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SCIENCE MEDICINES HEALTH

Informative webinar on PMS Product User Interface usage and key actions for Marketing Authorisation Holders (with demo)

29 October 2024, 10:00 - 12:00 CET

Presented by Marcos Fernández Gómez and Veronica Lipucci Di Paola
PMS Co-product Owners

Agenda

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1	**Welcome** *5 min*	**Veronica Lipucci Di Paola**, PMS Product Co-Owner, EMA
2	**PMS releases overview** *5 min*	**Veronica Lipucci Di Paola**, PMS Product Co-Owner, EMA
3	**Access PMS Product UI** *10 min*	**Veronica Lipucci Di Paola**, PMS Product Co-Owner, EMA
4	**Navigate through PMS Product UI (with demo)** *40 min*	**Marcos Fernández Gómez**, PMS Product Co-Owner, EMA
5	**Known data quality issues & key actions for MAHs** *20 min*	**Marcos Fernández Gómez**, PMS Product Co-Owner, EMA
6	**Next steps** *10 min*	**Marcos Fernández Gómez**, PMS Product Co-Owner, EMA
7	**Q&A** *25 min*	**Moderator: Caterina Scarpati,** PMS Change Management Team
8	**Closing** *5 min*	**Veronica Lipucci Di Paola**, PMS Product Co-Owner, EMA **Marcos Fernández Gómez**, PMS Product Co-Owner, EMA

*Please note that **this session is being recorded** and **will be made available** through **EMA Corporate Website and YouTube channel.***

*At certain points throughout the session, participants will be able to ask questions or give their input via the audience interaction tool **Slido**.*

*Interaction via Slido is voluntary, and you may opt to remain anonymous. If you chose to use Slido, **you consent to the processing of your personal data** as explained in the EMA Data Privacy Statement for Slido.*

Housekeeping notes – Q&A

Join at
slido.com
#PMSPUI

- Join via **QR code** or **slido.com -** *please provide your questions and comments in Slido only*
- **Send or upvote the questions** you want to hear answered – *before raising a question check whether its has been raised already and vote for it*

Q&A Management

- Questions will be shown on the screen and managed live in the Q&A session
- EMA colleagues will attempt to **address questions in writing throughout the session**
- EMA colleagues will **verbally address (unanswered) top voted questions** at the end in the live Q&A session.

Unanswered questions

- This can be due to high volume of questions or assistance of a specific colleague not available today is required.
- Unanswered questions will be reviewed, and the **most relevant ones may be addressed** in other webinars or in the PMS FAQ document.
- We may request that you ask **Questions on specific issues/cases** in Service Desk to be tracked, investigated and adequately assigned.

