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SCIENCE MEDICINES HEALTH

3.3 Update on the development of the European Shortages Monitoring Platform (ESMP)

Industry Stakeholder Group (ISG)

Presented by Sofia Zastavnik (ESMP Product Owner), Pedro Pina Ferreira (Monitoring VS Owner) and Marcos Fernandez Gomez (PMS Product Owner) on 28 June 2024

High level progress diagram

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Access Management

MAHs | NCAs | Public

Data collection

MAHs

Crisis / MSSG-led preparedness		Preparedness
User Interface	Alternative Therapies	User interface
Overview of critical medicines	Marketing status NAPs	Routine shortage reporting CAPs
Marketing status CAPs	Manufacturing details, production plan CAPs	
Availability of medicines	Production plan NAPs	

NCAs

Crisis	MSSG-led preparedness
User interface	User interface
Stock and supply	National demand
Patient estimation	
Medicine usage	

Analysis & Reporting

- Match supply and demand
- EMA dashboards and reports
- NCA dashboards and reports
- Public webpage

Shortages Management

- iSPOC registration
- Maintain lists of critical products
- Case management of CAP shortages

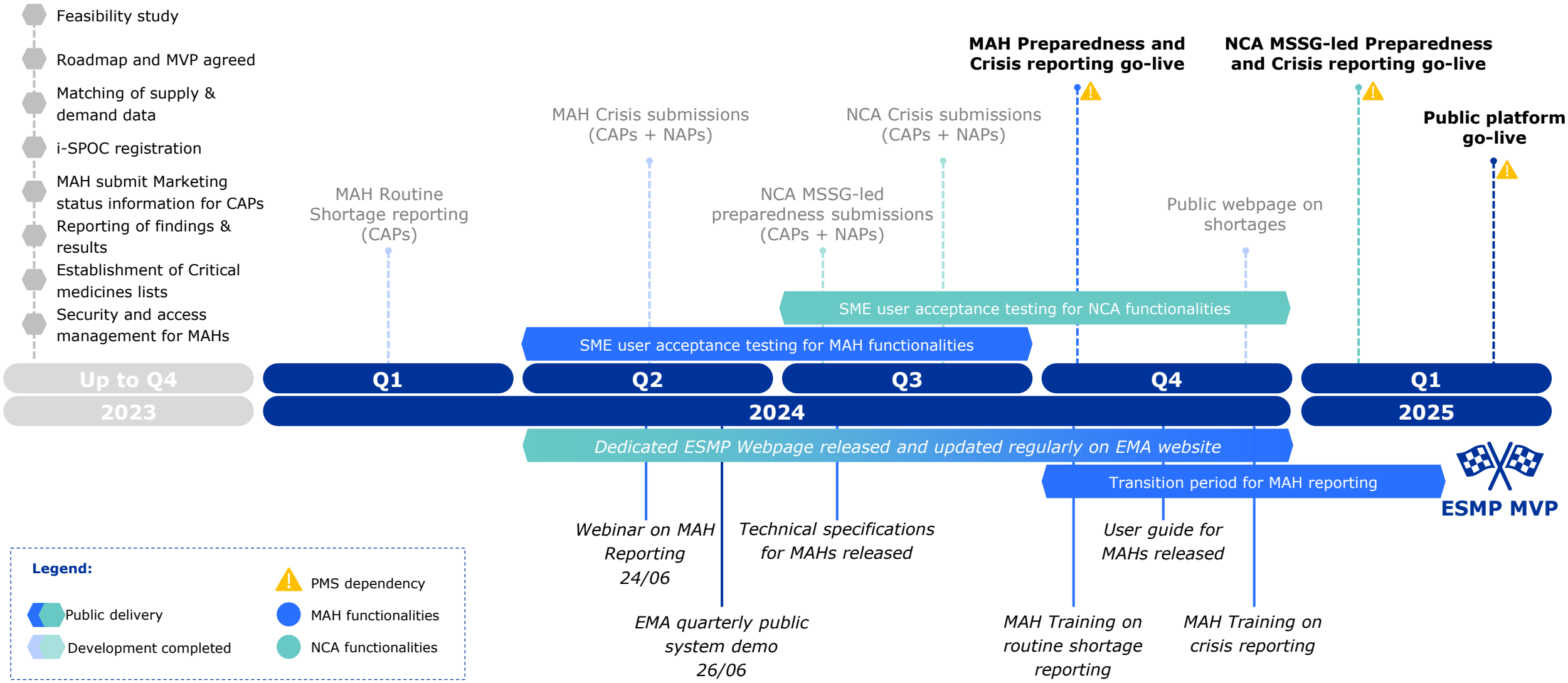
Data Integration

PMS integration (CAPs) | RMS integration | PMS integration (NAPs) | Interoperability

