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

07 August 2026

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.

Table of Contents

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/NCA. 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 has already an IRIS / eAF Industry Admin or IRIS / eAF Competent Authority Admin role, 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 (public and confidential data) of the authorised medicinal products under their organisation, while the **regular user role** has limited access to product data (only public), based on the requirements mentioned in Annex A to EU IG Chapter 5.

1.5. What is the difference between NCA user role and 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 roles). The distinction between these roles is at the level of the **edit functionality**: only granted to the

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 multiple ORG IDs 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.

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. During the initial migration of data to PMS, only the information from SIAMED and XEVMPD was captured. As the PMS data model is bigger than the data model from SIAMED or XEVMPD, not all fields mentioned in Chapter 2 of the EU IG are filled.

These missing data will be enriched by MAHs over time and based on priorities. The Agency will notify the users with sufficient time so they can gather this information and be ready to submit it to PMS.

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

The latest version of the European Union IDMP Implementation Guide (EU IG) Chapter 2 was released on August2025. In case of major updates the chapter will be further updated in the future. Users are recommended to monitor the updates at the following link.

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. PMS section in the SPOR portal has a direct link to the PLM portal.

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 are 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.

Please review the known issues section of this document to make sure you do not create tickets for issues that are already known and being worked on.

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

- Informative webinar on PMS Product User Interface usage and key actions for Marketing Authorisation Holders (with demo) on 29 October 2024;

- Training webinar on Product Management Service (PMS) Product User Interface (PUI) hosted on 16 October 2024;
- Product Management Service (PMS) Application Programming Interface (API) training session hosted on 8 July 2024;
- Product Management Service (PMS) Product UI training (access & navigation) hosted on 3 June 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) is currently created and maintained in XEVMPD and loaded into PMS as per migration rules reported in EU IG Chapter 7.

For the time being, PSMFL should be created and maintained following the rules stated in Chapter 3.II of XEVMPD. If, during the lifecycle of the product, changes on the PSMFL are submitted to XEVMPD, these updates will also be reflected in PMS following the deltas explained in EU IG Chapter 9.

2.6. An authorised medicinal product can have more than one packaged medicinal product, each of them can have a 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 statuses for different packaged medicinal products of the same authorised medicinal product the following rules applies:

- If all the packages have the same authorisation status, the applicable authorisation status value will be reflected at product level.
- If different values apply to the different packages, then, the following priority list should be used. That means that the first term in this list used in any package will define the authorisation status at product level.

Valid > Valid Transferred > Valid Renewed > Valid after lifting of suspension > Suspended > Expired due to Sunset Clause > Expired > Withdrawn > Not renewed > Revoked

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 AMPs.

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 IMPs.

On this aspect, the Agency is currently debating the most suitable technical solution to store IMPs 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 with 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. Where can I find the MPID assigned to my product and the PCID linked to my packaged medicinal product?

Please, consider, that for the moment only the PMS ID has been generated as part of the initial migration of data to PMS and only the PMS ID is generated when inserting new products (either from SIAMED or from XEVMPD).

In order to create the MPIDs and PCIDs, and as stated in EU IG Chapter 2, there are some data elements needed such as devices in case the product is combined with one or the package components. This data is not yet captured in PMS and that is why the generation of these IDs is not possible for the moment.

Therefore, in case you need to identify a medicinal product, use the PMS ID. In case you need to identify a specific packaged medicinal product, you can use the technical package ID generated by the system and that can be found in the PMS API or in the Dynamic Reports in the Product UI (Package ID column).

2.11. 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.

The Product UI and the write PMS API allow the submission and maintenance of this field for non-CAP products. Please, review EU IG Chapter 3 for additional information.

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

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

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

2.13. Free text fields coming from XEVMPD show the information in capital letters, why?

After any submission to XEVMPD, the system is converting the text to capital letters. This is the way XEVMPD captures the data for free text fields and therefore, as PMS is consuming from XEVMPD, it will also show these fields with capital letters. This is the case of the name parts or the package description.

2.14. In PMS there are different sections for ingredients. Where is this data coming from?

EU IG Chapter 7 states that ingredients can come from either SIAMED or XEVMPD, depending on the section. The ingredients for the manufactured item are sourced from SIAMED, meaning that this section will only be filled for CAPs. In contrast, ingredients in the pharmaceutical product section are sourced from XEVMPD.

The medicinal product section displays both the ingredients from the manufactured item and the pharmaceutical product. However, it's important to note that in some cases, SIAMED may capture the salt or hydrate of an active substance instead of the active moiety, while XEVMPD may capture the active moiety. When this occurs, both active ingredients will be displayed in the medicinal product section, while each form of the active substance will be referred to in the manufactured item and pharmaceutical product sections separately.

2.15. I have submitted an update to XEVMPD and a new PMS ID has been generated in PMS for my product. Why is this happening?

EU IG Chapter 9 explains that updates to grouping elements in XEVMPD will result in the generation of new PMS IDs. This means that any changes made to the authorized dose form, full presentation name, active substance or its strength, among others, would generate a new PMS ID since the defining elements of a PMS medicinal product have changed.

