorised medicinal product the following rules applies:

- If all the packages have the same authorisation status, the applicable authorisation status value should be used at product level and repeated at each package level for consistency.
- If different values apply to the different packages, the applicable authorisation status shall per reported in each authorisation status data field of each packaged medicinal product. In this scenario at the medicinal product level the authorisation status user shall report the first term used at package level as per updated business rules in EU IG Chapter 2 will define the authorisation status at product level.

2.7. Will the entire PMS product dataset be compulsory to be completed?

It depends by the PMS business rules mentioned in EU IG Chapter 2. For each of the classes of attributes a specific set of rules such as the conformance type has been defined. This information is available in the technical table reported under each of the PMS data elements and classes.

2.8. Is PMS designed to store only Authorised Medicinal Products (AMP) or also for Investigational Medicinal Products (IMP)?

At the moment, PMS is only storing AMP.

PMS is an ISO IDMP compatible database. ISO IDMP standards are developed to cover both Investigational and Authorised Medicinal Products; thus, PMS could be developed to also contain IMP.

On this aspect, the Agency is currently debating the most suitable technical solution to store IMP and whether PMS has the right capabilities to cover this task. This matter falls within the ongoing business strategy update, particularly concerning investigational medicinal products.

2.9. Will the Pharmaceutical Product Identifier (PhPID) be integrated in PMS?

For the moment the PhPID is not integrated in the PMS data model.

To move forward the implementation of PhPID in Europe and support the generation of the Global PhPID, the Agency is focused on few key activities such as the data cleansing of substances. This activity is ongoing.

Moreover, to implement the ISO identifier globally, EMA is cooperating with international groups (i.e. WHO, FDA, and other global regulators) to pilot the implementation of such ISO identifiers worldwide. The Agency is therefore working at local level in Europe as well as at global level to identify a global solution.

In addition to the above the priority of the Agency is to focus in making available the PMS database and enable the users to access and enrich their authorised product data in PMS to enable the

generation of the ISO Identifiers at Medicinal Product (MPID) and Packaged Medicinal Product levels (PCID) as well as PMS ID.

2.10. The Data Carrier Identifier is a data element mentioned in the EU IG Chapter 2. Will PMS users be required to provide and maintain Global Trade Item Number (GTIN) in the PMS?

Yes, the Agency is enabling companies to provide the product data carrier identifier, such as GTIN codes from barcodes, into PMS. As stated in EU IG Chapter 2, the provision of such information is optional. Nevertheless, users shall be aware that the provision of this data type will support use cases such as the easy access to patient information thorough the scanning of the data carrier identifiers as well as use cases on the matter of the supply chain and sales. Users are therefore recommended to provide such data in PMS as this will create efficiencies for patients.

3. PMS Product User Interface (PUI)

3.1. When will non-Centrally Authorised Products be available in PMS PUI in read-only mode?

Non-CAPs data, such as MRP, DCP and pure Nationally Authorised Products, will be available in read-only mode through PMS PUI in September 2024.

Please note that non-CAPs data are already visible via PMS Application Programming Interface.

3.2. How often the product data between XEVMPD and PMS PUI are synchronised?

In principle, the update of data in PMS following XEVMPD submissions is almost simultaneous. Depending on the volume of queue in XEVMPD, the update might take a bit longer to be processed and therefore reflected in PMS PUI.

3.3. Are Product EV Codes (PRD) made available PMS PUI?

Yes. When accessing PMS PUI, in each PMS product entity there is a data field called "EV code". This attribute is available in the main page named "Medicinal Product" and it contains the full list of EV code(s) linked to the relevant product.

In case of non-CAP, the EV code(s) reported in PMS are the result of the data synch from XEVMPD to PMS. In case of CAP, the EV code(s) reported are the result of the match and merge protocol run between SIAMED and XEVMPD as explained in EU IG Chapter 7.

3.4. Why some PMS data elements do not have any product data and what is the impact of this?

At the moment of the PMS Go-Live, some product data were missing. This is because authorised product data are loaded from two sources databases: SIAMED (EMA internal product management database) and XEVMPD (the product database in line with Article 57(2), second subparagraph of Regulation (EC) No 726/2004 accessible by external users) storing CAPs and non-CAPs data.

The XEVMPD and SIAMED data models are smaller than the one in PMS. While XEVMPD contains around 50 attributes, PMS has around 180 data elements. Thus, as result of the product data load, several data elements are empty (i.e. packaging material, manufacturing business operations etc). Based on this, the user will be required the data entry in PMS, where applicable.