Completed | In Progress | Not Started

PMS : Product Management Services
RMS : References Management Services

Development timeline



User acceptance testing: initial results

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Objective	Ensure platform meets user requirements, functions correctly, is user-friendly, and fulfils user expectations
Duration	22 – 30 April 2024
Participants	MAH subject matter experts (SMEs)

Functionalities and items tested

- **Routine shortage** reporting
- **Crisis** reporting
  - Marketing status CAP (link to IRIS portal)
  - Availability Information
  - Alternative therapies
  - My critical medicines pages

For all data submission flows:

- Submission history
- Generating and downloading pre-filled templates with products in scope of reporting requirements
- Data submission
- Implementation guide
- User guide

Positive feedback

- Appreciated **overall functionality** of the platform
- User-friendliness of the ESMP **user interface** and ease of navigation
- No issues reported about **data display**

Areas for improvement

- **Complex reporting templates** and **conditionality rules for** data submission → **ACTION TO BE TAKEN**: refined reporting templates to reduce manual insertion of data (e.g., reduced no. of columns for shortage root cause, merged fields for shortage end date and shortage expected end date)
- **Slow platform performance** → **ACTION TO BE TAKEN**: changes in mechanisms for data upload and processing, targeting largest and most comprehensive data submission flows to reduce long processing times
- **Overly comprehensive user guidance**, including instructions and technical specifications, difficulty accessing RMS lists and lack of clarity of some definitions → **ACTION TO BE TAKEN**: merged user, implementation guides and RMS lists within the same document, refinement of data element definitions with Industry representatives

ESMP Essentials: summary of webinar for MAHs

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Objective	provide an overview of the ESMP and pharmaceutical industry reporting requirements through the platform
Duration	24 June, from 10:00 to 12:30 CEST
Target audience	Pharmaceutical industry, marketing authorisation holders of CAPs and NAPs

KEY TOPICS

ESSENTIALS

EMA **shortage management** processes at EU/EEA level

Overview of **ESMP vision, objectives, benefits**, components

ESMP **milestones and dependencies** with other EMA products and MAH requirements

REPORTING

Reporting processes: crisis, MSSG-led preparedness, routine reporting

Reporting requirements: MAH requirements in crisis, MSSG-led preparedness, routine reporting

Data elements in scope of reporting requirements to EMA through ESMP

Q&A session to gather doubts and concerns and address them

Please note that the webinar was broadcasted live, recorded, and will be available on the dedicated event page soon.

PMS to ESMP bridge: data flow

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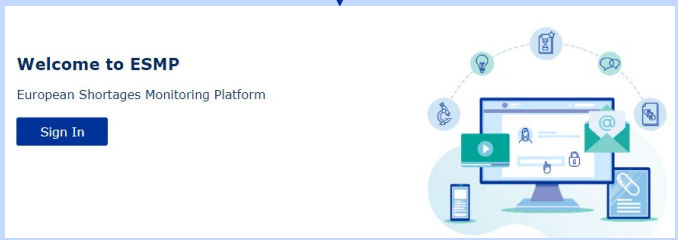
Member State data systems

NCAs 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

ESMP



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

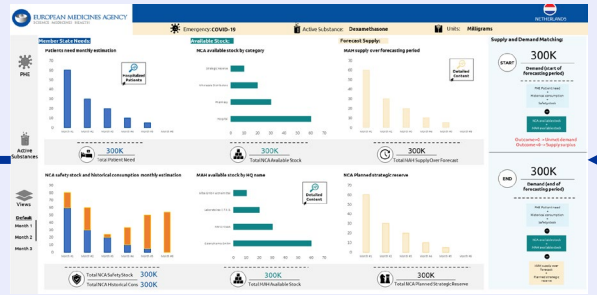
Packaged medicinal product data (PMS)