It's important for MAHs to be aware of this process so that they can take it into consideration when making updates to their products in XEVMPD. Ensuring that accurate and up-to-date information is maintained in XEVMPD can help to minimize the number of new PMS IDs generated and reduce the potential for confusion or errors.

2.16. Different EV Codes have been migrated under the same medicinal product in PMS. Nevertheless, they should not be grouped as they are considered different marketing authorisation even though all the data in XEVMPD is the same. They are just duplicate marketing authorisations. How can I split the products in PMS?

As explained in EU IG Chapter 7 and 9, EV codes from XEVMPD are merged under the same medicinal product when the grouping elements shared the same information. Depending on the authorisation country, the grouping elements might change. EMA is contacting the NCAs to understand if there is any specific use case that we need to take into account. Therefore, for the moment, until we have the information and we can implement a proper migration rule, in order to split the products in PMS for EV Codes that have the same information, small changes should be performed to any of the grouping elements in XEVMPD.

For example, spaces in the name can be included to one of the EV Codes so the system recognise these two EV Codes as different and two different medicinal products are created in PMS. Please,

include the spaces in the middle of the name and not at the end, as spaces at the end are not considered. For example: ibuprofen 50 mg tablets could be changed to ibuprofen 50 mg tablets (two spaces between ibuprofen and 50).

2.17. Why M4all product (registered under Art. 58) are present in PMS?

These products are managed by EMA and therefore are stored in SIAMED. As they are captured in SIAMED, they have been migrated to PMS.

The submission of these products is optional in XEVMPD and therefore MAHs might decide if they want to submit them or not. If so, they will be merged with the records in XEVMPD.

2.18. Are attachments (documents) maintained in PMS?

No. PMS is not maintaining any document for the moment.

During the initial migration of products from XEVMPD to PMS, the attachment's EV Codes where migrated to PMS, but this data has not been maintained since then.

In the Product UI, some products might present these EV Codes but this data should not be reviewed as it is not maintained.

3. Product User Interface (PUI)

3.1. How often the product data between XEVMPD and PMS PUI is synchronised?

In principle, the update of data in PMS following XEVMPD submissions is almost simultaneous.

Nevertheless, from the PMS API to the Product UI, the process takes some time as the integration routine runs for all the records we have in PMS. Some improvements have been done to the integration routine between PMS and the Product UI so updates captured in PMS should be reflected in the PLM Portal within the next couple of hours.

3.2. Are Product EV Codes (PRD) available in the 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. Moreover, in the packaged medicinal product section, users can see to which pack size, each EV code is linked to.

EV Codes can also be found in some of the Dynamic Reports that are available in the Product UI.

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.

3.3. A medicinal product or packaged medicinal product does not have an EV code associated. What is happening?

Non-CAP products are migrated only from XEVMPD so any packaged medicinal product created in PMS should have an EV code associated to it and therefore they should also appear in the Product UI at the level of the medicinal product.

In the case of CAPs, as explained in EU IG Chapter 7 and EU IG Chapter 9, CAPs are generated first from SIAMED and once the record is created in XEVMPD, the match and merge protocol links the presentation from SIAMED with the EV Code from XEVMPD.

If any of the packaged medicinal product for a CAP does not show an EV Code linked, it is because the match and merge have not worked and this could be due to different reasons.

Please, make sure first that the EV code for this specific presentation has been submitted to XEVMPD. The authorisation country should be EU.

Please, make sure that the MAH Org EV code is mapped to the same LOC ID that the product is referring in PMS (and coming from SIAMED). The match and merge protocol relies on the LOC ID from SIAMED and the ORG EV Code from XEVMPD. If the mapping is not present in OMS, it will not work.

Please, make sure that the Authorisation number and EU Number in XEVMPD are the same as the authorisation number from SIAMED.

If everything is correct but the match and merge has not happened, you can submit a dummy update to this record in XEVMPD (by including a dot in the package description for example). Wait to check if the EV Code is linked to your presentation. If that does not work, please, raise a ticket in Service Now.

3.4. Why some PMS data elements are empty 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: 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.

XEVMPD and SIAMED's data models are smaller than the PMS one. 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).

On this regard, the Agency is focusing on 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 allowed 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. In PMS PUI the Marketing status and marketing status dates are visible. From which system does this information come from?

Marketing status information is no longer visible through the Product UI. This information is managed in IRIS for CAPs and through ESMP for non-CAPs.

3.6. 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 synchronised 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 ESMP by using specific templates. Additionally, for non-CAPs, data on marketing status will only be requested during crises or MSSG-led preparedness exercises, such as monitoring specific product groups like antibiotics.

3.7. Is there a way to export all product data?

There are two ways to export product data.

Users connecting to the PMS API can download all the data for products under their organisation.

If the user has no access to the PMS API, then, some data can be downloaded through the Dynamic Reports from the Product UI. The PMS team has deployed different reports that can be used by users to download, in Excel or CSV format some data such as a list of products, list of pack sizes, products based on ATC Codes, list of manufacturers, etc.

Please, take into account that for the moment there is no way to download all the data for all the products in an Excel or CSV file.

