

Product Management Service (PMS) webinar on Product User Interface (PUI) edit functionalities for industry users

28 January 2025

10:00 – 12:00 CET

Presented by Veronica Lipucci Di Paola and Marcos
Fernández Gómez

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**.

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Join at
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#PMSEEDIT



- 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.

Housekeeping – Webinar materials sharing



Presentation will be available at:

- PLM Portal – PMS guide section
- EMA Event Web Page



Recordings will be available at:

- EMA YouTube Channel
- EMA Event Web Page



Aim of this webinar

Today's webinar aims at providing a **training session for MAHs** to explain how the single Minimum Viable Product (MVP) **enrichment process in PUI** works and showcase the edit functionalities for PUI in Product Lifecycle Management Portal.



DEEPEN YOUR KNOWLEDGE ABOUT THE PUI PORTAL

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



UNDERSTAND THE IMPORTANCE OF CONSISTENT DATA ENRICHMENT

Explore the core principles behind the implementation of the MVP 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 MVP product data via PUI.

Agenda

1

Welcome
5 min

Veronica Lipucci Di Paola,
PMS Product Co-Owner, EMA

5

Live demonstration
35 min

Veronica Lipucci Di Paola,
PMS Product Co-Owner, EMA

2

Background context
15 min

Veronica Lipucci Di Paola,
PMS Product Co-Owner, EMA

6

Next steps
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

7

Q&A
25 min

Moderator: Vivian Leamy,
PMS Change Management Team

4

MVP Data enrichment
20 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 Management Service (PMS) Vision



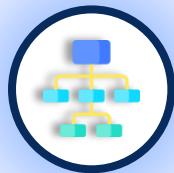
To make available, for human and machine interaction, **structured, standardised and consistent authorised product data** from across the European Medicines Regulatory Network.

PMS data to be used by regulators and industry in **regulatory and non-regulatory procedures** as well for the general benefit of European citizens.

Transform our stakeholders experience during the interaction with the regulatory Network by providing **an integrated customer and data digital journey through medicines regulatory processes, to the benefit of public human health in EU.**



Key changes



Enriched data set in ISO IDMP-compliant structure



Integrated data journey through regulatory procedures



Trustworthy and quality data in one single source

European Shortage Medicinal Product (ESMP) context



The EMA's role in **crisis preparedness and management** in reference to availability of medicinal products has increased significantly following the outbreak of the Covid-19 pandemic. **Regulation 2022/123** formalises the structures and processes established during the pandemic.



Improving the availability of medicines authorised in the EU is a key priority for the **European Medicines Regulatory Network (EMRN)**



Regulatory authorities - within and outside Europe - are increasingly **working together** to prevent shortages and to limit their impact whenever they occur

Vision



ESMP will enable **information exchange** for better **prevention, identification** and **management of shortages**, and communication between the EMA, National Competent Authorities and Industry stakeholders to **ensure medicines availability** for patients during Public Health Emergencies and Major Events.

Member State data systems

NCA's report critical national shortages and provide data on demand for medicinal products in crisis and in preparedness situations

Industry data systems

MAHs perform routine shortage reporting and provide data on supply of medicinal products in crisis and in preparedness situations

Welcome to ESMP

European Shortages Monitoring Platform

Sign In



Users access ESMP and download reporting templates or submit data through machine-to-machine interface

ESMP

Packaged medicinal product data / Manufacturing sites

Prefilled in ESMP templates/machine-to-machine

	A	B	C	D	E	F	G	H	I	J	K
1	Packaged	Medicinal product - (Full medicinal	Medicinal product	Active Substance	Strength	Pharmaceutical form	Pack Size	Packaging	PCID	Country of authorisation	Marketing Status
2	55880	Brintellix 5 mg - Film-coated tablet	Brintellix	Vortioxetine hydrobromide	5 mg	Film-coated tablet	100 tablets	Bottle	AT		Temporarily unavailable
3	55880	Brintellix 5 mg - Film-coated tablet	Brintellix	Vortioxetine hydrobromide	5 mg	Film-coated tablet	100 tablets	Bottle	BG		Marketed
4	55880	Brintellix 5 mg - Film-coated tablet	Brintellix	Vortioxetine hydrobromide	5 mg	Film-coated tablet	100 tablets	Bottle	IS		Marketed
5	55880	Brintellix 5 mg - Film-coated tablet	Brintellix	Vortioxetine hydrobromide	5 mg	Film-coated tablet	100 tablets	Bottle	LI		Temporarily unavailable
6	55880	Brintellix 5 mg - Film-coated tablet	Brintellix	Vortioxetine hydrobromide	5 mg	Film-coated tablet	100 tablets	Bottle	NO		Marketed
7	55878	Brintellix 5 mg - Film-coated tablet	Brintellix	Vortioxetine hydrobromide	5 mg	Film-coated tablet	98 x 1 tablets (unit dose)	Blister	BG		Marketed

Users **complete ESMP templates** with relevant information per product

Regulatory coordination

SPOC WP, MSSG, and EC

Measures to prevent, manage and mitigate shortages in EU/EEA, such as exploring MAHs supply capacity and possibility to increase production, regulatory support, etc.

Data analytics platform

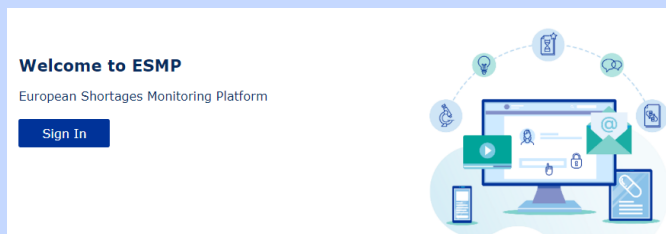


Matching of supply and demand data



Prevent, monitor and manage shortages





Users access ESMP and download reporting templates or submit data through machine-to-machine interface

ESMP

**Packaged medicinal product data /
Manufacturing sites**
Prefilled in ESMP templates/machine-to-machine

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Users **complete ESMP templates** with relevant information per product

ESMP consumes data from PMS.

More specifically, ESMP requires Medicinal Products, Packaged Medicinal Products, structured pack size data and Manufacturing Sites from PMS

ESMP pre-filled templates will show PMS data.

Product (package ID and name)

Active substance, strength and dose form

Structured pack size data
(quantity and units of
presentation)

Product Information									
Packaged medicinal product ID (PMS ID)	Medicinal product (Full medicinal product name)	Medicinal product (Invented name)	Active Substance	Strength	Pharmaceutical form	Pack Size	Packaging	PCID	Country of authorisation
P1.1	P1.2	P1.3	P1.4	P1.5	P1.6	P1.7	P1.8	P1.9	P1.10
Mandatory	Optional	Optional	Optional	Optional	Optional	Optional	Optional	Optional	Mandatory
76708	Xeljanz 5 mg - Film-coated tablet	Xeljanz	tofacitinib	5 mg	Film-coated tablet	60 tablets	Bottle		BE
76706	Xeljanz 10 mg - Film-coated tablet	Xeljanz	tofacitinib	10 mg	Film-coated tablet	180 tablets	Blister		NL
76707	Xeljanz 11 mg - Tablet, prolonged-release	Xeljanz	tofacitinib	11 mg	Prolonged-release tablet	112 tablets	Blister		AT
76709	Xeljanz 1 mg/ml - Oral solution	Xeljanz	tofacitinib	1 mg/ml	Oral solution	1 bottle + 1 syringe	Bottle		DE

ESMP users see PMS information as the basis and have to provide additional information such as marketing status for each pack size.

