EMA
EUROPEAN MEDICINES AGENCY

PMS Product User Interface (PUI) training: Product data submission & bulk edit made easy

6 October 2025

10:00 – 12:00 CEST

Presented by Marcos Fernández Gómez
and Veronica Lipucci Di Paola

PMS Product Owners

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.

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Join at
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- 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*

- 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** 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.

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Housekeeping – Webinar materials sharing

Presentation will be available at:

- EMA Event Web Page

Recordings will be available at:

- EMA YouTube Channel

- EMA Event Web Page

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Aim of this webinar

Today's webinar aims at providing a **training session for MAHs** to showcase the **Product UI functionalities**.

DEEPEN YOUR KNOWLEDGE ABOUT THE PUI PORTAL

Gain step-by-step guidance on accessing, navigating, and utilizing PUI, including detailed instructions for submitting structured authorised product data.

UNDERSTAND THE IMPORTANCE OF CONSISTENT DATA ENRICHMENT

Explore the core principles behind the implementation of the enrichment process and identify the PMS data elements included in its scope.

COLLECT FEEDBACK & CLARIFY QUESTIONS

Address any questions to ensure you are fully prepared for the submission of structured product data via PUI.

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Agenda

1 **Welcome**
5 min
Marcos Fernández Gómez,
PMS Product Co-Owner, EMA

5 **BI reports and known issues**
10 min
Marcos Fernández Gómez,
PMS Product Co-Owner, EMA

2 **Background context**
10 min
Marcos Fernández Gómez,
PMS Product Co-Owner, EMA

6 **Next steps**
5 min
Veronica Lipucci Di Paola,
PMS Product Co-Owner, EMA

3 **PUI access management**
10 min
Veronica Lipucci Di Paola,
PMS Product Co-Owner, EMA

7 **Q&A**
25 min
Moderator: Vivian Leamy,
PMS Change Management Team

4 **Enriching PMS + Live Demo**
50 min
Veronica Lipucci Di Paola,
PMS Product Co-Owner, EMA

8 **Closing**
5 min
Veronica Lipucci Di Paola,
PMS Product Co-Owner, EMA
Marcos Fernández Gómez,
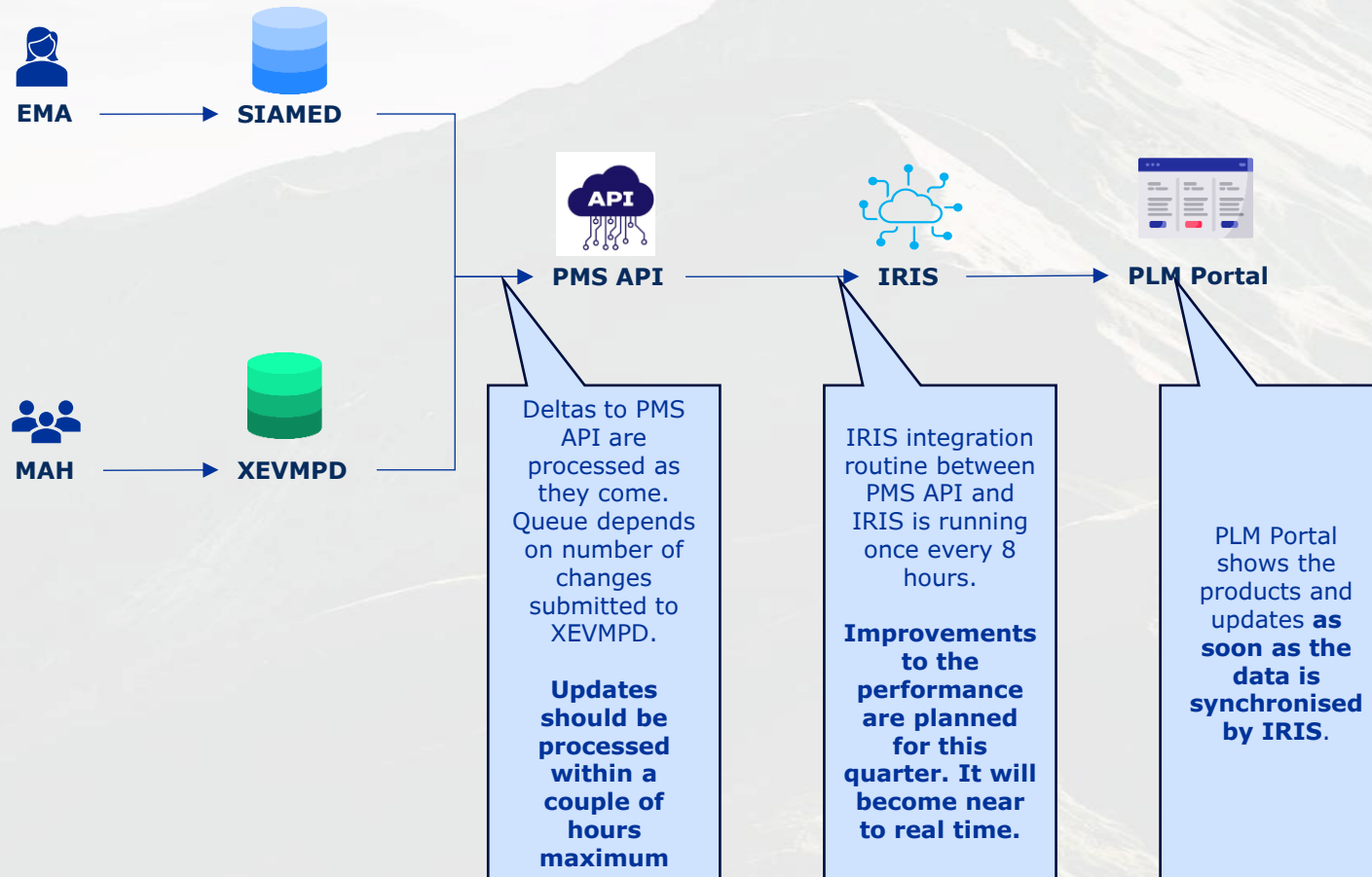PMS Product Co-Owner, EMA