3.8. Will centrally authorised products with authorisation country NO, IS and LI disappear from the Product UI?

Yes. To support other processes such as inspections, marketing status, or eAF, we have decided to remove existing records where the authorization procedure is 'centrally authorized procedure' and the country of authorization is different from EU. While these products must still be submitted to XEVMPD following business requirements, they are no longer required in PMS downstream systems, and only the EU record is needed.

It's important to note that XEVMPD rules still apply, meaning that these records must be submitted and maintained in the Art. 57 database, even though they will not be migrated to PMS.

Please, take into account that these records will still appear in the PMS API. The records are migrated from XEVMPD to the PMS API but they are not shown in the Product UI. These products are not subject to be enriched and should not be used. EMA will, whenever capacity permits, block the generation of CAP products with authorisation country NO, IS and LI in the PMS API.

3.9. Why some medicinal products don't have an MA number?

Please, take into account that, as explained in EU IG Chapter 2, MA numbers can be captured at two levels: medicinal product and packaged medicinal product.

In the same chapter it is explained that, only if all packages have the same MA number, then this will appear in the medicinal product.

Therefore, if your medicinal product is composed by different pack sizes with different MA numbers, the MA number at medicinal product will be empty and you can find them at package level. Only when all the packages have the same MA number, then, it will also be captured at medicinal product level. For the moment, only the root number concept is applied to Centrally Authorised Products. If NAPs have a root number for all packages, it will not appear at medicinal product.

3.10. The MedDRA version of XEVMPD and the Product UI don't match. Why?

In XEVMPD, when submitting the MedDRA codes, the latest version of MedDRA should be selected. These MedDRA codes are mapped to the RMS list and shown in the Product UI. In the Product UI, the version linked to each MedDRA codes comes from the attributes of each term and the version is linked to the latest version of MedDRA when the term changed. Therefore, if the same term has not changed since version 21.1 of the MedDRA list, that is the version that will appear in the Product UI even if in XEVMPD we have indicated version 27. There is no need to raise a ticket for this as it is not considered an issue.

3.11. During the enrichment process, who has access to the different change requests created?

For the moment, everybody from a specific organisation can view the change requests created for the products of that organisation. Nevertheless, only the owner of the change request can view the

changes, edit the change request and submit it. EMA is working to implement a feature by the end of Q1 2025 so any user from the organisation can have access to all the change requests, can edit them and submit them (only for the change requests with status draft and modified).

3.12. Duplicated EV Codes were removed in Q1 2026 but I still some duplicated EV Codes in the medicinal product page, why is this happening?

Please, take into account that the list of EV Codes in the medicinal product page might not reflect the real list of EV Codes. The correct list of EV Codes that are not nullified and linked to the product is the list of EV Codes present in the packaged medicinal product page.

In some cases, we have seen that an EV Code might be duplicated in the medicinal product page but not in the packaged medicinal product one. The second one is the most accurate one. EMA will work to try to have these two pages aligned.

3.13. Incorrect organisation names or addresses are displayed for some products in PUI. Is this a known issue, and when should users raise a ticket?

EMA is aware of the discrepancies visible in certain PMS records, particularly on manufacturer data. The issue is known and has been analysed.

A dedicated **OMS synchronisation initiative** is planned to address the root cause and improve consistency between OMS and consuming systems, particularly IRIS.

The discrepancies do not affect the authorised regulatory CAP information maintained by EMA, specifically in its system SIAMED.

Users do **not** need to raise individual tickets for CAPs or non-CAPs where the issue falls within this known category, specifically when:

- The manufacturer or MAH details/version are incorrect, but the **correct Organisation/Location (Org/Loc) ID** is displayed.
- The **manufacturer operation is missing**, where the operation is not required for CAPs (see Chapter 3, Section 7.2).

Users should continue to raise an individual ticket for CAPs and non-CAPs where any of the following applies:

- The **incorrect Org/Loc ID** is assigned to the manufacturer or MAH.
- The **manufacturer organisation is missing**.
- A **required manufacturer operation is missing** (except for the ones mentioned in Chapter 3, Section 7.2 for CAP only).
- A manufacturer has been **incorrectly added or removed**.
- There are **errors in the start or end dates**, except for known issues such as a one-day difference.

Further updates will be provided as the planned improvements are implemented.

4. PMS API

4.1. Who can access PMS API?

The restricted area of PMS API can be access by registered Marketing Authorisation Holders and National Competent Authority users based on the principles outlined in EU IG Chapter 5 and its Annex A. The access is granted at Organisation level (ie. ORG ID) and allows machine to machine connection between the user's system and PMS in order to read and edit authorised products data. The restricted area is not accessible for the general public.

4.2. Software vendors who do not own authorised product data can still access their clients' product information (e.g. Marketing Authorisation Holders or National Competent Authorities) via the PMS API. To do so, they must use the API secret credential assigned to the relevant IRIS/PLM Admin user of the client's specific organisation. Where can I find the documentation related to the PMS API?