ESMP pre-filled templates will show PMS data.

Product (PMS ID and name)

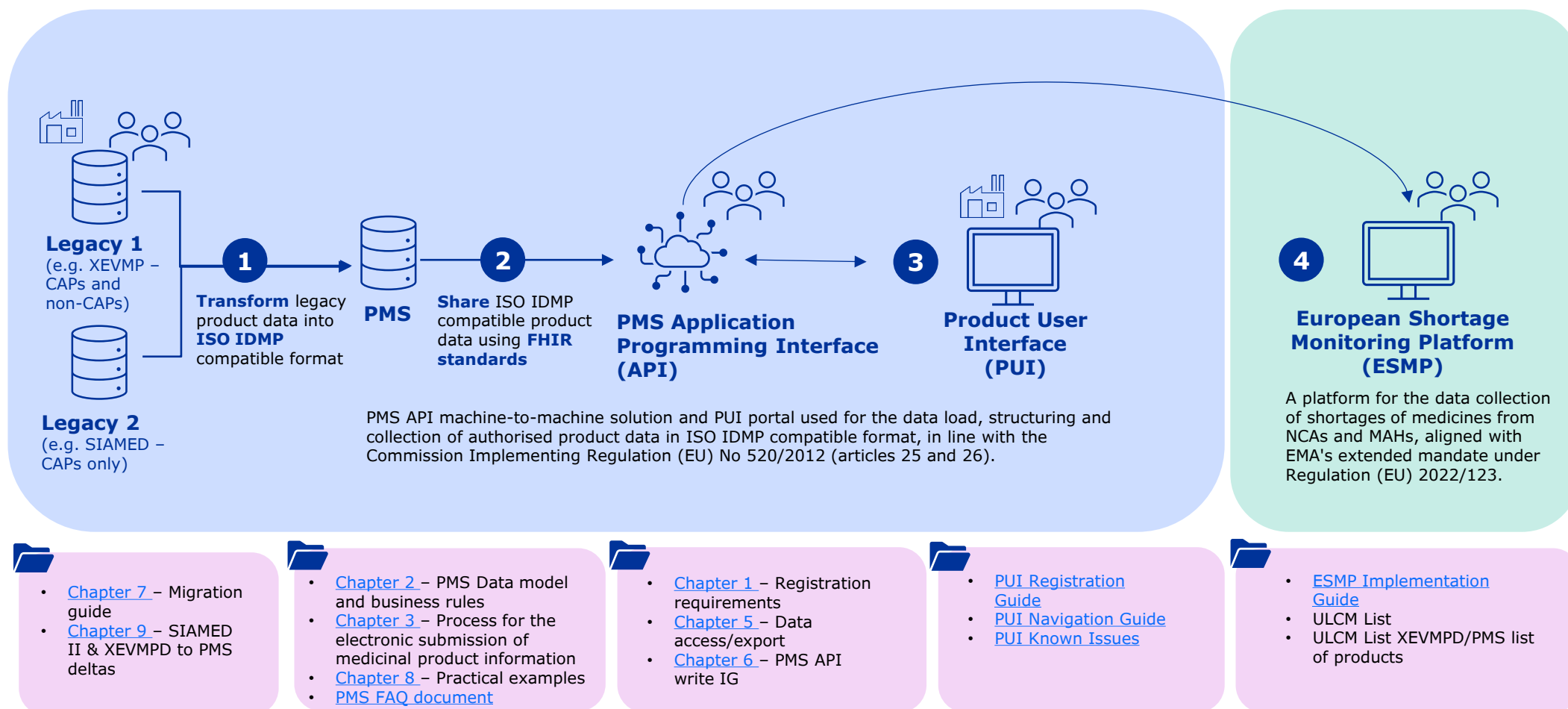
Manufacturers and MBOs

Product Information				Representative product		Organisation Information			
PMS ID (Medicinal product)	Full product name	Active substance SMS ID	Active substance	Representative product	Operation type ID	Operation type	ORG-ID (Manufacturer)	Manufacturer	LOC-ID (Manufacturer)
P1.1.2	P1.2.1	P1.3.1	P1.3.2	X1.1	O1.1	O1.2	O1.3	O1.4	O1.5
Mandatory	Optional	Mandatory	Optional	Optional	Mandatory	Optional	Conditional	Optional	Conditional
600000003161	Axazolol SUN 6.75 mg/0.9 ml - Solution for injection - 30 ml bottle/via 33456382;22345699		Paracetamol;Atosiban acetate		999999999999	Processing operations for the medicinal product	ORG-999999999	Sun Pharmaceutical Industries Limited	LOC-999999999
600000003161	Axazolol SUN 6.75 mg/0.9 ml - Solution for injection - 30 ml bottle/via 33456382		Paracetamol		1111111	Manufacturer of active substance	ORG-1000000000	Sun Pharmaceutical Industries Limited	LOC-999999999
600000003161	Axazolol SUN 6.75 mg/0.9 ml - Solution for injection - 30 ml bottle/via 22345699		Atosiban acetate		1111111	Manufacturer of active substance	ORG-1000000001	Sun Pharmaceutical Industries Limited	LOC-999999999