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Background context

Product data flow

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Product data flow

EMA → SIAMED

MAH → XEVMPD

SIAMED and XEVMPD → PMS API → IRIS → PLM Portal

PMS API: Deltas to PMS API are processed as they come. Queue depends on number of changes submitted to XEVMPD.

Updates should be processed within a couple of hours maximum

IRIS: IRIS integration routine between PMS API and IRIS is running once every 8 hours.

Improvements to the performance are planned for this quarter. It will become near to real time.

PLM Portal: PLM Portal shows the products and updates **as soon as the data is synchronised by IRIS**.

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Product data flow

EMA → SIAMED

MAH → XEVMPD

PMS API is updated **as soon as the status completed** is shown in the UI

PMS API is updated **as soon as successful message** is accepted by PMS

PMS API → IRIS → PLM Portal

Product UI

Enrichment of product data (manufacturers and structured pack size data)

Web-based variation form using PMS products

Variation eAF (web)

MAH

Enrichment of product data (manufacturers and structured pack size data)

Consuming systems (ESMP, IRIS RPM)

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Summary

- Updates in SIAMED and XEVMPD are reflected in the PMS API almost real time.

- From PMS API to Product UI, it might take up to 8 hours. Improvements are expected to this integration.

- Enrichment process only applies, for the moment, to manufacturers, MBOs, data carrier identifier and structured pack size data for non-CAPs.

- Deadline for enrichment of products linked to ULCM is extended to June 2026.

- Packages should still be submitted to XEVMPD so then, they are reflected in PMS.

PUI User access management

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Access PMS Product UI – Role's overview

Industry roles

Function	Role names	PMS Access Level (*EU IG Ch.5*)
Read & Edit	PUI Industry User	Level 2b
	PUI Industry Qualified User	Level 2a
Read only	PUI Industry Read User	Level 2b *Coming soon!*
	PUI Industry Qualified Read User	Level 2a *Coming soon!*

Admin roles

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

Regulator roles

Function	Role names	PMS Access Level (*EU IG Ch.5*)
Read only	PUI Competent Authority User	Level 3
Read & Edit	PUI Competent Authority Qualified User	Level 3 *Inactive*

Updated related documentation:

- EU IG Chapter 1 (Last update: September)
- PMS Product UI Registration Guidance (PLM portal) (Last update: September)
- Onboarding of SPOR user roles (Last update: June)

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PMS UI Access: Administrative role

IRIS/PLM Industry & NCA Admin user roles

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**

PMS UI Access: Read & Edit (User & Qualified User)

Industry/NCA

› Current roles released since the first go live in May 2024

› Valid for **Read & Edit access** to PMS UI data (**single & bulk** update functionalities)

› Based on **Multi-factor authentication (MFA)** in EMA Account management portal

Key role characteristics and recommendations

- **Industry users ->** Allowing **READ and EDIT 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

- **For the same user within the same Organisation, do not request multiple roles** (User <u>and</u> Qualified User). If so, the Qualified User role privileges prevail

- **PUI NCA Qualified User role is not enabled**. NCA users can request the regular PUI NCA User to access the full PMS product data set available in read-only mode, exceptionally.