The documentation explaining how to access, connect and use PMS API in production is available at the following link. Users are recommended to read the following documents: EU IG Chapter 1, European Medicines Agency Write PMS API implementation Guide and the related zip file.

4.3. How can I get access to the UAT environment of the PMS API?

All the information on how to access the UAT environment of the write PMS API can be found in PMS UAT API Registration Process - Industry.

4.4. 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 develop a public PMS API. It is expected to be released during Q2 2026.

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

4.5. I am not able to find all my products in the PMS API.

We have identified an issue with the pagination of the API. Sometimes, if there are many pages, the link contains a long query string, and it fails. Please, increase the _count parameter to reduce the number of pages. EMA is working to have this issue fixed.

5. Known issues in PMS

5.1. After reviewing my products in the PMS API or the Product UI I have found several issues with my data. What should I do in order to correct it?

Please, take into account that, **depending on the type of error, different actions might be needed from the MAH:**

1. If the **issue is coming from XEVMPD**, then, the solution might be needed in XEVMPD and the user might need to submit an update there.
2. On the other hand, if the **issue is found on data coming from SIAMED**, then, the MAH should **open a ticket in Service Desk** requesting the change there. Please, review EU IG

Chapter 7 and EU IG Chapter 9 to understand how the data is migrated from the different sources and make sure where the correction is needed.

3. Moreover, in this section you can find issues that are already known and for which the resolution has been prioritised. **Please, do not open tickets if you find any of these issues in your products.** *The PMS team will communicate as soon as these issues are solved so MAHs can check their products again.*

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List of known issues:

Issue	Description	Expected resolution date	Action for MAHs
Missing names in multilingual products	Some names were missing in multilingual products even though they were submitted to XEVMPD.	**Dec-24**	Submit an update to XEVMPD so the system can capture the missing name
Products from Luxemburg	During the initial migration a wrong business rule was implemented (the MA number was used as a grouping element). Now the same approach as the one used for Belgium products is followed so the correct grouping criteria is applied to the products from Luxemburg.	**Dec-24**	Review products from Luxemburg. If grouping of EV Codes is not correct, raise a Service Now ticket.
2-ISO letter codes wrongly displayed in the UI	In the Product UI, in the left filtering menu, the wrong 2-ISO letter codes are wrongly displayed for Estonia (EW), Liechtenstein (FL) and Finland (SF).	**Dec-24**	None
Nullified medicinal products	Nullified medicinal products and packages were available in the Product UI. Now they can't be seen in the product UI but they are still available in the PMS API.	**Dec-24**	None
Units of measurement 'each' was not mapped to any term in RMS	When in XEVMPD the strength of the active substance was submitted as per '1 single each', this term was not mapped to RMS and therefore the denominator is missing in PMS and the Product UI. The RMS team has created now the term 'item' in the units of measurement RMS list and the mapping has been created.	**Q4 2024**	If your product is impacted by this case, you can send a dummy update in XEVMPD to force the system to take this new mapping.
Marketing status data for CAPs	This section contained information coming from IRIS. This section is no longer available in PMS UI.	**Q2 2025**	None

Issue	Description	Expected resolution date	Action for MAHs
Cyrillic characters showing '?' in the full presentation name	This is not an issue, but a reflection of the data captured in XEVMPD. Please, remember that messages with special characters must be sent from XHTML view to avoid adding question marks characters instead of Greek or Cyrillic characters.	**Not an issue**	If XEVMPD already contains question marks, then, a new product version must be sent (using XHTML view)
Missing authorised dose form in Product UI	Some products in the PMS API have captured the authorised dose form as the EV Code instead of as the RMS ID. If this is the case, the authorised dose form is missing in the product UI.	**Q3 2025**	None
Wrong EV code linked to a packaged medicinal product.	In Product UI, each packaged medicinal product is linked to an EV Code coming from XEVMPD. Nevertheless, when there has been a transfer, the previous EV Code is still captured, and the new EV Code is not shown. In the PMS API, both EV codes are linked to this packaged medicinal product and updates to the new record will be captured in PMS. EMA will implement a solution, so the latest EV Code is shown instead of the old one. Additionally, a new process for transfer of MAH for NAPs will be implemented and described in Chapter 9 of the EU IG.	**Q3 2025**	None
Comparator field is missing	In some products, the comparator from XEVMPD is missing (terms such as 'equal' or 'more than').	**Q3 2025**	With normal updates to XEVMPD this data will be captured.
Units of measurement or presentation in the strength are missing	In some products, the units of measurement or presentation in the strength are missing.	**Q3 2025**	Datafix performed in Q1 2026. Some mappings are missing and will be created by RMS team.
Valid - pending products are shown as surrendered in the Product UI	This is due to an issue with the mapping between XEVMPD and RMS.	**Q3 2025**	Send a dummy update to XEVMPD so the correct status is captured.
Range of strengths are missing in the Product UI	If in XEVMPD, the strength of the ingredient is captured as a range, only the numerator is captured.	**Q3 2025**	Send a dummy update to XEVMPD so the correct status is captured.
Multiple authorised dose forms	Some products are capturing multiple authorised dose forms. There was a bug in the Product UI that only one was shown. This issue has now been solved and all of them are shown.	**Q4 2025**	None