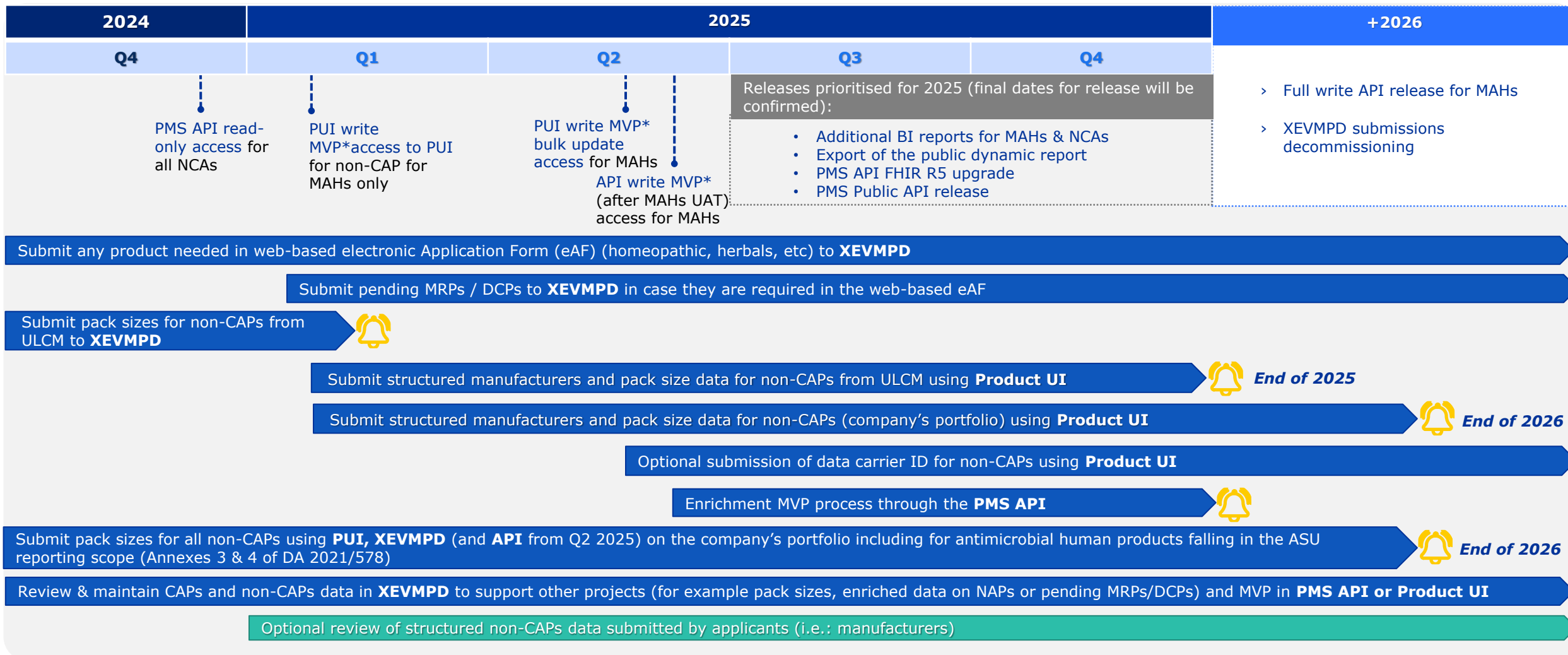
ESMP users see PMS information as the basis and have to provide additional information such as production capacity.



How ESMP relates to PMS?



Product Management Service (PMS) roadmap



* MVP: limited to pack size and manufacturer data only

Legend

NCA action

MAH action

Milestone



Deadline

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





PMS Product PUI

User access management

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Access PMS Product PUI – Role's overview

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	<i>Not available for the moment</i>

Updated user guide released in 2024:

- [EU IG Chapter 1](#) (Updated in Dec)
- [EU IG Chapter 5](#)
- [Annex A](#) to EU IG Chapter 5 (Updated in Dec)
- [On-boarding of users to SPOR data services](#)
- [PMS Product UI Registration Guidance \(PLM portal\)](#)



Access PMS Product PUI – Admin role



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**

Access PMS Product PUI – User & Qualified User roles



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 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 and 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.

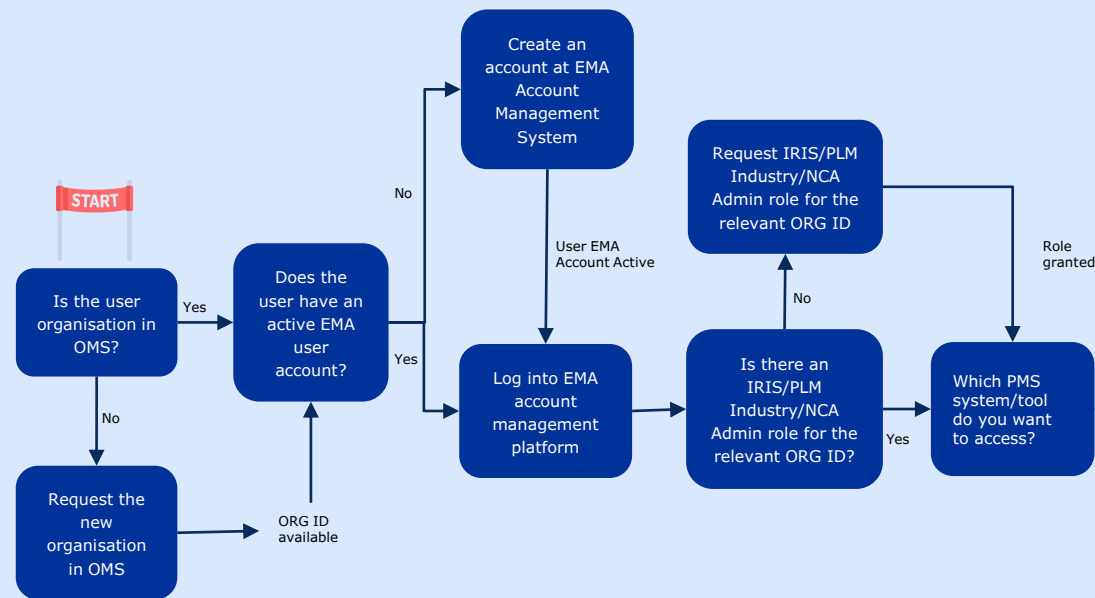


PMS PUI roles are in synchronisation with eAF roles

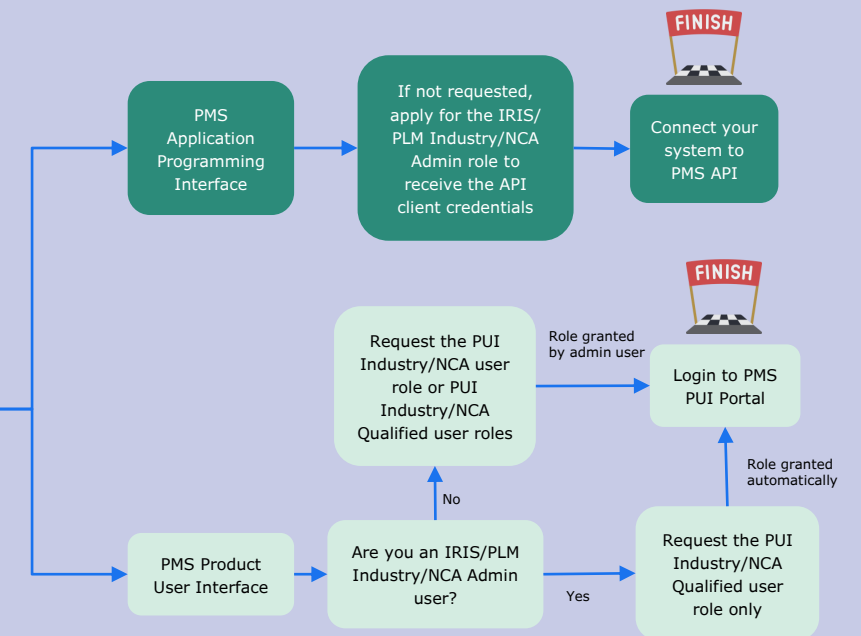
- PLM Users having **eAF Contributor** role shall request **PUI User role**
- PLM User having **eAF Coordinator/Manager** roles shall request **PUI Qualified User role**
- PLM Users **shall not request mixed eAF/PMS PUI roles for the same organisation** as this will result in the higher privileges bypassing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