PMS PUI roles are in synchronisation with eAF roles

- 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 Users having **eAF Contributor** role shall request **PUI User role**
  - PLM User having **eAF Coordinator/Manager** roles shall request **PUI Qualified User role**
- PLM User can have **different roles** across **different organisations**

PMS UI Access: Read-Only (User & Qualified User)

Industry

> Valid for **Read only access** to PMS UI data
> Based on **Multi-factor authentication (MFA)** in EMA Account management portal

Key role characteristics and recommendations

- Allowing **READ only PMS products data**
- Assigned to **single user** in IAM and at **ORG level**

- **Approved** by relevant **IRIS/ PLM Industry Admin** user(s) only
- **For the same user within the same Organisation,** not to mix read and non-read roles . If so, the role with highest level of privileges will prevail.

PMS PUI roles are in synchronisation with eAF roles

- PLM Users having **eAF Contributor** role shall request **PUI Read User role**
- PLM User having **eAF Coordinator/Manager** roles shall request **PUI Qualified Read User role**
- PLM Users **shall not request mixed eAF/PMS PUI Read 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**

Access PMS Product UI – User & Qualified User roles

START

Is the user organisation in OMS?

Yes → Does the user have an active EMA user account?

No → Request the new organisation in OMS

ORG ID available

Create an account at EMA Account Management System

User EMA Account Active

Log into EMA account management platform

Is there an IRIS/PLM Industry/NCA Admin role for the relevant ORG ID?

Request IRIS/PLM Industry/NCA Admin role for the relevant ORG ID

Which PMS system/tool do you want to access?

Role granted

PMS Application Programming Interface

If not requested, apply for the IRIS/PLM Industry/NCA Admin role to receive the API client credentials

FINISH — Connect your system to PMS API

PMS Product User Interface

Are you an IRIS/PLM Industry/NCA Admin user?

Yes → Request the PUI Industry/NCA Qualified user role only

No → Request the PUI Industry/NCA user role or PUI Industry/NCA Qualified user roles

Role granted by admin user → Login to PMS PUI Portal

Role granted automatically

FINISH

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Take aways on PUI access request

Roles can be requested via **EMA Account Management portal (IAM)**

Access is based on ORG ID (at Organisation level)

EU IG Chapter 5 and **Annex A** specify the different access levels per type of role

Read & Edit users can edit data singularly or in bulk, based on the need

Read only users will be available in Q4 2025 (UAT is ongoing)
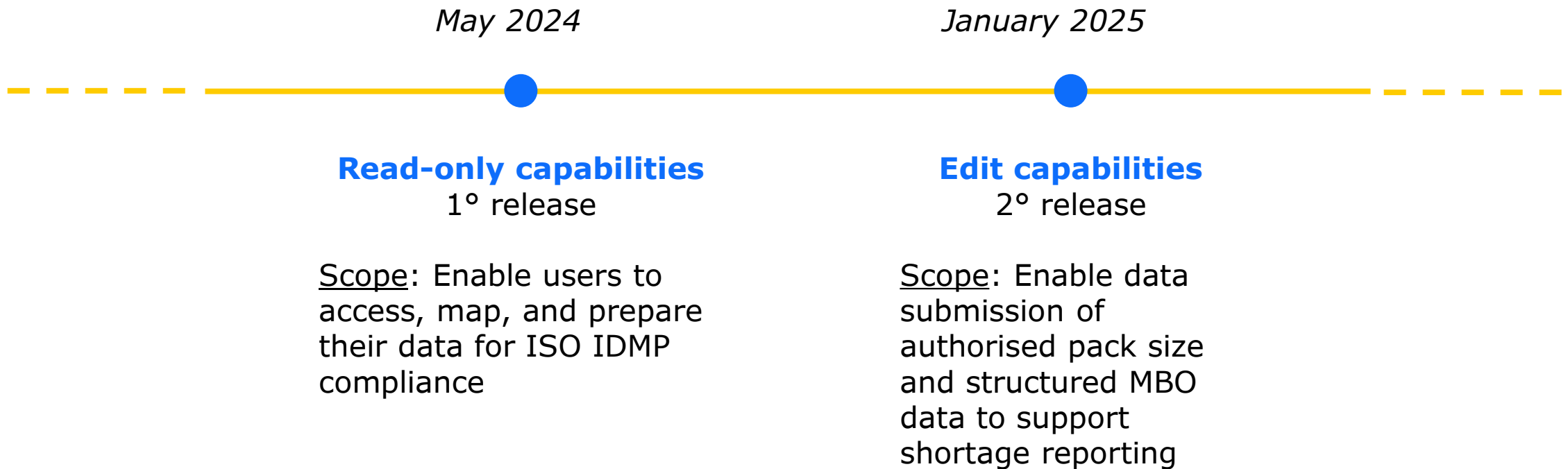
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Enriching PMS

History of delivered edit capabilities

May 2024

January 2025

Read-only capabilities
1° release

Scope: Enable users to access, map, and prepare their data for ISO IDMP compliance

Edit capabilities
2° release

Scope: Enable data submission of authorised pack size and structured MBO data to support shortage reporting

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PMS PUI Edit bulk functionality is live!