Issue	Description	Expected resolution date	Action for MAHs
	Also in the main page, filters will work with multiple authorised dose form.		
Some updates submitted to XEVMPD are not reflected in PMS	This issue is coming from XEVMPD, and the reason is that XEVMPD was sending an old version of the product to PMS. That is why the changes were not reflected in PMS.	**Q4 2025**	None
MA number at product level shouldn't be there	Products with multiple packages and different MA number per each pack size might have an MA number at product level, this shouldn't be the case based on the business rules from Chapter 2.	**Q4 2025**	Submit a dummy update to one of the EV Codes of the product to fix the issue.
Unit of presentation field in the pharmaceutical product is missing	In some products, the units of presentation of the pharmaceutical product are missing.	**Q4 2025**	Submit a dummy update to one of the EV Codes of the product to fix the issue.
Packaged medicinal products transferred in XEVMPD.	If in XEVMPD, users have submitted multiple EV Codes making reference to the same previous EV Code (because former MAH has only one EV code for multiple pack sizes and new MAH has split and submit multiple EV Codes, for example), only one packaged medicinal product is available in PMS. EMA will create the missing packaged medicinal products that are not available in PMS after the transfer	**Q1 2026**	None
Real duplicates merged in PMS – Procedure type	Please, review question 2.16 for additional information. In Q1 2026 it has been released a change that includes the Procedure type as a grouping element.	**Q1 2026**	For impacted products: Submit a dummy update on the EV Code whose procedure type differs from the one currently assigned to the medicinal product in PMS.
Duplicated packages (EV Codes)	In some cases, the same EV Code was duplicated in a medicinal product creating two packages with the same medicinal product. In some cases, the same EV Code was present in two different medicinal products. In both scenarios, one of duplicated packages have been nullified.	**Q1 2026**	None
Product updates from XEVMPD not captured	In case the ORG EV Code of the record in XEVMPD has been changed with an operation type 'Update' instead of following the normal transfer process, PMS is not taking this update and in consequence none of the following updates is	**Q2 2026**	If, for a specific EV Code, MAH has submitted an 'Update' to change the

Issue	Description	Expected resolution date	Action for MAHs
	being consumed. With the resolution of this bug, when updates are submitted to the impacted EV Codes, new products might be created as the MAH will change and this is a grouping element in PMS.		MAH and kept the auth status as 'Valid' from April 2024 till March 2026, check if the correct MAH is now captured. Otherwise, submit a dummy update in XEVMPD.
Duplicated products	Some medicinal products have been duplicated in PMS. Each of the duplicates have different EV Codes in different medicinal products but that belong to just one.	Q2 2026	
Product updates from XEVMPD not processed	In some cases, when XEVPRMs contain many EV Codes (inserts or updates), processing may be impacted. EMA is actively working on enhancements to further improve the handling of larger XEVPRMs.	Q2/Q3 2026	Try to send XEVPRMs with low amount of EV Codes when possible. Remember that the UTF-8 character set should be used.
Real duplicates merged in PMS	Please, review question 2.16 for additional information.	From Q3 2026	
Duplicated entries	In some specific cases, there might be some duplicated entities in some CAP medicinal products such as: • Indications • ATC Codes • Ingredients • Pharmaceutical product • Route of administration • Packaged medicinal product. EMA is working to improve the integration between SIAMED and PMS to avoid the generation of these duplicates.	2026	None
Product updates from XEVMPD not captured	In case the ORG EV Code of the record in XEVMPD has been changed with an operation type update instead of following the transfer process, PMS is not taking this update and in consequence none of the following updates is being consumed. With the resolution, new products might be created as the MAH will change and this is a grouping element in PMS.	**Q2 2026**	If your product is impacted, by updating XEVMPD, the change will be propagated to PMS.
Dates coming from SIAMED	Some dates coming from SIAMED such as the EBD or procedure start date/end date are not correct.	Unknown	None

Issue	Description	Expected resolution date	Action for MAHs
End date of manufacturing business operations	End date for manufacturing business operations from SIAMED (CAPs) is not captured. EMA is working to include this information in the deleted MBOs	Unknown	None
Duplicated or triplicated packages	Products authorised in multilingual countries have as many packages as EV Codes submitted to XEVMPD. Therefore, the same package is captured in different languages. EMA is discussing how to merge these pack sizes.	Unknown	None
Truncated full product names	There is a technical limitation of the Product UI and long product names might appear truncated. The full name is captured in PMS but due to the technical limitation not fully visible in the Product UI.	Unknown	None
Missing QPPV contact and Pharmacovigilance enquiry information data	QPPV code and the Pharmacovigilance enquiry information has been migrated to PMS, but it is not shown in the Product UI	Unknown	None
Incorrect organisation names/addresses displayed in the Product UI	If an organization/location has undergone changes in OMS due to updates in their name/address, it is possible that the old name/address may still appear in Product UI.	Unknown	Please follow instructions reported in section 3.13 of this document.
Access to products might not be possible if merges or acquisitions have been performed in OMS	In some cases, when an organisation has undergone a merge in OMS, even if the mapping between the LOC ID and the ORG EV Code is correct, products might have been allocated to the old ORG ID and therefore the products can't be accessible as the role in IAM is granted to the other ORG ID.	Unknown	Access can be requested to historical records in IAM. Please check this IAM info page.
International Birth date incorrect for CAPs	Please, consider that SIAMED does not maintain the IBD for legacy products but relying on the EURD list. Therefore, wrong IBDs can't be amended for the time being. Discussions will take place in the future in case we consume this information from another source rather than SIAMED.	Uknown	None
Full product name for products authorised in Greece	In the Product UI, in the medicinal product page, the name for Greek products is not display. This is due to a miss mapping with RMS language value leading to the unavailability of the name in this section.	Unknown	None
Missing, Wrong or Invalid Regulator in the Product UI	EMA is waiting for the impacted NCAs to provide the correct LOC ID. This issue has no impact on any regulatory process so products can still be used, for example in the web-based eAF.	Unknown	None

