Industry Standing Meeting Q1 2025

European Shortages Monitoring Platform (ESMP)

28 March 2025
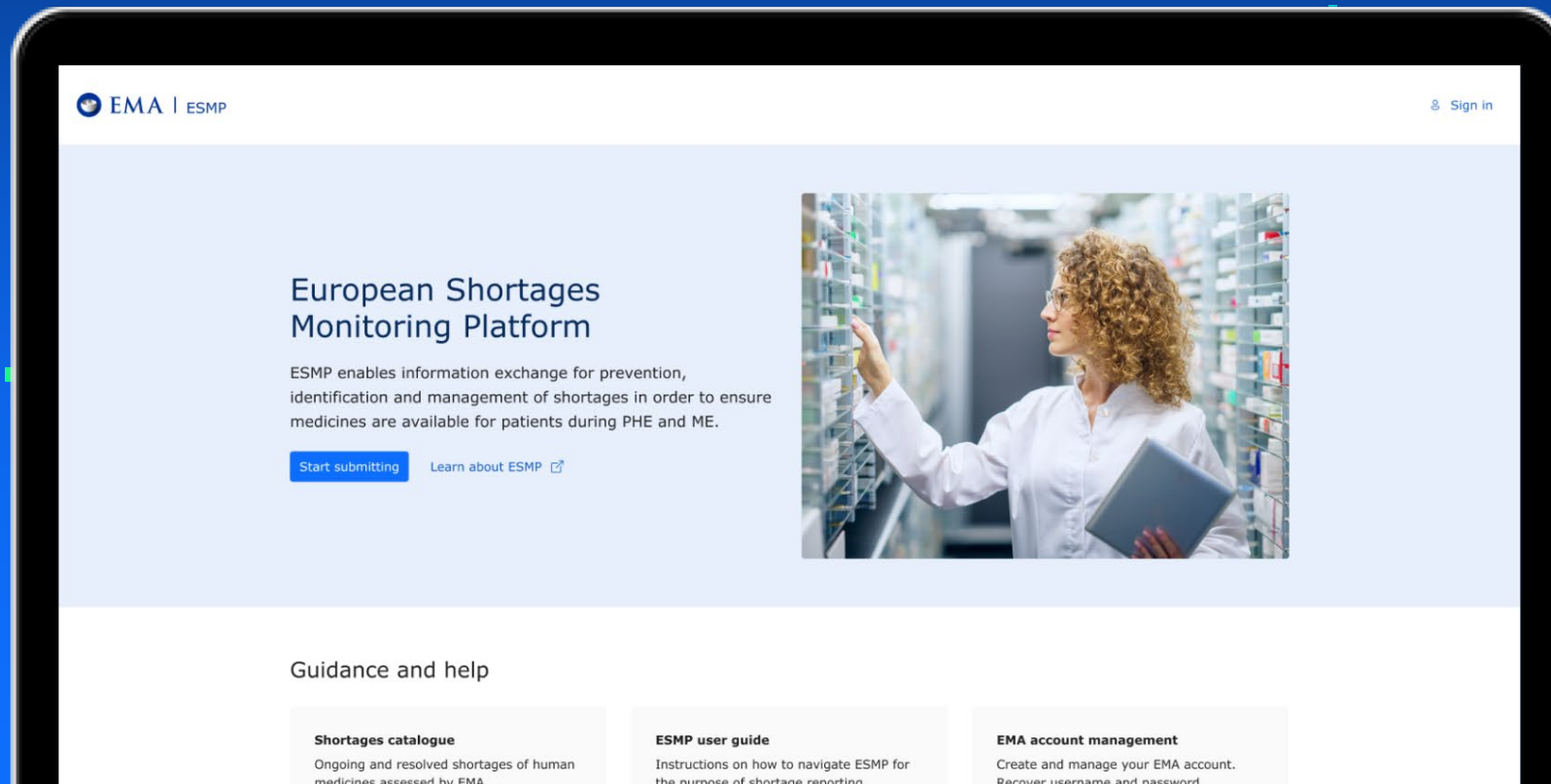
Agenda

- ESMP progress status

- PMS Readiness

- Previous and upcoming events

European Shortages Monitoring Platform (ESMP): progress update

November 2024

Go-live for industry routine shortage reporting for centrally authorised products (CAPs)

29 January 2025

Go-live for all industry and regulators' reporting

After February 2025

Maintenance and gap analysis for the inclusion of EMVS data

- The ESMP was successfully delivered **ahead of the regulatory deadline**, marking a significant achievement for EMA and everyone involved in its development.

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A team effort

- The **successful collaboration** with industry stakeholders, including SMEs and the ISG, was paramount to the delivery of the platform, ensuring it was **industry-aligned**, **innovative**, and **impactful**.