The PMS PUI Edit bulk functionality **went live on 22 September 2025**

Go-live communications:
- PLM Portal news
- PLM Newsletter (October issue)
- PMS EMA website

Questions and support:
The PMS team is available to answer your questions during Q&A sessions (currently planned until December 2025)

Key considerations for master data entry in PMS

Drivers

EMA considered challenges brought up by Industry vs PMS delivery

- **PUI Single product update** available as of 31 January 2025
- **PUI Bulk update and PMS API write** capabilities available from end **Q3 2025**
- Industry requires **6-9 months to set up their RIM** systems to submit data via PMS API

- Industry **heaviest workload** is on preparing/submitting **package sizes** to XEVMPD
- *Industry delays in submitting package sizes impacts overall **NCA** mapping efforts at package level*

Actions

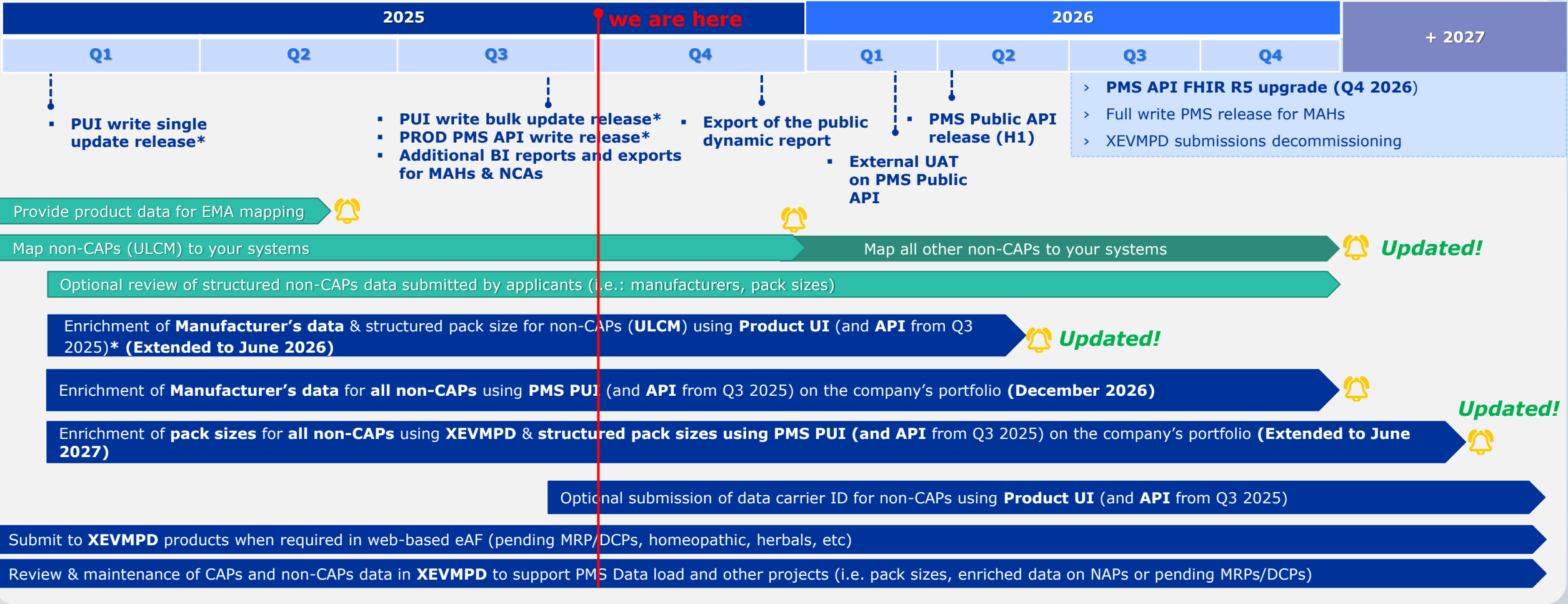**EMA agreed to extend the milestones for submission**

- Enrichment of **Manufacturer's & structured pack size data** for non-CAPs on the **ULCM** using Product UI and API

→ **Extended to June 2026**

- Enrichment of **pack sizes** for **all non-CAPs on the company's portfolio** using XEVMPD & **structured pack sizes** using PMS PUI and API
- *NCAs will map all other non-CAPs to their systems*

→ **Extended to June 2027**

EMA requires **actionable assurances** from industry associations to comply with new deadlines (i.e. ISG in Dec)

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Product Management Service roadmap