Access PMS Product PUI – User & Qualified User roles

Step 1: Check/Request Admin role



Step 2: Role application-based request





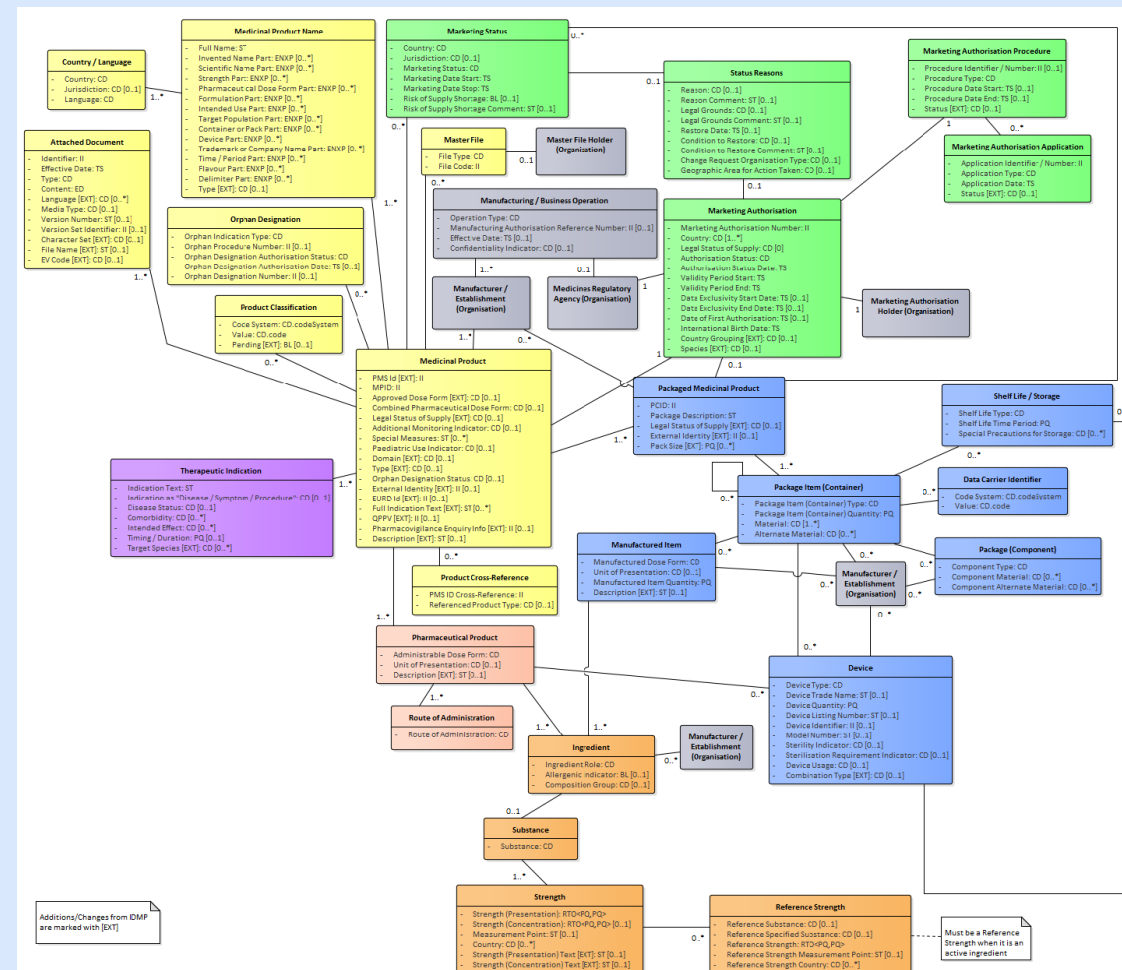
MVP Data enrichment

Slido #PMSEdit

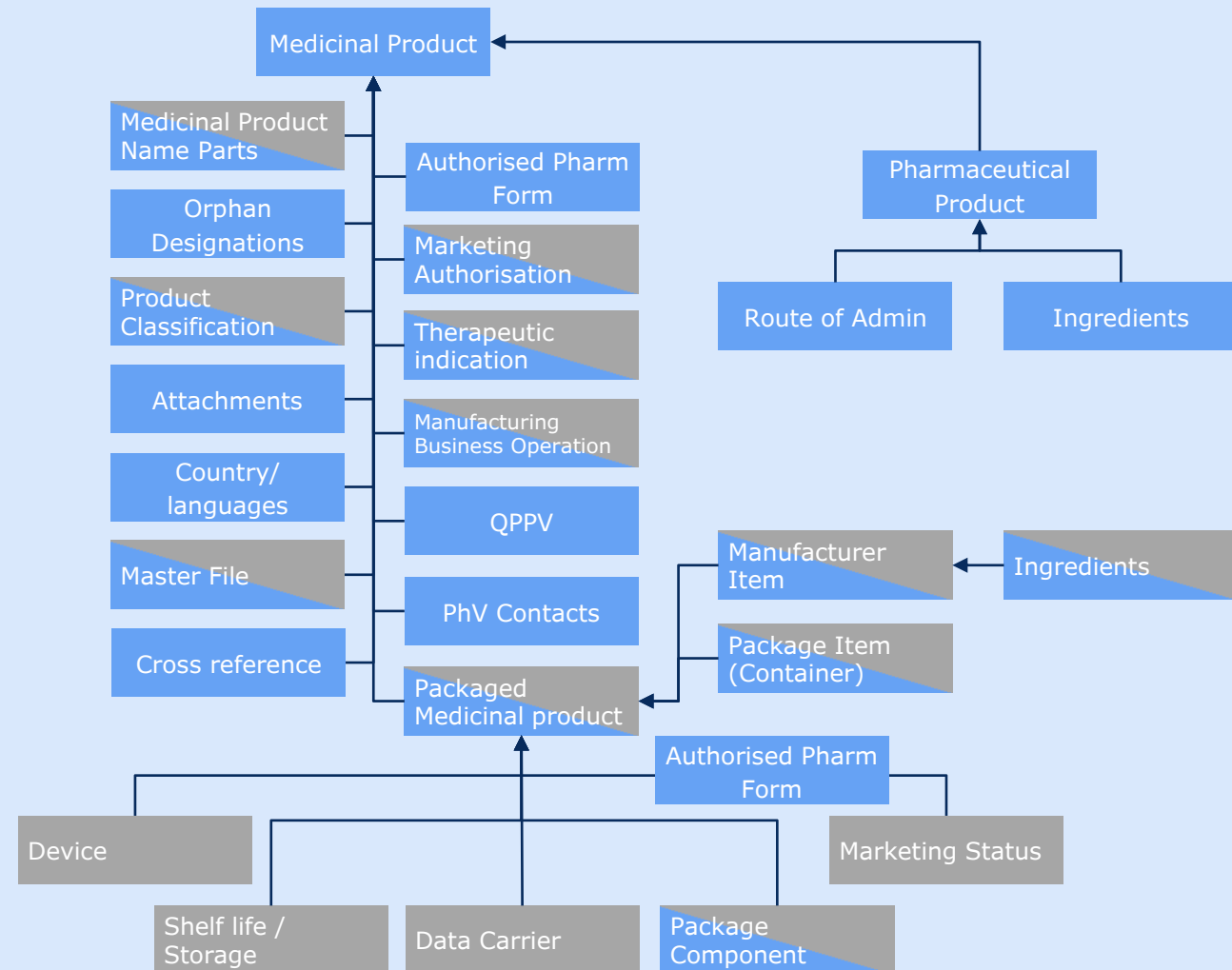
PMS data model



ISO IDMP	Description
ISO 11238	Data elements and structures for unique identification and exchange of regulated information on Substances
ISO 11239	Data elements and structures for unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging
ISO 11240	Data elements and structures for unique identification and exchange of units of measurement