Issue	Description	Expected resolution date	Action for MAHs
PEI included as regulator for products authorised by BfArM	EMA is investigating how we can correctly link products either to PEI or BfArM. For the moment, with the deltas, products are assigned to PEI. There is no impact on the product, and the product can be used for different business processes (eAF, enrichment, etc).	Unknown	None
Package size for CAPs not showing the correct information	If the pack size for CAPs contains more than one unit of presentation (e.g. 3 tablets + 2 vials), only one of the values might be present. EMA is checking how the generation of structured data can be improved from free text in SIAMED.	Unknown	None
MBO Start date for CAPs is one day before the real one	PMS is capturing the start date of the MBOs for CAPs (coming from SIAMED) one day before the date it was approved. This is due to the time zone that PMS uses. We will be fixing this issue in due course.	Unknown	None
Quantity operator value not displayed in PMS PUI	PMS captures the Quantity Operator value when it is submitted through either the PMS PUI or the PMS API. However, due to a data synchronization finding between PMS and IRIS, the submitted value is currently not displayed in the PMS PUI. The synchronization has been resolved on the 5th of August 2026. With the implementation of this fix, Quantity Operator values submitted for new products will be synchronized and reflected in the PMS PUI immediately from that point onward. Previously submitted product data will not be automatically synchronized as part of this fix. This historical data will need to be manually corrected and made available in the PMS PUI, with this work planned to be completed by end of Q3/beginning Q4 2026.	**Q3/Q4 2026**	None

5.2 Taking into account the known issues, how should I manage the verification of data in PMS?

First of all, it is important to understand that some of the known issues are not affecting all products in PMS. That means that not all products have duplicated pharmaceutical products, or the name is truncated.

We also understand that, for Product UI users, revision of some specific data might be difficult as there is no way to export it for all their products at the same time (i.e. there is no way, for the moment, to download all indications in an excel or CSV format).

If the user has access to the PMS API, then, the recommendation is to review as many data as possible to make sure that the migration from SIAMED and/or XEVMPD was performed correctly.

For the Product UI users, the revision might be a bit limited, but there are still some checks they can perform.

Among these checks, users should make sure that all their products have been migrated from SIAMED/XEVMPD and whenever applicable, the correct packaged medicinal products have been migrated under the correct medicinal product. Also, make sure that new records submitted to XEVMPD are migrated correctly.

Users should also check that specific terms coming from the source and mapped to RMS, reflect the correct term (e.g. authorised pharmaceutical dose form, ATC codes, MedDRA Codes, legal status of supply, etc.)

Users can also check that ingredients coming from XEVMPD are reflected correctly and the correct mapping between XEVMPD and SMS is reflected.

6. Submission of data to support ESMP.

6.1. What is the deadline for the enrichment of data in PMS?

The European Shortage Monitoring Platform (ESMP) requires information on manufacturers and manufacturing business operations so additional information such as production capacity can be provided in case of a crisis or a MSSG preparedness exercise to prevent, monitor and manage shortages.

For CAPs, this data has already been migrated from SIAMED and it is maintained with the changes performed in SIAMED. Therefore, MAHs are just required to review the information stored in PMS and make sure it is kept up to date.

For non-CAPs, this information has to be provided either through the PMS API or the PMS Product UI, based on the timelines specified below.

Updated relevant deadlines for MAHs:

- **June 2026:** Enrichment of structured manufacturer data and pack size for non-centrally authorised products (non-CAPs) featuring on the Union list of critical medicines (ULCM) by using the PMS product user interface (PUI) and application programming interface (API).
- **December 2026:** Enrichment of structured manufacturer data for all other non-CAPs (not part of ULCM) on the company's portfolio using PMS Product UI and API.
- **June 2027:** Enrichment of pack sizes for all other non-CAPs on the company's portfolio using XEVMPD and structured pack sizes using PMS PUI and API.

The ULCM list is based on ATC codes, so MAHs can identify if products of their portfolio are affected or not via accessing the dynamic product report available at PLM - PMS Product UI Navigation Guidance.