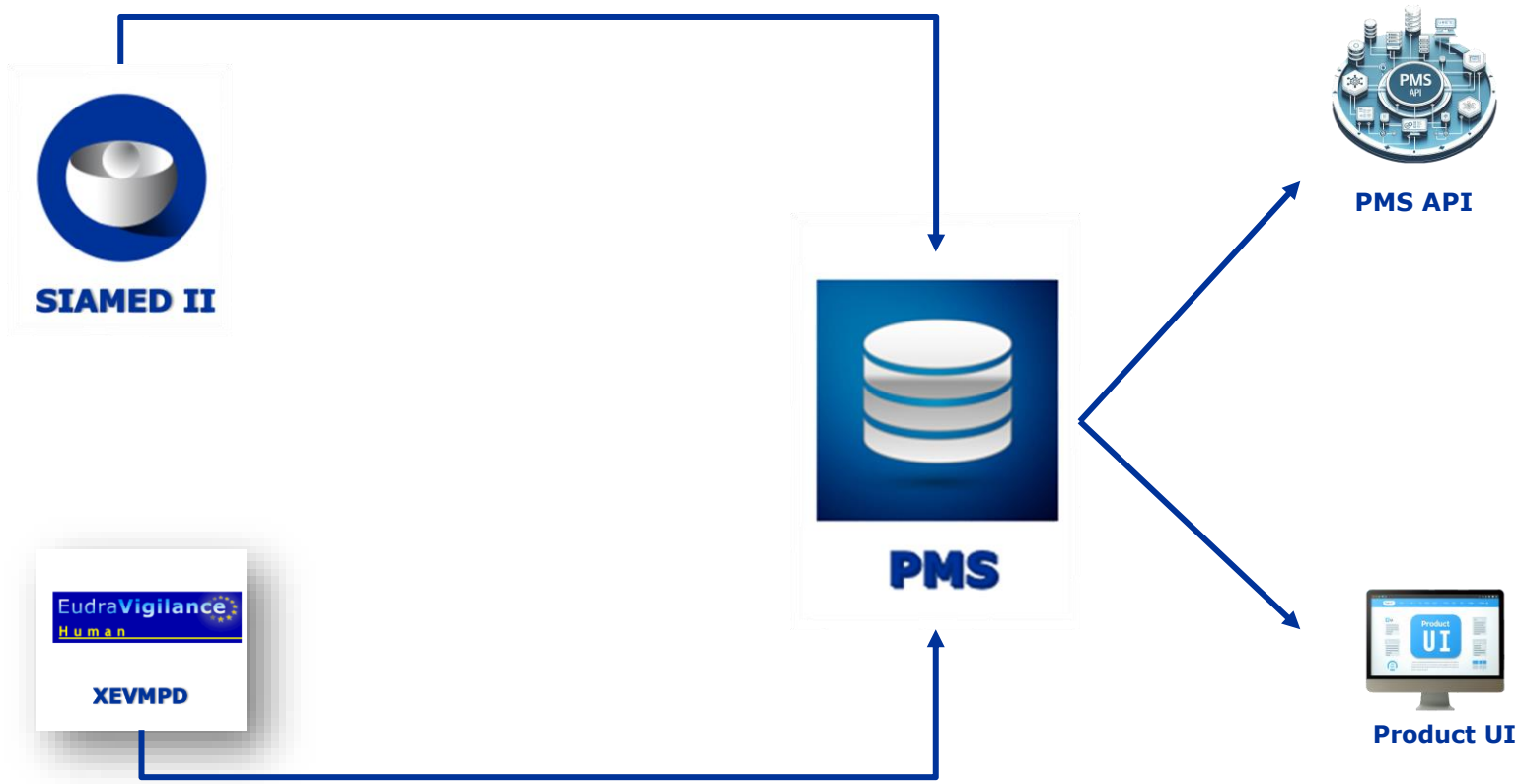
Aim of this webinar

Today's webinar aims at sharing:

- An overview of PMS releases
- The process to request access to Product UI
- Navigation through the Product UI
- List of known data quality issues
- Key actions for MAHs
- Next steps

PMS releases overview

Migration and data access



Migration and deltas rules can be found in EU CH 7 & 9

Where we are in the journey to access PMS data

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+4500 CAPs

+400K non-CAPs

Authorised product data

Read-only mode

PMS data is **accessible to**:

- All EU Regulators (PUI)
- H&V EU Regulators (API)
- MAHs (API & PUI)
- General Public (PUI)

Released systems:

- Product User Interface (PUI)
- Application Programming Interface (API) for MAHs
- API for H&V NCAs

Next release:

- API for H-only NCAs

Access to PMS Product UI

PMS User Registration Process – Roles overview

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PMS User roles

Admin roles

User	Admin role names
Industry user(s)	IRIS/PLM Industry Admin
NCA user(s)	IRIS/PLM NCA Admin
EMA user(s)	IRIS/PLM EMA Admin

Industry roles

User	Role names	PMS Access Level (*EU IG Ch.5*)
Industry user(s)	PUI Industry User	Level 2b
	PUI Industry Qualified User	Level 2a

Regulator roles

User	Role names	PMS Access Level (*EU IG Ch.5*)
NCA user(s)	PUI Competent Authority User	Level 3
	PUI Competent Authority Qualified User	Level 3 ***Not available for the moment***

User guide releases in Mid-May 2024:

- EU IG Chapter 1 version 3
- EU IG Chapter 5 version 2
- Annex A to EU IG Chapter 5
- On-boarding of users to SPOR data services
- PMS Product UI Registration Guidance (PLM portal)

IRIS/PLM Industry & NCA Admin user roles

› **Existing role in IAM!** *previously named IRIS / eAF Industry Admin and IRIS / eAF Competent Authority Admin* respectively, PMS PUI roles are thus merged with eAF/ePI/IRIS privileges.

› Users having this **role granted prior the date of PMS go live (31 May 2024)** will see their **role name updated** in their IAM account management platform and do not need to request it again.