ISO 11616	Data elements and structures for unique identification and exchange of regulated pharmaceutical Product information
ISO 11615	Data elements and structures for unique identification and exchange of regulated medicinal Product information



PMS data migration



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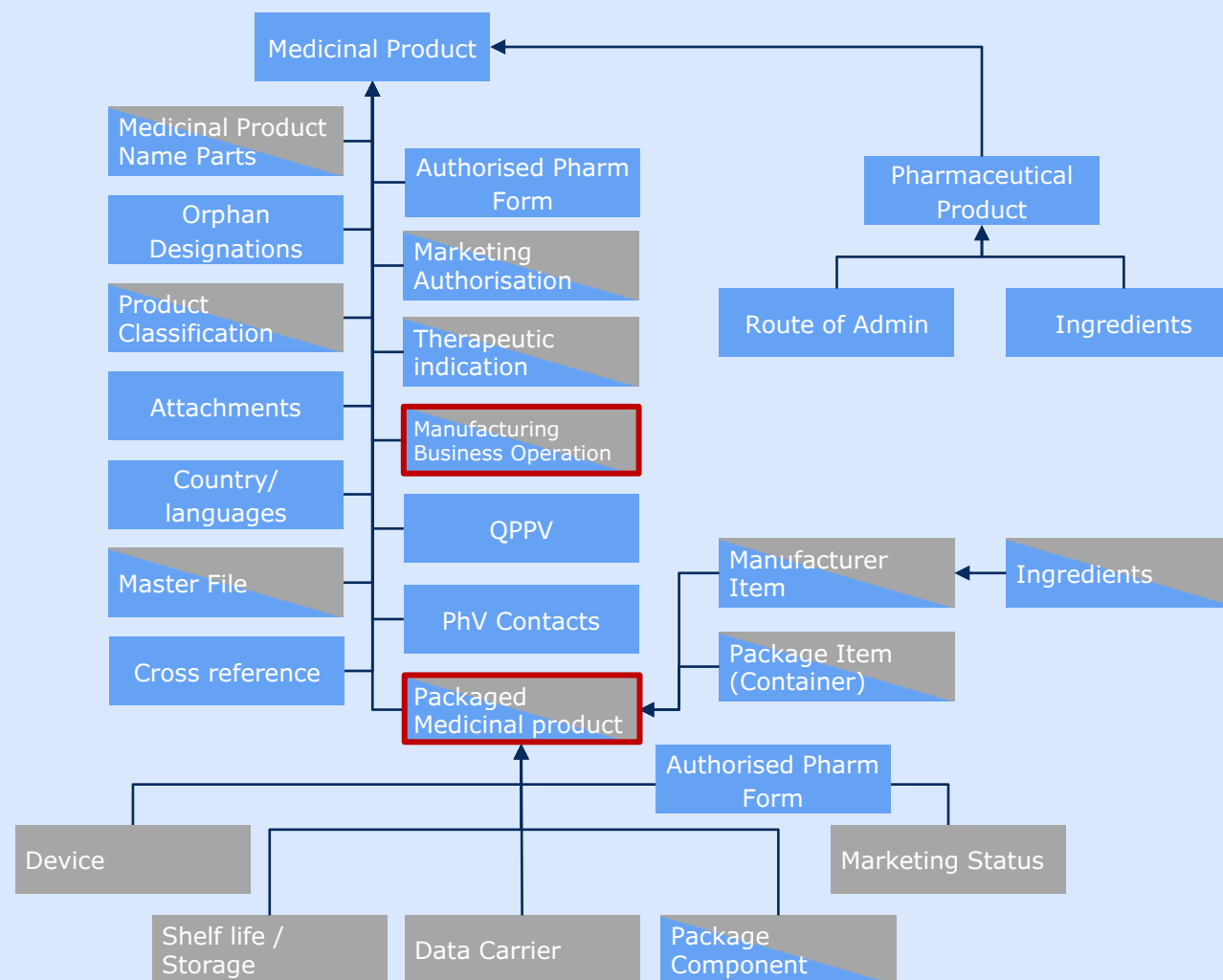
Which PMS elements can be enriched?

- Chapters 2 - PMS Data model and business rules
- Chapter 7 – Data migration rules

Data migrated from
SIAMED/XEVMPD

Data not migrated
from SIAMED/XEVMPD

MVP Data Enrichment
PMS fields (non-
CAPs)