- **We are grateful** to everyone who collaborated with us to reach this important milestone. Across the Network and Industry, many people contributed to this milestone and success.

National competent authorities (NCAs)

- Network Product Owner
- Subject Matter Experts (SMEs)
- MSSG Members
- ESMP-MSSG Members
- SPOC WP Members
- IT Directors
- Volunteers for UATs

Marketing authorisation holders (MAHs)

- Subject Matter Experts (SMEs)
- Industry Standing Group
- Industry Trade Associations
- Volunteers for UATs

UAT: User Acceptance Testing

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Interoperability: Machine-to-Machine (API)

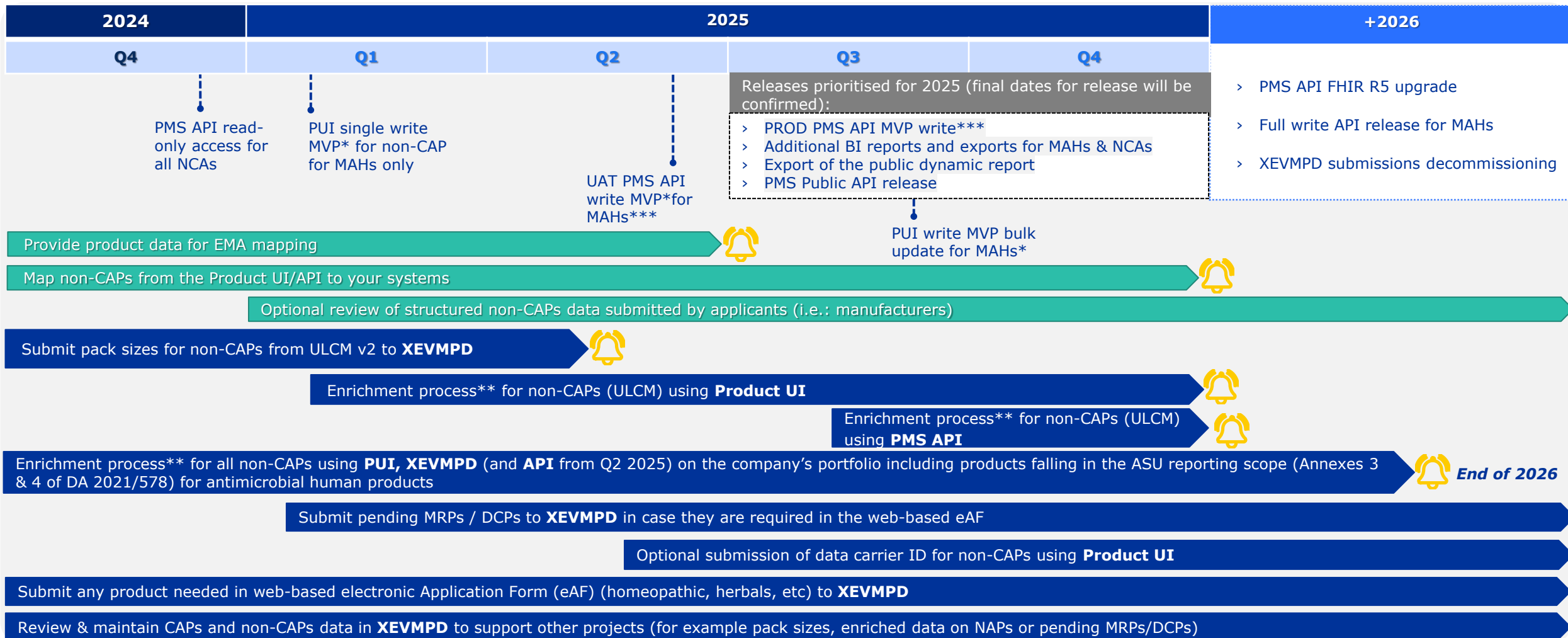|	National competent authorities (NCAs)	Marketing authorisation holders (MAHs)
Scope	• MSSG-led preparedness (CAPs+NAPs)	• Routine shortage reporting (CAPs)
Development status	• Completed	• Completed
Technical Documentation	• Final version shared	• Final version shared
Webinars	• 17 February 2025	• 24 March 2025 (event page)
Test environment available	• 14 March	• 28 March
Available (Production)	• 21 March	• 4 April

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Interoperability: API workshop with MAHs

- **Who:** MAHs of centrally authorised products (CAPs)

- **What:** workshop to demonstrate the usage of the ESMP API for routine CAP shortage reporting

- **When:** 24 March 2025

- **Why:** support stakeholders in adopting the ESMP, enabling effective shortage reporting through clear guidance and engagement opportunities

What else can you do?