Key role characteristics and recommendations

- **No direct READ access to PMS API/PUI**
- Allow to receive **PMS API Client Credentials** *generated only upon request by the Admin users to* ***READ PMS API***
- Allowing to **revoke/grant** other **PMS PUI's user** roles
- **1st Admin** of Organisation is **approved by IRIS / PLM EMA Admin;** from 2nd Admin onwards, Org Admin can approve it
- Each organisation recommended to have **at least two Admin users**
- Multiple roles for the **same ORG ID** allowed (user can also request either **User or Qualified User**)
- If Admin also requests User or Qualified User role, requests are **automatically approved in EMA Account Management System**

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Industry/NCA User & Qualified User roles

- **New roles in IAM!** Valid to access **PMS PUI**
- PMS PUI access based on **Multi-factor authentication (MFA)**, additional verification of identity

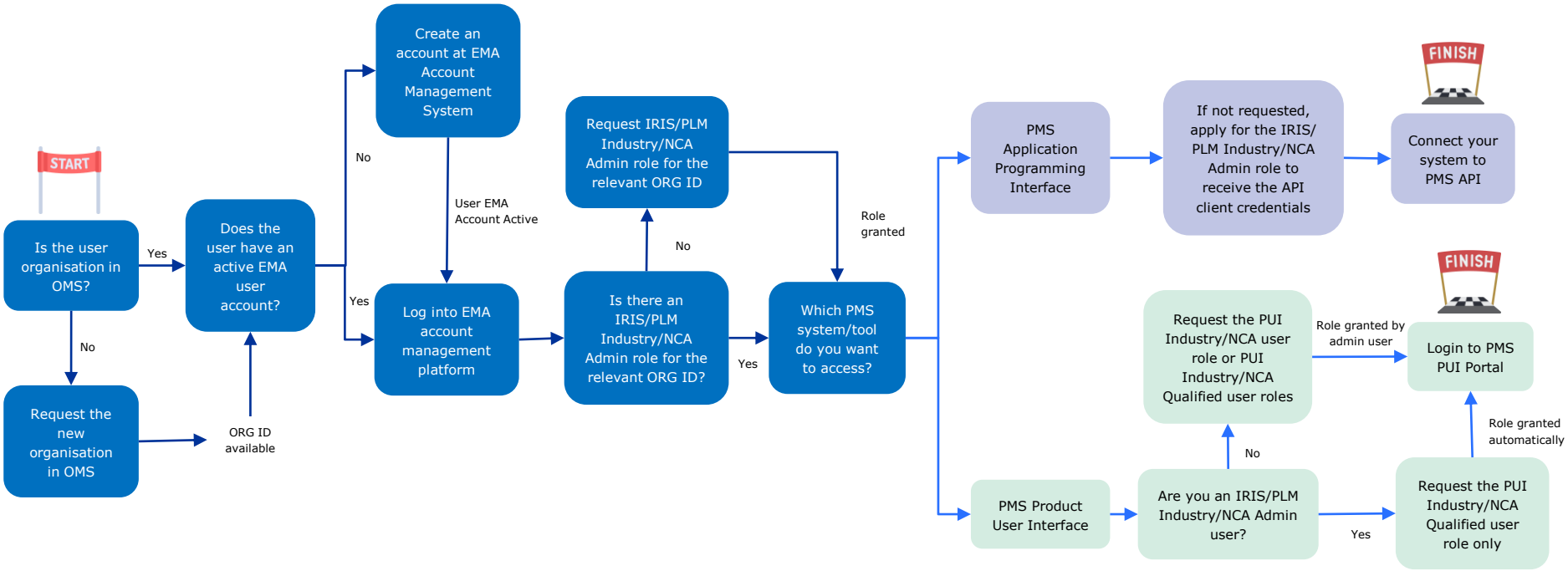
Key role characteristics and recommendations

- Allowing **READ of PMS products data**
- Assigned to **single user** in IAM and at **ORG level**
- **Approved** by relevant **IRIS/ PLM Industry/ NCA Admin** user(s) only
- **Do not request multiple roles** (User and Qualified User) for the **same Organisation.** If so, the Qualified User role privileges prevail
- **PUI NCA Qualified User role is currently not available**. NCA users can request the regular PUI NCA User to access the full PMS product data set available.