2025				we are here		2026				+ 2027
Q1	Q2	Q3			Q4	Q1	Q2	Q3	Q4	

- **PUI write single update release***
- **PUI write bulk update release***
- **PROD PMS API write release***
- **Additional BI reports and exports for MAHs & NCAs**
- **Export of the public dynamic report**
- **External UAT on PMS Public API**
- **PMS Public API release (H1)**

> **PMS API FHIR R5 upgrade (Q4 2026)**
> Full write PMS release for MAHs
> XEVMPD submissions decommissioning

Provide product data for EMA mapping 🔔

Map non-CAPs (ULCM) to your systems ▸ Map all other non-CAPs to your systems 🔔 *Updated!*

Optional review of structured non-CAPs data submitted by applicants (i.e.: manufacturers, pack sizes)

Enrichment of **Manufacturer's data** & structured pack size for non-CAPs (**ULCM**) using **Product UI** (and **API** from Q3 2025)* **(Extended to June 2026)** 🔔 *Updated!*

Enrichment of **Manufacturer's data** for **all non-CAPs** using **PMS PUI** (and **API** from Q3 2025) on the company's portfolio **(December 2026)** 🔔

Updated!

Enrichment of **pack sizes** for **all non-CAPs** using **XEVMPD** & **structured pack sizes using PMS PUI (and API** from Q3 2025) on the company's portfolio **(Extended to June 2027)** 🔔

Optional submission of data carrier ID for non-CAPs using **Product UI** (and **API** from Q3 2025)

Submit to **XEVMPD** products when required in web-based eAF (pending MRP/DCPs, homeopathic, herbals, etc)

Review & maintenance of CAPs and non-CAPs data in **XEVMPD** to support PMS Data load and other projects (i.e. pack sizes, enriched data on NAPs or pending MRPs/DCPs)

* (MVP) limited to structured pack size, manufacturers and MBOs data for non-CAPs

Acronyms

- **API:** Application Programming Interface
- **ASU:** Antimicrobial Sales and Use
- **CAPs:** Centrally Authorised Products
- **DCP:** Decentralised Procedures
- **eAF:** electronic Application Form
- **MAHs:** Marketing Authorisation Holders

- **MRP:** Mutual Recognition Procedure
- **MVP:** Minimum Viable Product
- **NCAs:** National Competent Authorities
- **PUI:** Product User Interface
- **UAT:** User Acceptance Testing
- **ULCM:** Union List of Critical Medicines

Legend

NCA action	MAH action	⋮ Milestone 🔔 Deadline

PMS data elements for enrichment

Manufacturer data:

- Manufacturer
- Manufacturing Business Operation type
- Manufacturing operation start date/end date
- Confidentiality indicator
- Manufacturing authorisation reference number
- Effective date
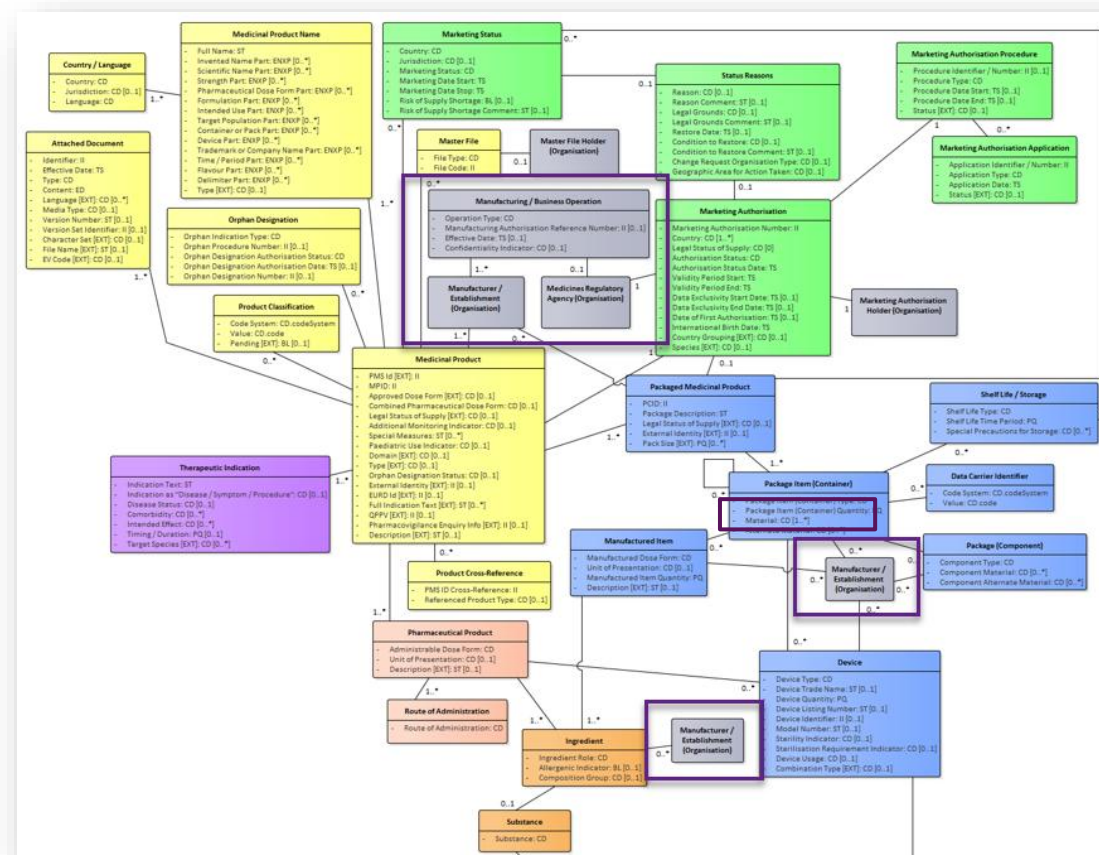- Medicines Regulatory Agency Organisation