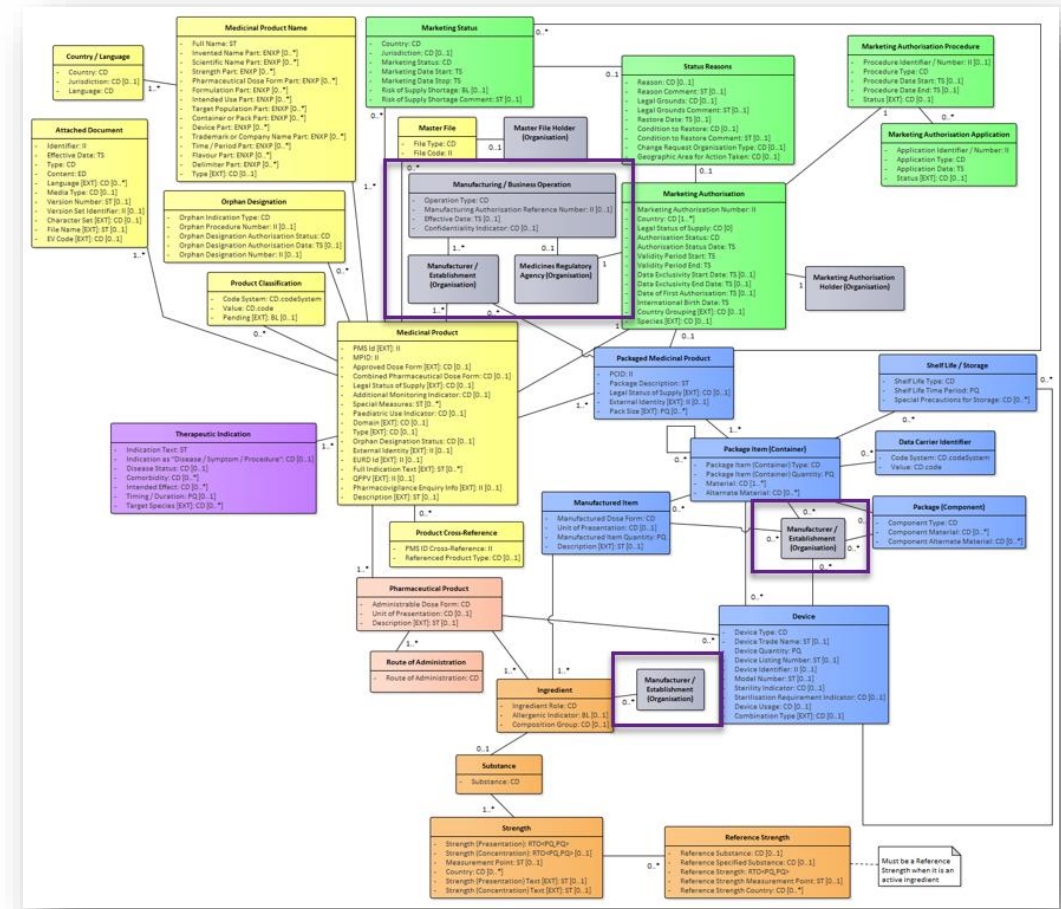


Structuring manufacturer and business operation data

Manufacturer data

Manufacturer data can be linked at the following levels:

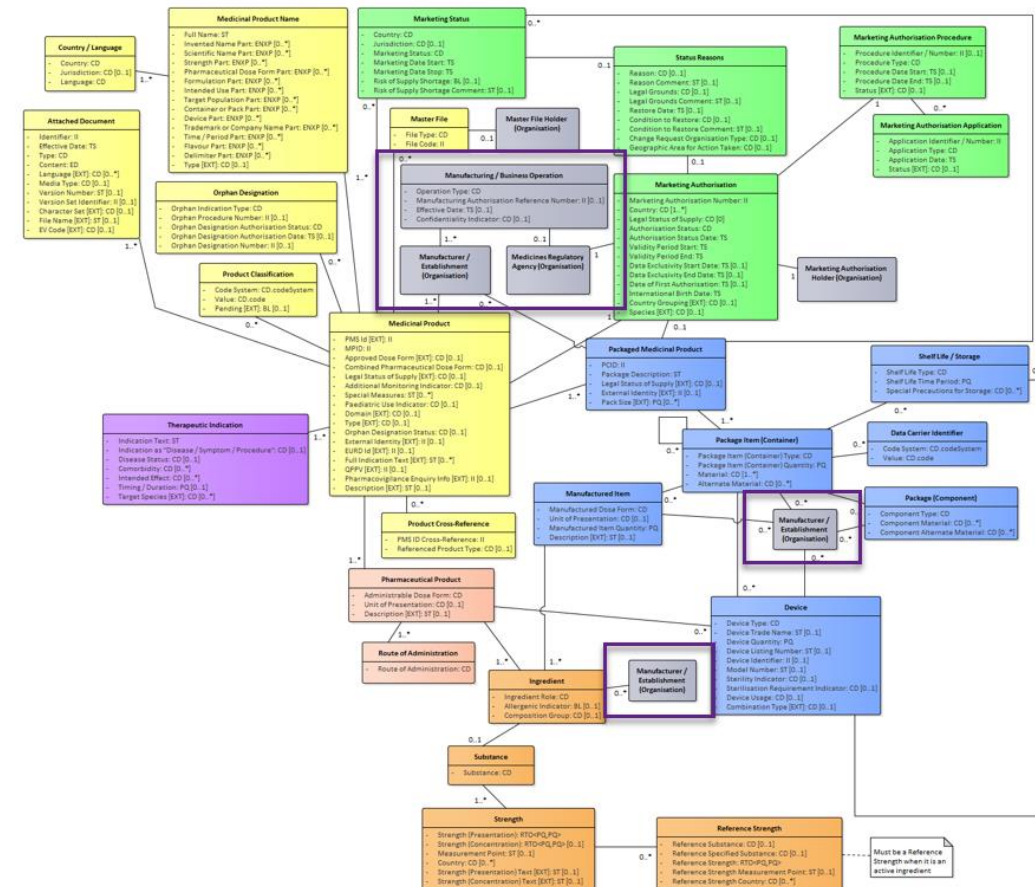
- Medicinal Product
- Packaged Medicinal Product
- Medical Device
- Manufactured Item
- Ingredients



Structuring manufacturer and business operation data

Manufacturer data

Attribute	Conformance	Value
Manufacturer	Mandatory	LOC ID
Manufacturing business operation type	Mandatory	Manufacturing Activity RMS list
Manufacturing operation start date	Conditional	DD-MM-YYYY
Manufacturing operation end date	Conditional	DD-MM-YYYY
Confidentiality indicator	Mandatory	Confidential or Public (Data Classification RMS list)
Manufacturing authorisation reference number	Conditional	Reference number
Effective date	Conditional	DD-MM-YYYY
Medicines Regulatory Agency Organisation	Mandatory	LOC ID



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Note: Refer to Chapter 2 for data element definitions.

Structuring manufacturer and business operation data

Manufacturer data

Attribute	Conformance	Value
Manufacturer	Mandatory	ORG ID/LOC ID
Manufacturing business operation type	Mandatory	Manufacturing Activity RMS list
Manufacturing operation start date	Conditional	DD-MM-YYYY
Manufacturing operation end date	Conditional	DD-MM-YYYY
Confidentiality indicator	Mandatory	Confidential or Public (Data Classification RMS list)
Manufacturing authorisation reference number	Conditional	Reference number
Effective date	Conditional	DD-MM-YYYY
Medicines Regulatory Agency Organisation	Mandatory	ORG ID/LOC ID

Create Manufacturing Operation

Manufacturer

Manufacturer: LOC-100043615: OAK Healthcare GmbH

Manufacturer details

Name *: OAK Healthcare GmbH

Address: Bahnstrasse 51
Steinbach (Taunus) 61449
Germany

Org ID: ORG-100026994

LOC ID: LOC-100043615

Manufacturing business operation

Operation Type *: Manufacturing of active substance

Manufacturing operation start date *: 12/01/2025

Manufacturing operation end date: DD/MM/YYYY

Confidentiality Indicator *: Confidential

Manufacturing authorisation reference number: test1

Effective date: 05/01/2025

Medicines regulatory agency organisation *: Austrian Agency For Health And Food Safety

Slido #PMSEDT

Note: Product data displayed in this slide are invented. Refer to Chapter 2 for data element definitions.