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
8											

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

Data analytics platform



Matching of supply and demand data

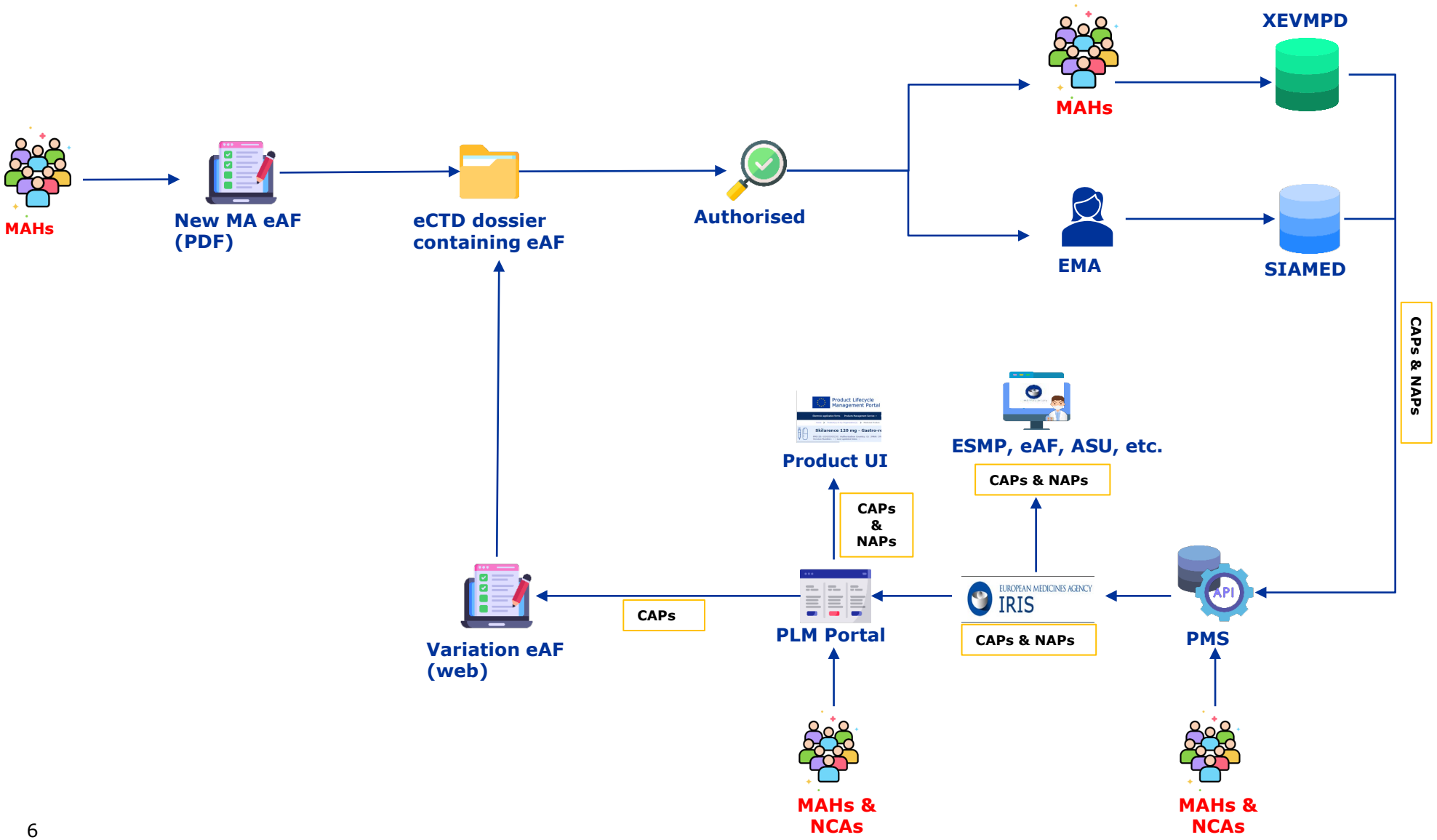
Regulatory coordination

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.