Pack size data:

- Unit of presentation
- Quantity

Data Carrier Identifier:

- Identifier value
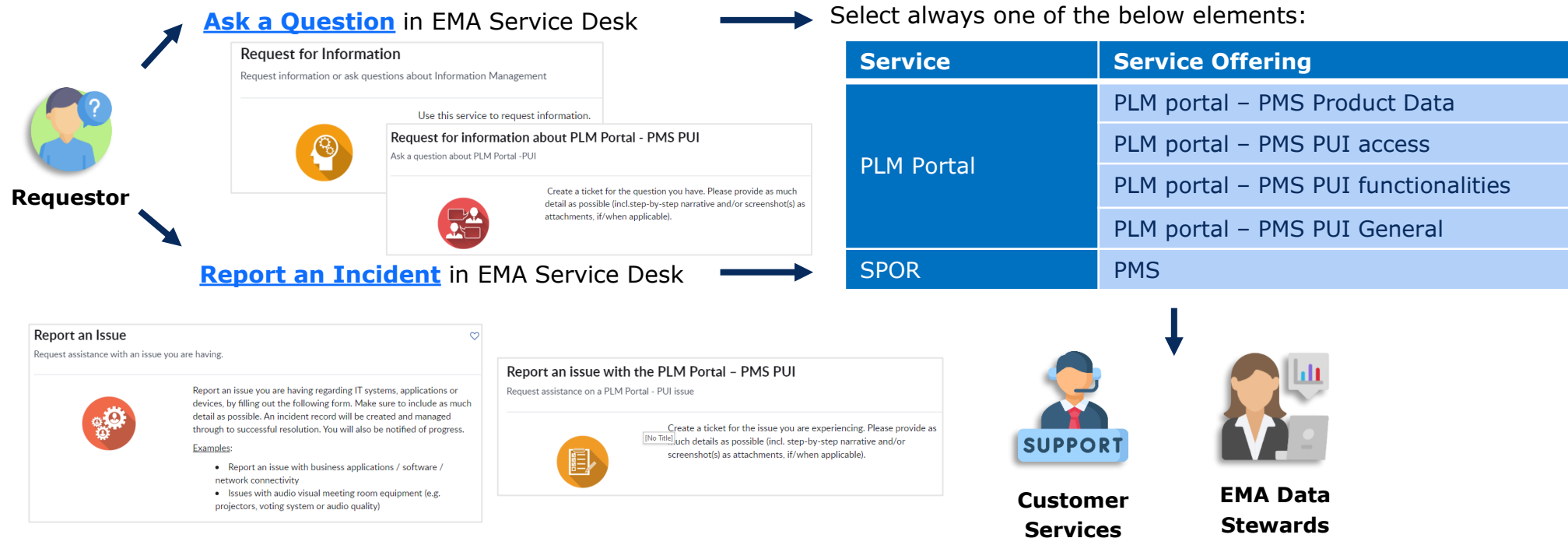- Identifier type

What to do before enriching my product?

1 Ensure packages are submitted in XEVMPD to retrieve the Package PMS ID (Instructions)

2 Ensure the packaged description is submitted in XEVMPD (Instructions)

3 Register to PMS PUI via EMA Account Management portal

4 Access the ULCM list & PUI "All ATC codes report" dynamic report to know if your product is impacted

5 Prepare in advance the product data to be structured in PMS

6 Enrich PMS with structured authorised products data reading the PUI Navigation guide/re-watching today's demo

7 Submitted data are synchronised into PUI within 1 calendar day, depending on API speed. Notify EMA in case of synch issues.

8 Remember to maintain your data updated during the product lifecycle

9 For data quality issues, please refer to PMS FAQ for the listed PMS data quality known issues before opening a ticket.

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How to notify EMA?

Which Service Desk ticket type can PMS users select?