On this regard, the Agency is focusing in enabling the product data enrichment process on a step-based approach. As a matter of priority and as communicated in the past webinars, in order to support ESMP implementation, in 2025 users will be enabled to submit manufacturers of non-CAPs in PMS and

gradually allow the product data enrichment of additional fields to support PMS and other projects. Please check the ESMP web page for further information on this platform.

3.5. Why the QPPV data, PSMF enquiry email, and phone number are only available in PMS API and not in the PMS PUI?

This information indeed exists in the PMS API database, and it is not displayed in the PMS PUI pages. However, since the export functionality in PMS PUI is linked to PMS API, users can also access these data via exporting product data in XML from PUI.

A user story is available for this capability to be developed, aimed to completed by the end of Q3 or beginning Q4 2024. When this capability is deployed in PUI production environment, the product data will be visible to registered users.

3.6. In PMS PUI the Marketing status and marketing status dates are visible. From which system does this information come from?

At the moment, this product data is not available in PMS API as either XVEMPD or SIAMED stores it.

However, this data set is accessible from PMS PUI for Centrally authorised products only as this is originating from IRIS Data Verse feeding PMS PUI. The Agency is internally discussing how this information should be managed whether in IRIS on directly in PMS. This is because for CAP products the marketing status product data is managed in IRIS while for non-CAP marketing status data are managed in ESMP, both systems requiring the use of a specific template.

Nevertheless, marketing status data are not synchronised back in PMS from these two systems.

The Agency will communicate in due time any update on this matter.

3.7. Will the Marketing status captured in IRIS be synced with PMS PUI in real-time?

Currently, marketing status for CAPs is managed in IRIS and is not stored in PMS. This process will remain unchanged. For NAPs, data on marketing status must be submitted using templates provided by ESMP. However, PMS is not syncronised with this data set.

There will be future discussions about possibly integrating this data into PMS since it exists in the data model. However, for now, the process remains with IRIS and the ESMP by using specific templates. Additionally, for NAPs, data on marketing status will only be requested during crises or MSSG-led preparedness exercises, such as monitoring specific product groups like antibiotics.

4. XEVMPD submission of packaged medicinal products

4.1. Is it possible for PMS PUI users to create Medicinal Product entities referring to pack sizes directly in PUI instead of in XEVMPD?

No. Currently, the only way to submit product data to PMS is through XEVMPD. Medicinal product entities shall be created in XEVMPD as per regulatory requirements outlined in Article 57 legislation. Upon submission of product data in XEVMPD the relevant medicinal product entity will be loaded and generated in PMS.

For further details on how to submit medicinal products packages through XEVMPD to PMS, please refer to the hosted Public webinar on pack size submissions: from XEVMPD to product management service (PMS) (11 July 2024).

4.2. Does the content of the PMS package description match with the XEVMPD package description?

As stated in EU IG Chapter 7 the data reported in the PMS package medicinal product description are migrated from SIAMED (EMA internal database) for CAPs and from XEVMPD for non-CAPs. Thus, the PMS package description will match with the data submitted in XEVMPD for non-CAPs.

4.3. In relation to the activities of product data enrichment in PMS, what is the deadline for the MAHs to update the information of their Marketing Authorisation in XEVMPD?

As communicated at the PMS Info Day hosted on 16 April 2024 and European Shortages Monitoring Platform Essentials and Industry Reporting Requirements hosted on 24 June 2024, the type of product data enrichment the Agency is seeking pertains the pack sizes of medicinal products listed under the Union List of Critical Medicines (ULCM). The Agency recommends MAHs reviewing the ULCM list to identify the affected products and if there is any. As result of the ULCM review, impacted MAHs should submit via XEVMPD the authorized pack sizes for the affected products listed in the ULCM list so the relevant product entities can be reflected in PMS. Currently, this is the only enrichment we are focusing on. The **deadline for this activity is 1 February 2025**.

For further information on how to submit pack size data in XEVMPD please refer to the Public webinar on pack size submissions: from XEVMPD to product management service (PMS) (11 July 2024).

4.4. The user is requested to specify the pack sizes of authorised medicinal products in. the package description available in XEVMPD. Will the free text reported in XEVMPD be transformed in structured data in PMS?

No. In XEVMPD the package description is a free text attribute while in PMS the pack size is composed by a numeric value and unit (e.g., 28 tablet).

As mentioned at the Public webinar on pack size submissions: from XEVMPD to product management service (PMS) (11 July 2024), in order to ensure consistency in PMS, the user is requested to submit in XEVMPD product entities at package level so these can be reflected in PMS.

In case of CAPs, the PMS product entity at package level is already reflected in PMS as the product data such as the pack size are coming from SIAMED match and merged with XEVMPD data. However, in case of non-CAPs, the relevant PMS product entity at package level is loaded from XEVMPD.