6.2. Should products in UK and Northern Ireland be enriched?

No. It has been confirmed by the ESMP team that products authorised in UK are out of the scope of the enrichment.

It has also been confirmed by the ESMP team that, they are not monitoring products in Northern Ireland for the purpose of shortages and therefore, enrichment is not required.

6.3. Is it possible for PMS PUI users to create pack sizes directly in the PUI or the PMS API 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 pack sizes 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).

All the information on how to submit additional pack sizes through XEVMPD can be found in the Public webinar on pack size submissions: from XEVMPD to product management service (PMS) (11 July 2024) and also in Chapter 3.II of XEVMPD.

6.4. What information should be included in the package description in XEVMPD?

As stated in Chapter 3.II of XEVMPD, the package description field is more important and therefore some more meaningful information should be provided. For those products, where the authorisation number is the same for all pack sizes, national IDs should also be provided in the package description. Other information such as the pack size (quantity and units of presentation) or the material can be provided either on the national language or in English.

During the Public webinar on pack size submissions: from XEVMPD to product management service (PMS) additional information on the national IDs was also shared, but an updated table can be found here. Please, take into account that it is the MAH's responsibility to know how the non-CAP products were authorised by the national competent authority and the national code assigned to each pack size. MAHs can contact the NCA in case they need additional information.

Please, consider that for medicinal products authorised in countries with more than one official language (i.e. Belgium, Liechtenstein and Finland), the package description in the XEVMPD records that belong to the same pack size, should be the same (same information in the same language). This will allow the PMS team to merge those EV codes under the same packaged medicinal product. This requirement is also reflected in the package description section of Chapter 3.II of XEVMPD.

Country	MA number level	National ID at pack
Austria	MP level	Packungsnummer (internal), Pharmazentralnummer for marketed packages (PIP code)
Belgium	between medicinal product level and packaging level	CTI Extended
Bulgaria	MP level	
Croatia	Both	Yes.
Cyprus	MP level	only internal
Czech Republic	MP level	yes: SUKL code.
Denmark	MP level	
Estonia	MP level	Yes. There is a national package code generated by our internal database. Package code
EU	Pack size	Ø
Finland	MP level	Yes
France	Both	The package number (CIP with 13 characters) from the SmPC should be used as MA number.
Germany	MP level	nationale Packungs-ID
Greece	MP level	
Hungary	Pack size	
Iceland	MP level	Yes. Nordic article number and GTIN/NTIN but only for marketed packages
Ireland	MP level	No
Italy	Pack size	Ø
Latvia	MP level	"Product ID" (in LV: Produkta ID).
Liechtenstein		
Lithuania	Pack size	Ø
Luxemburg	MP level	Yes. "Numero national" or national number (7 digits)
Malta	MP level	No additional identifier is given for each pack
Northern Ireland		
Norway	MP level	Yes. Nordic article number and GTIN/NTIN but only for marketed packages
Poland	MP level	
Portugal	Pack size	Name in PT "Número de registo" (registration number).
Romania	Pack size	Ø
Slovakia	MP level	"ŠÚKL kód" (ŠÚKL code (SIDC code))
Slovenia	Pack size	Ø
Spain	MP level	Codigo nacional
Sweden	MP level	Yes. NPL pack id
The Netherlands	MP level	No

6.5. 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 field for package description is 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.

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

No. The information submitted in the package description field in XEVMPD will be migrated to the packaged description field of the packaged medicinal product in PMS.

Please, review Chapter 3.II of XEVMPD to understand how the package description should be submitted in XEVMPD so we have meaningful information in PMS.

The structured data on pack sizes (pack size field in PMS) is composed by a numeric value and a unit (e.g. 28 tablet). For CAPs, this data is captured from SIAMED but for Non-CAPs, this field is empty. To structure the pack size data, users should submit an update to PMS. This update will fall under the PMS enrichment process which will be available from Q1 2025.

6.7. Do I need to submit all authorised pack sizes for all my products, or shall I do it only for those products that fall under the ULCM (Union List of Critical Medicines)?

Please, take into account that it depends on the type of product and how the authorisation has been granted by the National Competent Authority.

At the end of Chapter 3.II of XEVMPD you have a diagram explaining which information you need to submit depending on which type of product we are referring to.

6.8. When submitting the manufacturers and manufacturing business operations as part of the enrichment process, which manufacturers should be included?

As explained during the Submission of Manufacturers, Manufacturing Business Operations (MBOs) and structured pack size data to Product Management Service (PMS) | European Medicines Agency (EMA) webinar, only those manufacturers and manufacturing business operations that are submitted withing the eAF should be reported, for the moment, to PMS.

Please, refer to this webinar and to EU IG Chapter 3 for additional information.

6.9. Manufacturing business operation for CAPs are not captured as in the eAF. Why?

The RMS list for manufacturing activity is a hierarchical list. While in the eAF, whenever available, the RMS terms of the second level are submitted, SIAMED is only capturing the first level. For example, while in the eAF, the selected term for a manufacturer of the medicinal product can be Chemical / Physical testing (second level term), in SIAMED, only Quality control testing of medicinal product is captured.