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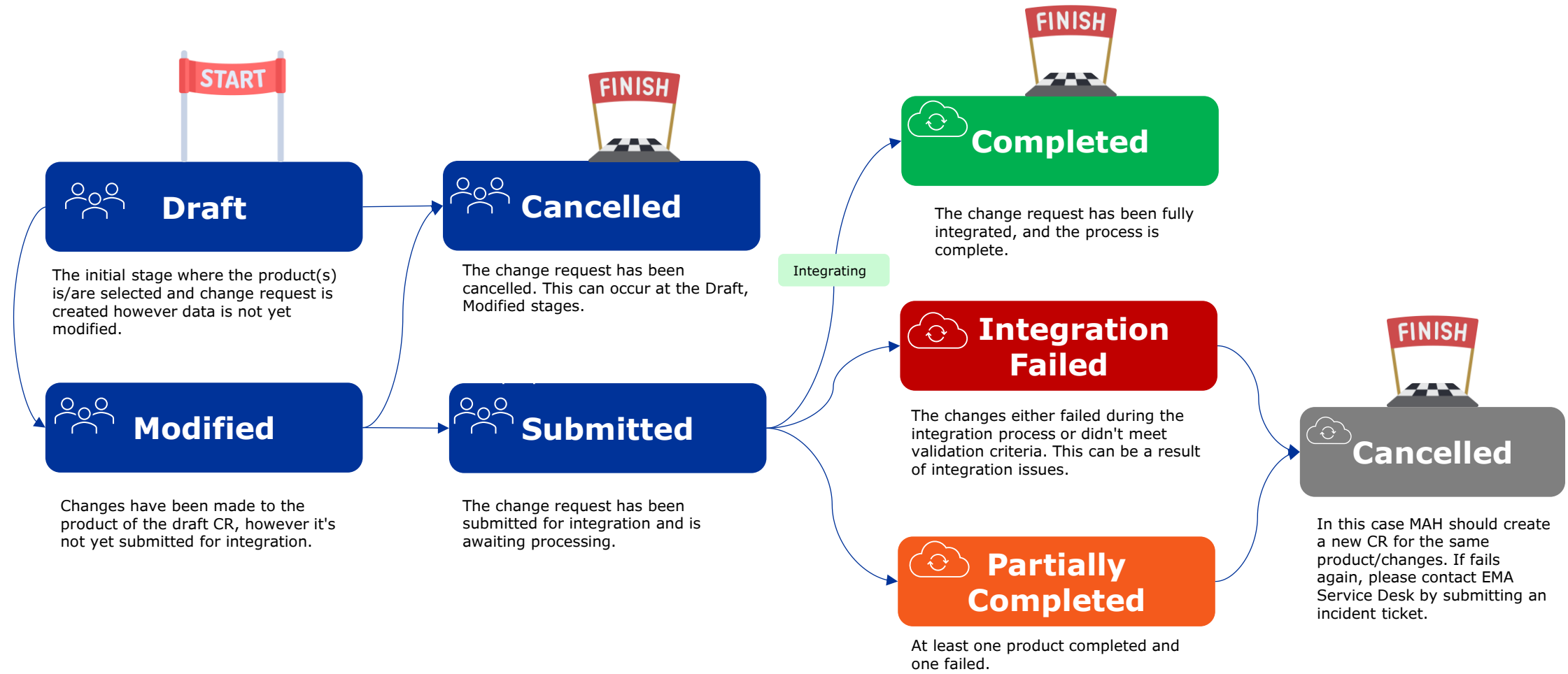
Requestor

Ask a Question in EMA Service Desk

Request for Information
Request information or ask questions about Information Management

Use this service to request information.

Request for information about PLM Portal - PMS PUI
Ask a question about PLM Portal -PUI

Create a ticket for the question you have. Please provide as much detail as possible (incl.step-by-step narrative and/or screenshot(s) as attachments, if/when applicable).

Report an Incident in EMA Service Desk

Report an Issue
Request assistance with an issue you are having.

Report an issue you are having regarding IT systems, applications or devices, by filling out the following form. Make sure to include as much detail as possible. An incident record will be created and managed through to successful resolution. You will also be notified of progress.

Examples:
- Report an issue with business applications / software / network connectivity
- Issues with audio visual meeting room equipment (e.g. projectors, voting system or audio quality)

Report an issue with the PLM Portal – PMS PUI
Request assistance on a PLM Portal - PUI issue

[No Title] Create a ticket for the issue you are experiencing. Please provide as much details as possible (incl. step-by-step narrative and/or screenshot(s) as attachments, if/when applicable).

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

Customer Services

EMA Data Stewards

Live demonstration!

Product data displayed during the demo are invented

PUI Change status

Draft

The initial stage where the product(s) is/are selected and change request is created however data is not yet modified.