PMS PUI roles are in synchronisation with eAF roles

- PLM Users having **eAF Contributor** role shall request **PUI User role**
- PLM User having **eAF Coordinator/Manager** roles shall request **PUI Qualified User role**
- PLM Users **shall not request mixed eAF/PMS PUI roles for the same organisation** as this will result in the higher privileges bypassing the lower ones
- PLM User can have **different roles** across **different organisations**

PMS User Registration Process



Navigate through PMS Product UI

Overview of guidance documents

PMS Product User Interface guides:

- PMS Product UI Registration Guidance
- PMS Product UI Navigation Guidance
- PUI - Known Issues

PMS EU IDMP Implementation guide:

- EU IG Chapter Introduction – EU Implementation guide
- EU IG Chapter 1 version 5 → registration requirements
- EU IG Chapter 5 version 2 → Data access to medicinal products for human use
- Annex A to EU IG Chapter 5

SPOR Guide:

- On-boarding of users to SPOR data services

Product UI Demo

Live Demonstration

Known data quality issues

Known issues

Some issues were identified in the PUI and already prioritised to be fixed

Please **do not open a ticket** in Service Desk if **you identify them** when reviewing your products and product's data → stakeholders will be notified as we solve the issues.

List of currently known issues available in next slides and in the PMS Q&A document available in the PLM Portal

Note: Only some products are affected by these issues.

Currently known issues (1/8)

Nullified products can be seen in the Dynamic reports

Nullified products have been removed from the Product UI initial page but can be seen in the dynamic reports.

EMA is working to remove these products from the dynamic reports as well.

You can check the XML export or the PMS API and look for the status:

Currently known issues (2/8)

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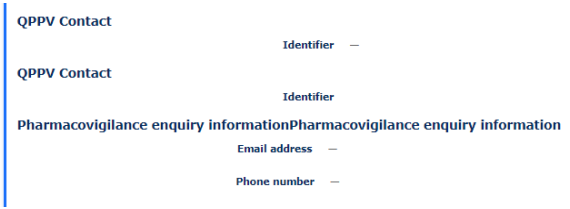
Full product name might be truncated if it's too long.

For multilingual countries, just one name in one language is shown in the main page of the Product UI.

All names are displayed when opening the product.

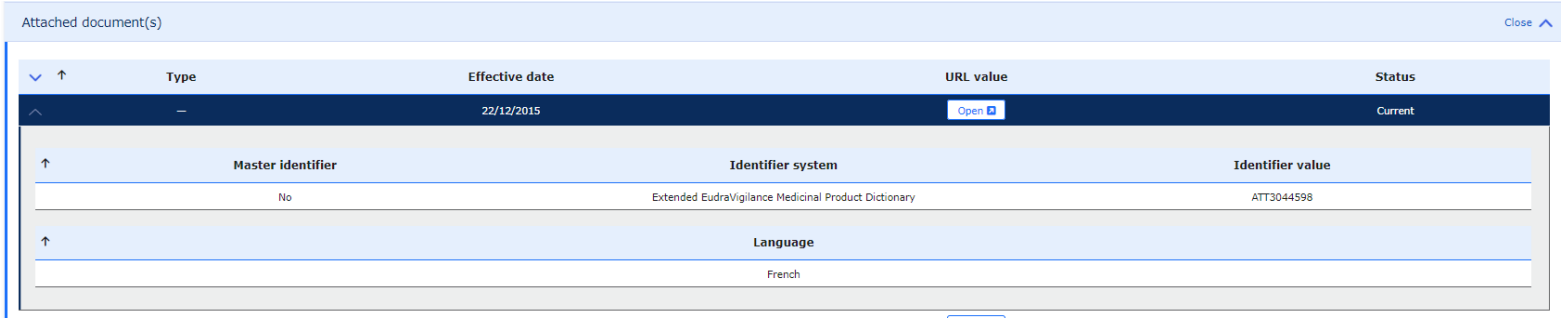
The QPPV Contact and Pharmacovigilance Information are not yet visible in PUI despite of data available in PMS



Currently known issues (3/8)

Attached document(s) section:

- Only the documents present during the initial migration appear.
- Documents IDs (EV Codes) are not maintained for the moment.
- URL is not working as the physical document have not been migrated yet.



Additional Monitoring Indicator may not be reflected correctly for all products

Marketing status data is not showing as registered in IRIS (for CAPs)

Currently known issues (4/8)

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Removed indications & removed manufacturers might still appear in the PUI

Some fields or sections might be duplicated on CAPs:

- ❑ Indications
- ❑ ATC Codes
- ❑ Ingredients
- ❑ Pharmaceutical product
- ❑ Route of administration
- ❑ Packaged medicinal product

Route of administration
Subcutaneous use
Subcutaneous use
Subcutaneous use
Subcutaneous use
Subcutaneous use
Subcutaneous use

Currently known issues (5/8)

Some dates coming from SIAMED reflect the day before the one is captured in SIAMED (e.g., instead of 9 March 1990, in the Product UI we see 8 March 1990)

Products from LU were migrated following some business rules that are not accurate (using the MA number as grouping element).