- **Active participation** – join workshops, webinars, and discussions to stay informed and provide feedback

- **Engage with the platform** – access the testing environment (available soon) and participate in user acceptance testing

- **Tell us your thoughts** – contribute to the upcoming surveys to share insights and improve the platform

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Product Management Service roadmap

2024	2025				+2026
Q4	Q1	Q2	Q3	Q4	

Releases prioritised for 2025 (final dates for release will be confirmed):
- › PROD PMS API MVP write***
- › Additional BI reports and exports for MAHs & NCAs
- › Export of the public dynamic report
- › PMS Public API release

+2026
- › PMS API FHIR R5 upgrade
- › Full write API release for MAHs
- › XEVMPD submissions decommissioning

PMS API read-only access for all NCAs

PUI single write MVP* for non-CAP for MAHs only

UAT PMS API write MVP*for MAHs*

PUI write MVP bulk update for MAHs*

Provide product data for EMA mapping 🔔

Map non-CAPs from the Product UI/API to your systems 🔔

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

Submit pack sizes for non-CAPs from ULCM v2 to **XEVMPD** 🔔

Enrichment process** for non-CAPs (ULCM) using **Product UI** 🔔

Enrichment process** for non-CAPs (ULCM) using **PMS API** 🔔

Enrichment process** for all non-CAPs using **PUI, XEVMPD** (and **API** from Q2 2025) on the company's portfolio including products falling in the ASU reporting scope (Annexes 3 & 4 of DA 2021/578) for antimicrobial human products 🔔 *End of 2026*

Submit pending MRPs / DCPs to **XEVMPD** in case they are required in the web-based eAF

Optional submission of data carrier ID for non-CAPs using **Product UI**

Submit any product needed in web-based electronic Application Form (eAF) (homeopathic, herbals, etc) to **XEVMPD**

Review & maintain CAPs and non-CAPs data in **XEVMPD** to support other projects (for example pack sizes, enriched data on NAPs or pending MRPs/DCPs)

* MVP: limited to structured pack size data, manufacturers and MBOs
**only for structured pack size data, manufacturers and MBOs
*** Subject to Industry user's readiness

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
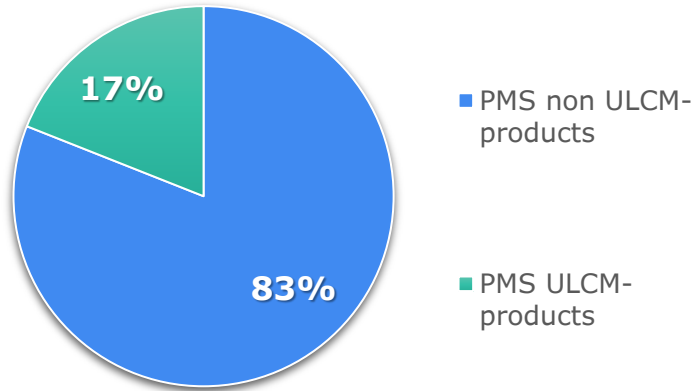- **MAHs:** Marketing Authorisation Holders
- **MRP:** Mutual Recognition Procedure
- **MVP:** Minimum Viable Product
- **NCAs:** National Competent Authorities
- **PUI:** Product User Interface
- **UAT:** User Acceptance Testing
- **ULCM:** Union List of Critical Medicines
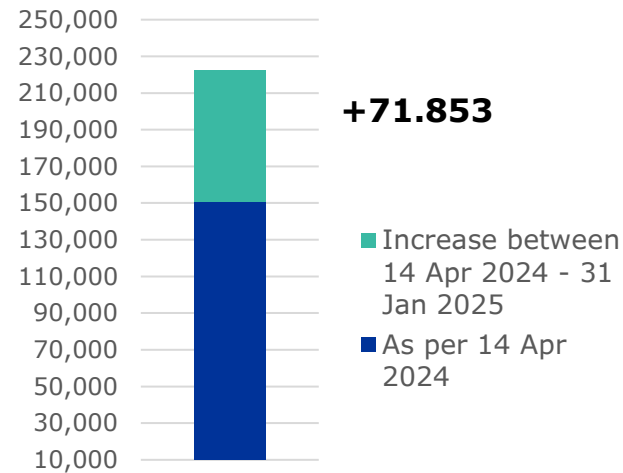
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PMS: MAH readiness

Overview of PMS products

Pie chart:
- 17% — PMS ULCM-products
- 83% — PMS non ULCM-products

Total products in PMS: 505.774

Calculation is based on ULCM v2

Packages of UCLM-products in XEVMPD

Bar chart y-axis values: 250,000; 230,000; 210,000; 190,000; 170,000; 150,000; 130,000; 110,000; 90,000; 70,000; 50,000; 30,000; 10,000