Structuring manufacturer and business operation data

Manufacturer data

Create Manufacturing Operation

Manufacturer

Manufacturer: LOC-100043615: OAK Healthcare GmbH

Manufacturer details

Name * OAK Healthcare GmbH

Address Bahnstrasse 51
Steinbach (Taunus) 61449
Germany

Org ID ORG-100026994

LOC ID LOC-100043615

Manufacturing business operation

Operation Type * Manufacturing of active substance

Manufacturing operation start date * 12/01/2025

Manufacturing operation end date DD/MM/YYYY

Confidentiality Indicator * Confidential

Manufacturing authorisation reference number test1

Effective date 05/01/2025

Medicines regulatory agency organisation * Austrian Agency For Health And Food Safety

The **Manufacturing Activity RMS list** has been updated on **23rd January 2025** upon revision of the multidisciplinary group of experts.

Short names and term **descriptions** have been included to each RMS term where it was missing or required updates.

User can select the most appropriate term using the star key (*)

Note: Refer to the list of operations applicable during the enrichment is described in **Annex II of EU IG Chapter 3** and take into account the **ESMP** and **eAF requirements**.

Lookup records

*active*substance

Choose one record and click Select to continue

✓	↑	Name
☐		Active substance intermediate physical processing
☐		Active substance physical processing
☐		Extraction of active substance from natural sources
☐		Manufacturing of active substance
☐		Manufacturing of active substance by chemical synthesis
☐		Manufacturing of active substance intermediate

Showing 1 to 10 of 15 entries

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Note: Product data displayed in this slide are invented. Refer to Chapter 2 for data element definitions.

Structuring pack size data

Pack size data

Attribute	Conformance	Value
Unit of presentation	Mandatory	Unit of presentation RMS list
Quantity	Mandatory	Numeric value

Add Pack Size

Unit of Presentation * ✕ 🔍

Quantity *

Medicinal Product ⤴ ⤵ Packaged Medicinal Product + Add Package

Download 📄

MA number	Package size(s)	PCID	EV code	Legal status of supply	Authorisation Status
035618014	6 Tablet	—	PRD513813	—	Valid

Package description 6 TABLET Language —

Pack Size + Add structured pack size data

Unit of Presentation	Quantity
Tablet	6

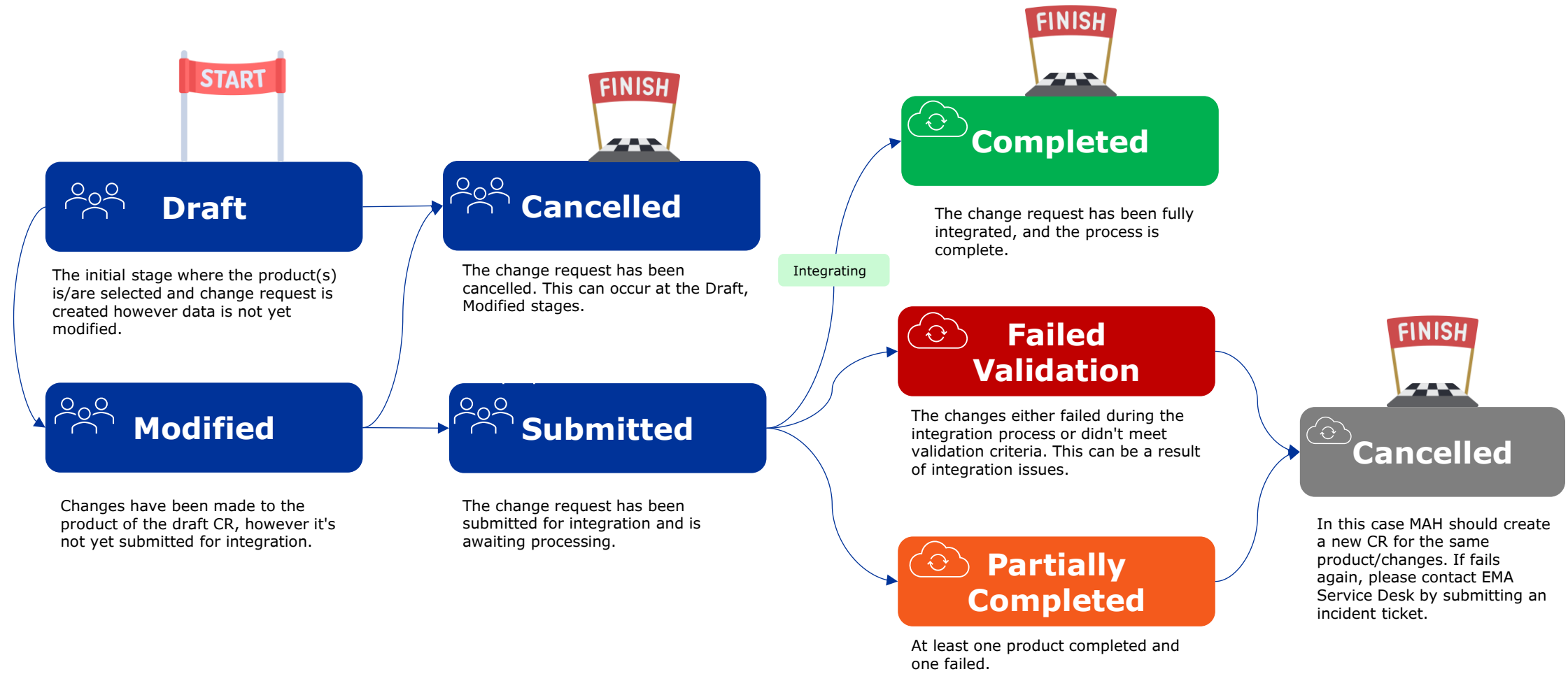
Definition: **The total number of units of the manufactured item or package item and represented per unit of presentation.** Refer to EU IG Chapters 2 and 8 for further details and examples.

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What do I need to know before enriching my product?

- 1 Ensure MAHs has submitted the packages in XEVMPD to retrieve the Package PMS ID ([Instructions](#)) ✓
- 2 Ensure, where applicable, MAHs has submitted the packaged description in XEVMPD ([Instructions](#)) ✓
- 3 Access the ULCM list released ✓
- 4 Access the ULCM PMS/XEVMPD list to see if my product is impacted ✓
- 5 Register to PMS PUI via [EMA Account Management portal](#) ✓
- 6 Check the correctness of your products data. If incorrect, notify EMA ✓
- 7 Refer to [PMS FAQ](#) for the listed PMS data quality known issues ✓
- 8 Gather the product data in the scope of the data enrichment ✓
- 9 Access [PUI portal](#) and submit structured products data through Change Request (CR) enrichment-type using the step-by-step PUI Navigation guide/Demo ✓
- 10 Check if the data is reflected in PUI (in case of issues/questions, notify EMA) & maintain it updated overtime ✓

PUI Change Request status



MAH's requirements: non-CAPs

PMS Data submission deadlines

- MAHs are required to submit structured manufacturer and pack size product data in PMS Product UI, as these data are not available in SIAMED or XEVMPD.
- Products **under ULCM** list: Deadline for data submission is **December 2025**.
- All **other products**: Deadline for data submission is **December 2026**.
- Ensure authorised product data are **kept updated** in both **XEVMPD** and **PMS**.
- Based on the queue, PMS updates data may not reflect immediately after submission in PUI.