During December, we will change the business rule so same approach as the products from BE (procedure number as grouping element) is followed.

The 2-ISO letter codes are wrongly displayed for Estonia (EW), Liechtenstein (FL) and Finland (SF) in the search menu. The correct country appears in the results table.

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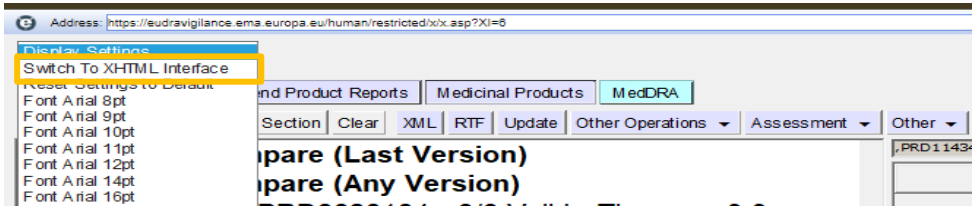
Cyrillic characters showing '?' in the full presentation name.

This is not an issue but a reflection of what we have 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.

If the database field already contains question marks then a new product version must be sent (using XHTML view) to amend the missing Greek or Cyrillic characters.

	↓ PMS ID	Full Name
☐	700000124933	????????? ????????? 150 mg ?????? ???????
☐	700000118667	????????? ????? 100 mg ????????? ????????
☐	700000113781	???????? 100 mg/g ???
☐	700000111370	???????????????? ??????? 500 mg ???? ? ?????????? ?? ?????????? ???????



Currently known issues (7/8)

Some ingredients might not appear in product UI or wrong ingredients might be captured

We have had an issue with ingredients that have been moved or disappeared in the Product UI.

This issue will be solved by mid-November.

This might impact eAF if the ingredients are not reflected. Please, check your product before creating a web-based eAF.

Currently known issues (8/8)

Old MAH's name might appear if there has been an update to OMS

This issue is affecting other system such as IRIS and eAF and EMA is working to solve this issue.

If your Organisation in OMS has changed the name or a merge has happened, the old name of the organisation might still appear in the Product UI even if the correct LOC ID is captured in PMS.

Summary of actions & tips to review products in PMS PUI (1/4)

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KNOWN ISSUES ARE NOT AFFECTING ALL THE PRODUCTS.

DYNAMIC REPORTS DO NOT ALLOW EXPORT OF FULL PMS PRODUCT DATA BUT PRODUCT DATA VERIFICATION CAN STILL BE PERFORMED

Request your access

1. **Request a role** in IAM for your organisation
2. **Log in to the PLM portal** and navigate to your owned products

What can MAHs check?

- If you have access to the **PMS API**, you can **export and review all product data**
- If you only have access to the **Product UI**, you can **still perform some checks**.

Summary of actions & tips to review products in PMS PUI (2/4)

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1 Review product migration

- Make sure all your **products have been migrated** from XEVMPD to PMS *(Consider EU IG Chapters 7 & 9 rules)*
- If there are **multiple EV codes** linked to one specific medicinal product, make sure that they have been **migrated together**

You can use the dynamic reports for this activity

Summary of actions & tips to review products in PMS PUI (3/4)

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2 Review specific data fields

- **MAHs can review specific data fields coming from XEVMPD and that mappings to RMS are correct**
  - Authorised dose form / administrable dose form
  - Legal basis
  - Ingredients / strengths
  - MedDRA codes
  - ATC Codes
  - Other fields coming from XEVMPD such as pediatric use, additional monitoring, MA numbers, package description, dates, etc
- **MAHs can review data coming from SIAMED**
  - Manufacturers
  - Ingredients on the manufactured item
  - Package size and package description

Some of these checks can be done using the dynamic reports but other should be done through the Product UI.

Summary of actions & tips to review products in PMS PUI (4/4)

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Tips for review

- **Changes in XEVMPD may affect the structure** of your product (updates to grouping elements in XEVMPD will lead to the generation of new medicinal products in PMS – check EU IG Ch 9)

  → Please, make sure you review these fields and check they are correctly reported in XEVMPD so no changes are made by you or the validation team.

- **Focus first on products to be used by other consuming systems** such as ESMP or eAF.