Cancelled

The change request has been cancelled. This can occur at the Draft, Modified stages.

Completed

The change request has been fully integrated, and the process is complete.

Integrating

Modified

Changes have been made to the product of the draft CR, however it's not yet submitted for integration.

Submitted

The change request has been submitted for integration and is awaiting processing.

Integration Failed

The changes either failed during the integration process or didn't meet validation criteria. This can be a result of integration issues.

Cancelled

In this case MAH should create a new CR for the same product/changes. If fails again, please contact EMA Service Desk by submitting an incident ticket.

Partially Completed

At least one product completed and one failed.

PUI User action   System action   Note: Change Request status are all visible to users in PUI My Workspace area.

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BI reports and data quality

Events and useful resources

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Summary

- BI reports can be accessible based on user roles and for products of your organisation.

- Public report with full list of valid products in PMS can't be extracted yet. EMA is working on this functionality.

- There is no plan to create a report with the complete product data. Relationships and granularities in the PMS data model would generate an unmanageable report.

- The different reports can be used for multiple purposes:

  ◦ Reporting

  ◦ Analyse and compare data

  ◦ Support other reporting activities (e.g. shortages mitigation and prevention plans)

Known issues

- Main issues that can be found:

  ◦ If **transfers of MA** have not been done EV code to EV code, additional packages created are not visible in PMS. Expected resolution by Q4 2025.

  ◦ **Units of measurement or presentation** in the strength of active substance is missing. Main bug is fixed. A data fix is expected to be performed.

  ◦ **Duplicated products** or packages.

    – EMA is working to fix the source of the bug – Q4 2025

    – A possible data fix should be planned (analysis of the impacted products and perform the data fix)

  ◦ **Merged EV Codes** that should belong to different medicinal products:

    – EV Codes with the same data but belonging to different products (i.e. different MA numbers)

    – EMA is discussing with SMEs and NPO to gather all the country specific scenarios to implement the specific business rules.

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Known issues

- Stay informed on the known issues and their resolution by checking the [PMS Q&A document](#)

- Please, **do not** submit a ticket to SNOW if your product is impacted by a known issue. Those issues affect multiple products and will be prioritised and solved when capacity permits.

Next steps

Events and useful resources

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Upcoming events

SPOR & XEVMPD status update webinars

Live broadcast on event page

8 October 2025 (10:00 – 12:30 CET): Event page

Keep up to date with the latest developments across all Master Data services.

PMS API webinar

Unlocking PMS API potential: Edit functionality training for MAHS

16 October 2025 (10:00-11:30 CEST) Event page

Gather insights and training on API edit functionalities, including capabilities, registration, access, and security.

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Upcoming Q&A Clinics
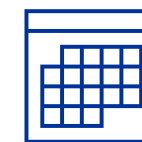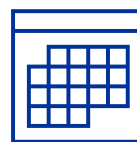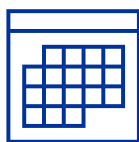
Q&A Clinics on SOR

- **13 October 2025** (11:00 – 12:00 CEST): Register here
- **10 November 2025** (11:00 – 12:00 CET): Register here
- **15 December 2025** (11:00 – 12:00 CET): Register here

The SOR team is available to answer questions regarding the SMS, RMS and OMS.

Q&A Clinics on PMS

- **14 October 2025** (11:00 – 12:00 CEST): Register here
- **18 November 2025** (11:00 – 12:00 CET): Register here
- **18 December 2025** (11:00 – 12:00 CET): Register here

The PMS team is available to answer questions regarding the PMS PUI and API.

Q&A Clinics on XEVMPD

- **14 October 2025** (14:00 – 15:00 CEST): Register here
- **18 November 2025** (14:00 – 15:00 CET): Register here
- **18 December 2025** (14:00 – 15:00 CET): Register here

The XEVMPD team is available to answer questions regarding the XEVMPD service.

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PMS Progresses | How to stay informed

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

- **Q&A Clinics** to answer users' questions
- **Targeted training sessions** on PMS systems' use

Check EMA's Website Events Pages (when also targeting Industry), EU-NTC (for Network only)

PMS FAQ Document + PLM Portal Forum

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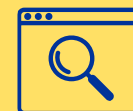- Ask questions (Forum)

Check regularly

Quarterly System Demos

- See the latest developments
- Give your feedback on features and priorities
- **Next system demo:** 26 Mar 2025

Announced via EMA's Website Events Pages - broadcast live

PMS Web Page

Find:
> PMS overview
> EU Implementation Guide

Check for general info on PMS

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Next issue mid-October

Subscribe to quarterly PLM Insights newsletter

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Q&A

⏱ 25'

- **Join Slido.com** using this code **#PUIBULKEDIT** 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

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