Prevent, monitor and manage shortages

Data process flow – from XEVMPD to other systems



From XEVMPD to PMS, used in ESMP

- Pack sizes submitted to XEVMPD will appear in PMS as well.
- From PMS, these pack sizes will be available in ESMP

Actions for MAHs

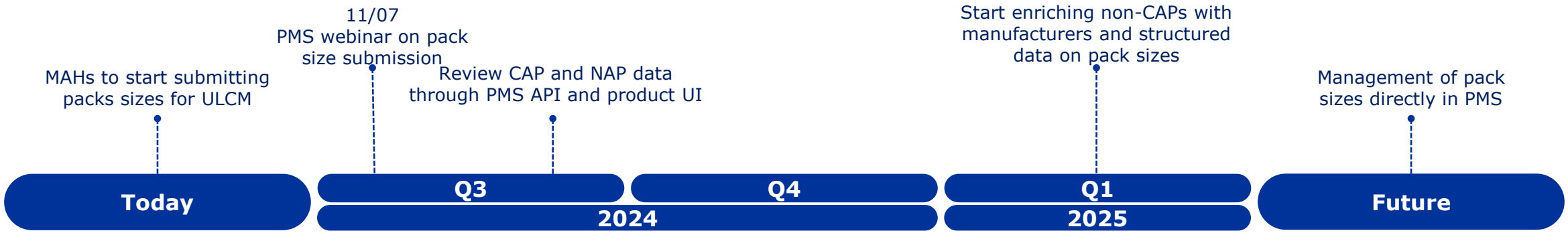
Make sure **authorised pack sizes** for products under the **Union List of Critical Medicines** are submitted to XEVMPD before **February 2025**

In case of a crisis or an MSSG-led preparedness exercise, MAHs will have **14 days** to submit pack size information to XEVMPD
By submitting the information now, **late submissions** by applicants may be **avoided**

From July 2024, MAHs will be able to review product information through the **product UI and PMS API** (pack sizes migrated from XEVMPD among other information)

From Q1 2025, MAHs will be able to provide **manufacturers** data for non-CAPs as well as **structured data for the pack sizes** (quantity and units of measurement) directly to PMS.

*PMS Team will host a **webinar on 11th July, 10:00 to 11:30 (CEST)**to provide information on pack size submission to XEVMPD*
Registration link



Actions for NCAs

National Competent Authorities

- From July (when NAPs are available in Product UI and PMS API):
  - NCA users can map PMS products to their database
  - NCA users can request EMA support for the mapping exercise

Next steps

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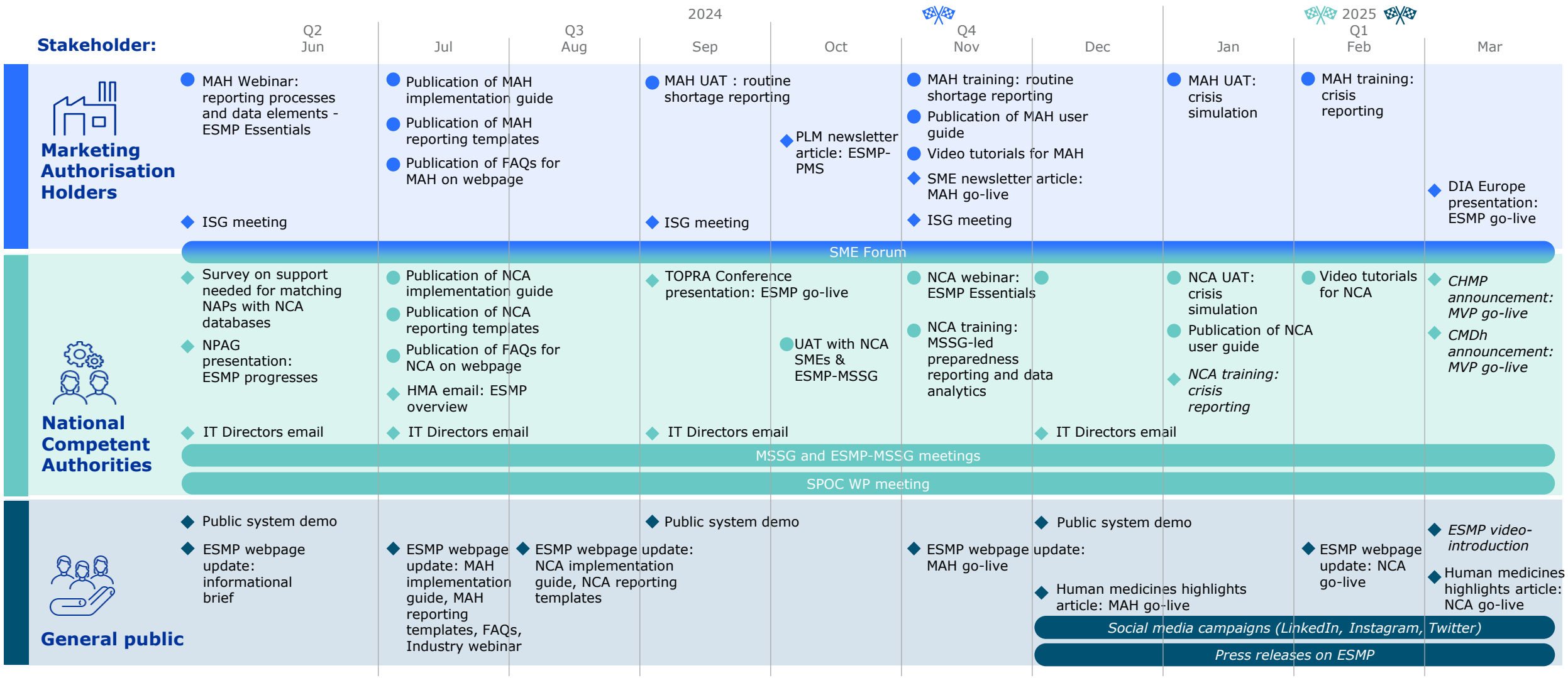