+71.853

Legend:
- Increase between 14 Apr 2024 - 31 Jan 2025
- As per 14 Apr 2024

Total packages as per 7th March 2025: 222.665

UCLM-products: status of manufacturers data in PUI

Pie chart:
- 7% — UCLM products without manufacturing data
- 93% — UCLM products with ≥ 1 manufacturer
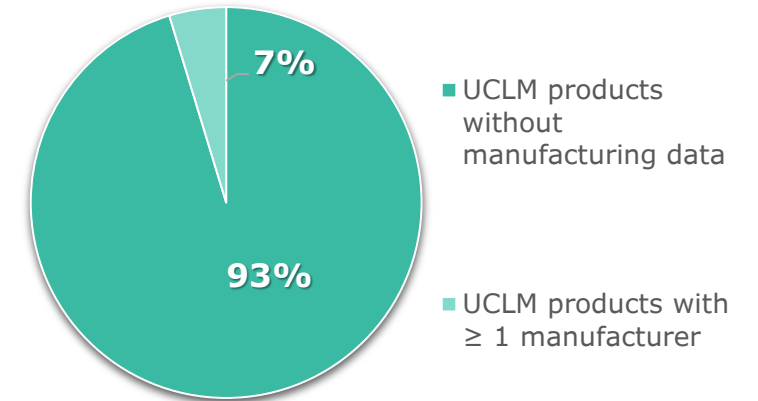
Calculation is based on ULCM v2 and as of 7th March 2025

Call to action for MAHs:

- **Complete submission of Packages in XEVMPD by end of May** - *needed ASAP to not impact NCA data mapping*
- **Complete submission of Manufacturers and structured Pack size data in PUI/PMS API**
  - › **CAPs** – submission not required as data is available, MAHs should confirm that PMS data is correct
  - › **Non-CAPs in ULCM list**– as of 31st January 2025 and until **end of December 2025**
 - › **Other non-CAPs**– as of 31st January 2025 and until end December 2026

ESMP change adoption survey: main outcomes

- **Who:** MAHs of centrally authorised products (CAPs)

- **What:** survey to assess whether users have started using ESMP to report shortages of CAPs to EMA, to gather insights on awareness, ease of use, challenges, and areas for improvement

- **When:** 22 January – 14 February 2025

- **Why:** evaluate the level of adoption and user confidence, identify success areas and areas for improvement, inform future improvements and initiatives

Audience

- 28 total respondents, between current and future users

- Have already used ESMP
- Have NOT used ESMP yet

36%

64%
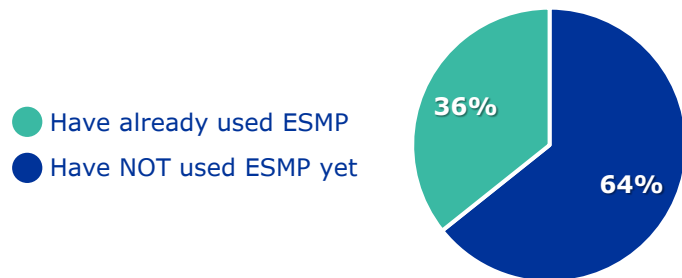
Positive feedback

- Users understand the different **reporting instances** via ESMP

- Current users have a clear understanding of **PMS and IRIS dependencies**

- Most users know where to find ESMP **guidance materials** and find them helpful

Areas for improvement

- Adding functionalities to enhance **usability**

- Users feel that companies have yet to **clearly define roles and responsibilities** for shortage reporting via ESMP

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Main recent and upcoming events

 20 November 2024: **MAH training** on routine shortage reporting

 29 January: Full **MAH User guide** published

 19 February: **MAH training** on crisis and MSSG-led preparedness reporting

 25 February: **MAH Q&A Clinic** on routine CAP shortage reporting

 24 March: **API workshop** for MAHs on routine CAP shortage reporting

 21 May: **PMS Info day**

 31 March – 25* April: **Survey** to gauge interest in API usage

* Post-meeting note: survey deadline extended

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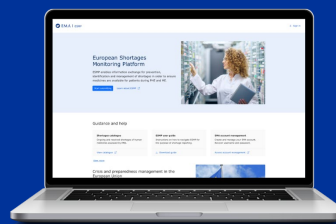# Useful links and resources for MAHs

User guide

Comprehensive **step-by-step guidance** to fulfill reporting requirements and data analysis.

Central **hub for information**, progress updates, guidance documents, timelines, **FAQs**, and more to keep you informed.

ESMP webpage

ESMP portal

Implementation guide

Detailed **technical specifications** and reporting data guidelines to ensure accurate submissions.

Structured **visual guides** to support you in following ESMP reporting processes.

Training recordings and video tutorials

All mentioned resources (and more) are published and linked on the dedicated ESMP webpage on the EMA corporate website.

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Thank you

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