- In case of **any discrepancies or doubts about the data displayed**:

  1. **First**, check Chapter 7 and Chapter 9 of the EU IDMP Implementation Guide (IG) – where migration rules are explained - and/or the known issues document;
  2. **In case of additional questions** MAHs should open a EMA Service Desk Ticket by following the instructions in the "Support" section of the PUI navigation guide.

Recommendation for PMS Users in case of issues

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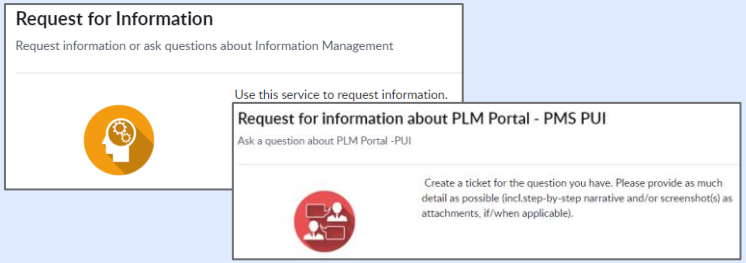
Which Service Desk ticket type can PMS users select in case of issues?

NOTE: Please provide as much information as possible (PMS IDs, MA numbers, documents if needed, screenshot, tool and role used to access data etc).

Requestor

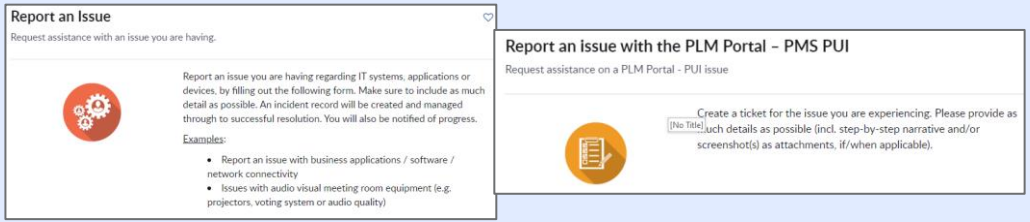
Ask a Question in EMA Service Desk



Select always one of the below elements:

Service	Service Offering
PLM Portal	PLM portal – PMS Product Data
	PLM portal – PMS PUI access
	PLM portal – PMS PUI functionalities
	PLM portal – PMS PUI General
SPOR	PMS

Report an Incident in EMA Service Desk



Customer Services

EMA Data Stewards

Next steps

Upcoming events

Q&A Clinics on PMS API & PUI:

- **5 November 2024** (10:00 – 10:30 CET): register here
- **22 November 2024** (10:00 – 10:30 CET): register here

H var electronic Application Form (eAF) Training Session and Q&A Clinic for Industry stakeholders

- **8 November 2024** (10:00 – 11:00 CET): register here

Webinar: Submission of Manufacturers and Manufacturing Operations to PMS

- **25 November 2024** (10:00 – 11:30 CET): register here

Public system demo: 12 December 2024

How to stay informed on PMS Work

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PMS News page

Check:

- News
- Events announcements
- Downtime comms

Check regularly

PLM Newsletter

- See planned PMS engagement activities for upcoming quarter
- **Subscribe** here

Receive via email quarterly after subscription

PMS webinars

Latest training sessions:

- Access & use PMS PUI (3 Jun 2024)
- Access & use PMS API (8 Jul 2024)
- Pack sizes submissions webinar (11 Jul 2024)

Announced via EMA's Website Events Pages - usually with registration

Updated on 21 Oct 2024

PMS FAQ Document + PLM Portal Forum

- Check FAQs on PMS (Document)
- Ask questions (Forum)

Check regularly

Quarterly System Demos

- See the latest developments
- Give your feedback on features and priorities
- **Next system demo:** 12 Dec 2024

Announced via EMA's Website Events Pages - broadcast live

PMS Web Page

Find:

- PMS overview
- EU Implementation Guide

Check for general info on PMS

Subscribe to quarterly PLM Insights newsletter

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Further details on **planned PMS engagement activities** provided on the **quarterly PLM Newsletter**.

Next edition to be** published in **mid-Jan 2025

Subscribe by scanning the **QR code** or through this link.

Q&A Session

- **Join Slido.com** using this code **#PMSPUI** or scanning the QR code
- Ask your questions or vote the ones you would like to be answered
- We will read out **selected questions** that will be answered verbally

Thank you for your interest!

Further information

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