XEVMPD/PMS Data submission timelines

Regulatory activity	XEVMPD	PMS (<i>Best practice</i>)
Initial MA	Within 15 calendar days from the date of MA notification	Within 15 calendar days from the date of MA notification
Post-approval ie. variation	Within 30 calendar days from the date of the authorized changes	Within 30 calendar days from the date of the authorized changes



For the moment, EMA accepts that PMS MVP Dataset is updated monthly.

Ref. [Electronic submission of medicinal product information by marketing-authorisation holders](#) and [PMS EU IG Chapter 3](#).

MAH's requirements: CAPs

PMS vs SIAMED data

- Structured manufacturer and pack size product data are accessible in PMS Product UI (sourced from SIAMED, per [PMS EU IG Chapter 7](#)).
- Review manufacturer details that have been migrated from SIAMED.
- Use the dynamic “Manufacturing Operation” report in the Product UI for insights.
- No additional information needs to be submitted to PMS.
- If incorrect data are found, raise an incident ticket to amend data in SIAMED (provide PMS ID and supporting documentation).
- PMS updates data in real time after each variation is approved in SIAMED.



Recommendation to MAHs



As of January 31, 2025, PUI enrichment functionality is available, however some data (e.g., ingredients, pharmaceutical products, ATC codes) may be temporarily inaccessible on the PLM PUI Portal due to ongoing data reloads.

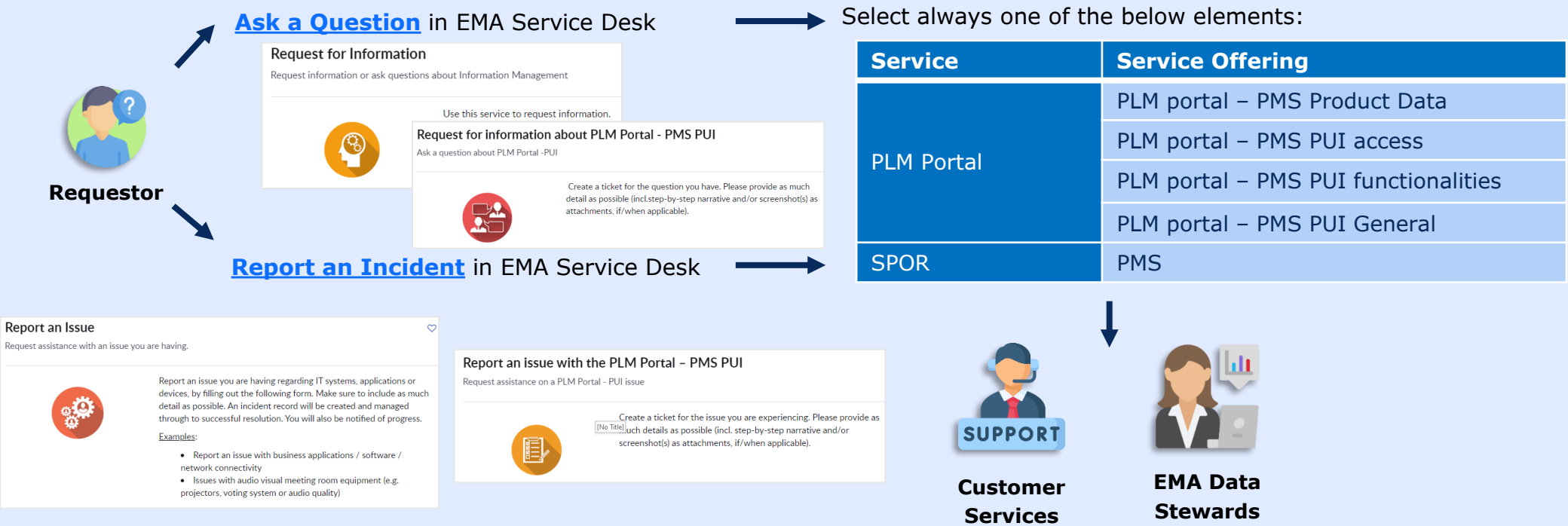
Updates to SIAMED or XEVMPD will be visible in PUI after the process completes, expected on February 14, 2025.

- **Verify Product Data:** Check if your product contains the correct and latest data (refer to the [PMS FAQ](#))
- **Proceed with Data Enrichment:**
 - If data are correct, proceed with single MVP data enrichment in PUI.
 - If data are incorrect or unavailable, wait for data to be fully loaded before submitting MVP data in PUI.
- As of **January 31, 2025**, MAH users can submit Change Requests in PUI for **single product updates** (update one product at a time)
- **Bulk update** functionality, allowing updates for multiple products simultaneously, will be released in **Q2 2025**.

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).



Live demonstration!

“Tell me and I forget, teach me and I may remember, involve me and I learn.”

Benjamin Franklin

Note: Product data displayed in this demo are invented.





What will be demoed?

TEST CASE 1:

- Create, modify and deactivate a CR

TEST CASE 2:

- Create, validate & submit a CR with structured manufacturer data & pack size in a single product

TEST CASE 3:

- Create, validate & submit a CR with structured data in multiple products

TEST CASE 4:

- Create, validate & submit a CR to remove previously submitted structured data in a single product

In each test case access to “Change Request details” and “My Workspace area” are shown.



Next steps

Events and useful resources

Slido #PMSEdit

Official release date of PMS Product PUI edit functionalities

31st January 2025 at 9 AM



Upcoming events



Q&A Clinics on PMS API & PUI

- **4 February 2025** (11:00 – 11:45 CET): [Register here](#)
- **13 February 2025** (10:30 – 11:15 CET): [Register here](#)
- **18 February 2025** (11:00 – 11:45 CET): [Register here](#)
- **25 February 2025** (11:00 – 11:45 CET): [Register here](#)

Public system demo

26 March 2025

***Live broadcast on
EMA's website
event page***

SPOR & XEVMPD status update webinars

***Live broadcast on
event page***

- **9 April 2025** (10:00 – 12:30 CET): [Event page](#)
- **9 July 2025** (10:00 – 12:30 CET): [Event page](#)
- **8 October 2025**
(10:00 – 12:30 CET): [Event page](#)

PMS Info-Day

21 May 2025 (9:00 – 17:30 CET)

***Live broadcast on
[event page](#)***

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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Slido #PMSEDT





Q&A



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



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Thank you



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