By submitting in XEVMPD a product entity at package level, the relevant XEVMPD package description will be directly reflected in PMS as the package description (this field is a free text attribute in both systems). To structure the pack size data users should submit an update to PMS entity records. This update will fall under the PMS enrichment process not yet available.

For further information on the scope and how to submit in XEVMPD product entities at package level please refer to the above link of the webinar.

5. electronic Application Form (eAF)

5.1. eAF retrieves authorised product data from PMS. What is the impact on the use of eAF when products data are not up-to-date in XEVMPD?

As stated in the Legal notice on the implementation of Article 57(2) of Regulation (EC) No. 726/2004 marketing authorisation holders (MAH) are required to electronically submit authorised product data and maintain product data up-to-date in XEVMPD according the established timelines. Shall the MAH not be compliant with the legal obligations, it will be deemed as failing to meet its responsibilities. **Non-compliance with the legal obligation in XEVMPD** triggers:

- **Inability to use the eAF**: eAF is re-using PMS data loaded from XEVMPD and SIAMED. Shall the MAH's product is not submitted in XEVMPD and/or maintained updated the eAF cannot be used as data will not be loaded into the relevant systems.
- **Potential rejections**: If the product data is incorrect, the submitted eAF may be rejected by NCAs based on the incorrect information reported.
- **No structured changes**: With the upcoming structured changes in the eAF, it is crucial for MAHs to keep product data information up to date in the systems.
- **Inspections and reviews**: The Agency monitors the quality of the product data in XEVMPD. In case of identified discrepancies these are reported to NCAs' inspectors who will contact the relevant MAH.

To prevent any of the above-mentioned issues, the Agency recommend the MAH to ensure that the authorised product data is consistently updated and accurately reported in XEVMPD so these can be loaded across the relevant systems and application.

6. Guidance & Support

6.1. How shall any identified PMS related data quality issue or questions be reported?

Users can find the relevant instructions in the Product User Interface (PUI) training and PMS API training sessions where **guidance to users through troubleshooting scenarios** is provided. e.g. product search challenges and how to send a Service Desk request if issues persist.

Depending on the type of issue encountered by the marketing authorisation holders, different solution might apply.

For **general** or **technical support** with the **PMS**, please report an EMA Service Desk request

- Report an issue with the PMS, to create a ticket for the issue you are experiencing with PMS API;
- Request information about the PMS, to create a ticket for the question you may have on PMS in general or PMS API. To ensure that the ticket reaches the most appropriate team, users are recommended to select "Service: SPOR" and "Service Offering: PMS".
- Request SPOR API Services, to request support on specific SPOR API services and accesses. To ensure that the ticket reaches the most appropriate team, users are recommended to select "SPOR API request type: PMS" and "Environment: PMS - API PROD".

For **technical support** with the **PLM Portal**, please use directly the PLM Portal-PUI section of the EMA Service Desk portal. This includes issues related to creation of new accounts, access to existing accounts, accessing data and performance of PMS PUI portal.

If you have a user account for a system hosted by EMA, you should use the same username and password for this service. Otherwise, please Sign up for a new account or reset your login credentials.

The Service Desk portal is optimised for use with Chrome, Edge, Firefox or Safari web browsers. If you encounter problems, please use one of these browsers instead.

- Report an issue with the PLM Portal – PMS PUI, to create a ticket for the issue you are experiencing;
- Request information about the PLM Portal – PMS PUI, to create a ticket for the question you may have.

Depending on the issue or question, you can select from different **problem areas**:

- PLM portal – PMS PUI General (topics covering multiple aspects and/or general nature)
- PLM portal – PMS Product Data (issues and questions with the product data as exposed/published in PUI)
- PLM portal – PMS PUI access (issues and questions on the access to PUI)
- PLM portal – PMS PUI functionalities (issues/discrepancies/errors with capabilities i.e. filtering, exporting, sorting, searching etc.)

Please provide a clear description of the issue and provide screenshots or any supporting document as attachment as these can help to solve the query faster.

6.2. Where are all PMS guidance documents stored?

All PMS guidance documents are available on the dedicated PMS Guidance documents page within the PLM Portal. This page includes links to the following resources:

- **User Guides**: Access all chapters of the EU Implementation Guide, the onboarding document for SPOR users, and PUI user guides.
- **Training Session Materials**: Find links to event web pages for relevant training sessions, including presentations and recordings.

6.3. Where can users find regular news on PMS work?

The PMS news page on the PLM Portal is regularly updated with the latest information on PMS, including development announcements and event promotions. Please visit the page frequently to stay informed about the latest updates.

Additionally, stakeholders interested in PMS can subscribe to the PLM Insights Newsletter, which is distributed quarterly.