MAHs are not required to raise any ticket in those cases, as it is accepted by ESMP to capture the data like this for CAPs.

EMA will be discussing if in the future there is a need to enrich this data or make any changes, but for the moment, for CAPs, this data is correct.

For non-CAPs, as explained in EU IG Chapter 3, the same values as in the eAF should be captured.

6.10. When inserting a new pack size in XEVMPD, instead of a new packaged medicinal product, a new medicinal product is created in PMS. Why is this happening?

As described in EU IG Chapter 7 and EU IG Chapter 9, there are some data elements from XEVMPD that are used to group EV codes under the same medicinal product. If a record from XEVMPD that is supposed to belong to a specific medicinal product contains different data in one of these fields, it will not be merged correctly.

The PMS team recommends checking the data from the other EV codes to make sure it is correct and the same as the one that is going to be submitted with the new EV code. Take into account that legacy records in XEVMPD might have been validated and some changes performed by the XEVMPD validation team.

Take also into account that any change performed during the lifecycle of the record might impact the structure of the product in PMS if any of those grouping elements is changed. Please, review EU IG Chapter 7 and EU IG Chapter 9 for additional information.

6.11. For CAPs, with date is captured as Start Date for the MBO?

SIAMED captures the approval date of the procedure as start date of a specific manufacturing business operation. Users should follow the same approach and not provide the submission date or the implementation date, but the date when the procedure was approved.

Additionally, as explained in the known issues table, the date shown in the Product UI is one day before the one captured in SIAMED. This is due to the time zone that PMS uses and that creates a discrepancy of one day in the date. This will be fixed in due course. Please, do not open tickets asking for this correction.

7. PMS and the web-based electronic Application Form (eAF)

7.1. 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.

7.2. I want to use the web-based eAF for products that are not in scope of XEVMPD, such as herbal or homeopathic products. What shall I do?

eAF is consuming data from PMS, and, at the same time, PMS is fed by XEVMPD. Therefore, any product that is needed in eAF should be submitted to XEVMPD.

XEVMPD already allows the submission of these type of products, so please, review Chapter 3.II of XEVMPD to understand how to submit these products. Once submitted, they will be available in the PLM portal (Product UI and eAF).

7.3. For MRPs and DCPs, after a medicinal product is authorised in the Referenced Member State but while it is under the national phase on the Concerned Member States, a variation might need to be submitted. How and by when these pending products can be submitted to XEVMPD so they appear in the PLM Portal?

A new authorisation status is available in XEVMPD for the submission of these products to XEVMPD. Chapter 3.II of XEVMPD has being updated to explain how to submit and maintained these records.

Please, take into account that this use case only applies to MPRs and DCPs. Pending pure NAPs can't be submitted to XEVMPD as no variations can be submitted to pending pure national products. Only once the national product is authorised, a variation can be submitted.

This authorisation status is to be used only when the medicinal product has been newly authorised by the Reference Member State but is under evaluation in the Concerned Member States. The authorisation status in the RMS should be Valid (1) and Valid – pending national phase (12) in the CMS(s).

This authorisation status should be used when the medicinal product has not been authorised yet by the CMSs. Once the product is authorised in CMS(s), the authorisation status should be updated to Valid. This status SHALL NOT be used when a variation is being evaluated by the CMSs once they have already authorised the initial MAA of the product.

For the pending medicinal products, some data might not be available as it is to be approved by the CMS(s). Therefore, this is the information that should be reflected until the product is authorised and an update is submitted to XEVMPD to provide the correct information:

- Use EU other approval/authorisation procedure (13) so these EV Codes are not considered in the fee calculations
- Authorisation number: 'Not assigned' (unless it is already known, in which case, it can provided)
- Authorisation date: same as the one provided for the RMS and to be updated once authorised in the CMSs
- Full presentation name: the proposed name can be included in the local language and to be updated once authorised
- For the rest of the fields, the same data as the one provided in the RMS (e.g. Indications, ATC codes, composition, etc)

8. Guidance & Support

8.1. 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 (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.

8.2. 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.

8.3. 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.

8.4. How technical support can be requested for the PLM Portal?

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.

8.5. Which Service Desk ticket type can PMS users select?

As a questor you can:

1. Ask a question in EMA Service: request information about the PLM Portal – PMS PUI
2. Report an Incident in EMA Service Desk: report an issue with the PLM Portal – PMS PUI
3. Report an Issue with PMS: report a technical issue with the use of the Product Management Services (PMS) solution
4. Request SPOR API Services: technical questions or requests for API access to the different SPOR Services (the Management Services of Substances, Products, Organisations and Referentials of the EMA).
5. PMS Data Quality Enquiry: request to investigate data quality issues in PMS

Depending on the issue or question in points 1 and 2 above, you can select from different problem areas:

Service	Service Offering	Description
PLM Portal	PLM portal – PMS Product Data	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.
	PLM portal – PMS PUI General	Topics covering multiple aspects and/or general nature
SPOR	PMS	Technical issues with the use of the Product Management Services (PMS) solution

NOTE: 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 a lot faster (e.g. PMS IDs, MA numbers, tool and role used to access data etc).