Legend: Training activities; Communication and engagement activities; MAH; NCA; General public; Go-live

Please note: the presented timings may be subject to change. Specific dates will be confirmed closer to each deadline.

Main recent and upcoming events

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- 17 April: **ESMP webpage** live on EMA website
- 24 June: **Webinar** on ESMP Essentials and MAH Reporting Requirements
- 26 June: EMA Quarterly public **System demo**
- 28 June: **Industry Standing Group** presentation
- July: ESMP **Communication plan** published

Legend: MAH NCA General public

Annexes

Overview of medicines' lists

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	Union list of critical medicines	List of medicines to be monitored for MSSG-led crisis preparedness	List of critical medicines for a public health emergency/major event
Available in:	Normal circumstances	Preparedness (PHE, ME)	Crisis (PHE, ME)
Purpose:	• Help tracking of EU manufacturing capacity • Ensure security of supply and availability of critical medicines at EU level	• Drawn up for crisis preparedness • Listing medicines needed for managing a particular event (e.g. predicted antibiotic shortage) • Helping closely monitor supply and demand of medicinal products in scope	• Drawn up after a PHE/ME is declared • Listing medicines needed for PHE/ME • Helping closely monitor supply and demand of medicinal products in scope
Defined by:	EMA / Heads of Medicines Agencies (HMA)	Executive steering group on shortages and safety of medicinal products (MSSG)	
Data submission requirements:	• Pack size and manufacturing site data for NAPs submitted to EMA Product Management Service (xEVMPD/PMS) • **No immediate reporting requirements to ESMP***	European Shortages Monitoring Platform (ESMP) reporting	European Shortages Monitoring Platform (ESMP) reporting

**notifications of shortages for CAPs to follow the routine shortage reporting process*

Reporting instances to ESMP

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	Routine shortage reporting	MSSG-led preparedness	Crisis
Available in:	Normal circumstances	Preparedness (PHE, ME)	Crisis (PHE, ME)
Purpose:	Early reporting of shortages to allow for efficient shortage prevention, management and mitigation	Specifically driven by the MSSG to address events that might lead to a PHE/ME	Focused on immediate actions to handle and mitigate the impact of ongoing or imminent crises, such as a PHE or ME
Submission trigger:	Potential or actual shortage of a marketing authorisation holders' product	MSSG announcement of preparedness exercise	EC recognition of a PHE/ME
Products in scope:	All centrally authorised products (CAPs)	List of medicines to be monitored for MSSG-led crisis preparedness (CAPs and NAPs)	List of critical medicines for a public health emergency/major event (CAPs and NAPs)
Frequency of reporting:	As required, updated when new relevant information is available	Defined by the MSSG	Defined by the MSSG

For questions: www.slido.com Code: #ESMP-ESS

PHE: public health emergency ME: major event

Any questions?

Further information

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