EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Shortages Monitoring Platform (ESMP) Essentials and Industry Reporting Requirements Webinar

24 June 2024, 10:00 – 12:30 CEST

Housekeeping

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

*Participants can 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.*

Agenda

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1. **Welcome and opening of the webinar**, Pedro Pina Ferreira
2. **Shortage management in the EU**, Monica Dias
3. **Overview of the European Shortages Monitoring Platform (ESMP)**, Sofia Zastavnik

Coffee Break

4. **Development timeline and dependencies**, Sofia Zastavnik
5. **Dependencies: Product data submission required in XEVMPD/PMS**, Marcos Fernandez Gomez
6. **ESMP functionalities**, Sofia Zastavnik
7. **Next steps**, Pedro Pina Ferreira
8. **Q&A**
9. **Closing remarks**, Pedro Pina Ferreira

Goals and objectives

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1 **DEEPEN YOUR KNOWLEDGE ABOUT THE PLATFORM**

Learn about the product vision, purpose, benefits, milestones, features, and dependencies

2 **COLLECT FEEDBACK & QUESTIONS**

Participants will have the opportunity to raise questions via Slido, and give personal input and feedback

3 **AWARENESS OF THE NEXT STEPS**

The Webinar is an opportunity to keep the participants aware of the next steps and key upcoming developments

Send your questions via Slido

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Join at

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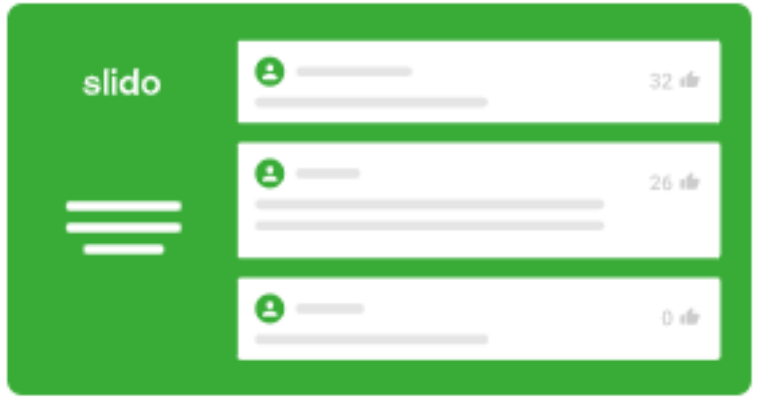
1. Join via the QR code or link

2. Send or upvote the questions you want to hear answered



3. Questions will be shown on the screen and managed live in the Q&A session

Shortages management in the EU

Monica Dias, *Head of Supply and Availability of Medicines and Devices*

Shortages management in the EU

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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

The joint **HMA/EMA Task Force on the Availability of Authorised Medicines** for Human and Veterinary Use (TF-AAM) provides **strategic support** to tackle disruptions in medicine supply and ensure availability

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EMA’s extended mandate

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.

- Provides a framework for activities established by the European Medicines Agency to **prevent**, **monitor** and **mitigate potential and actual shortages of medicines**
- Sets **processes/tools for shortages reporting** and coordinates **responses** of EU countries to shortages of critical medicines during crisis and for monitoring of events which might lead to a crisis situation
- Established the “**Medicines Shortages Steering Group**” (MSSG) supported by the **SPOC Working Party** and a network of contact points from pharmaceutical companies (MAH i-SPOCs)
- Foresees the development of the **European Shortages Monitoring Platform** (ESMP) by February 2025

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Coordinating medicine availability in the EU

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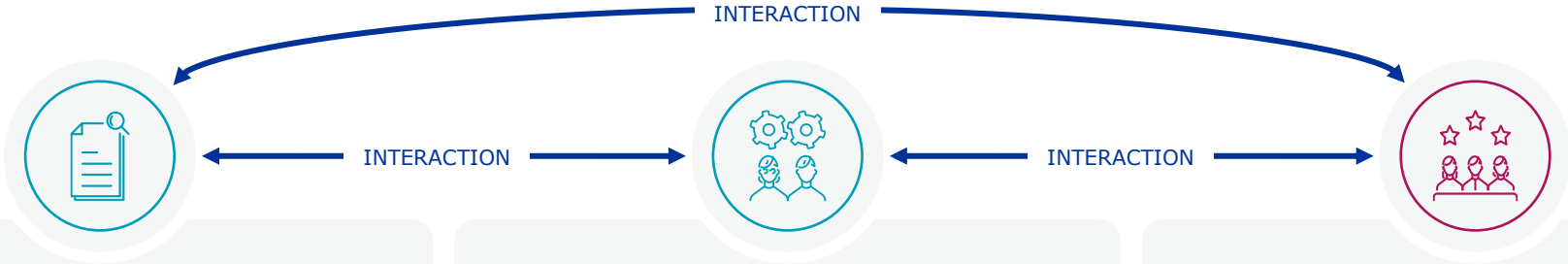

	EMA/HMA Task Force on availability of authorised medicinal products (TF AAM) POLICY GROUP	**Medicine shortages SPOC working party** OPERATIONAL GROUP	**Executive steering group on shortages and safety of medicinal products (MSSG)** EXECUTIVE GROUP
Operates in:	**Normal circumstances**	**Normal circumstances** **Crisis and preparedness (PHE, ME)**	**Crisis and preparedness (PHE, ME)**
Functions:	• Supply and availability hub • Structural and strategic solutions • Development of guidance and policy	• Monitoring of shortages • Drawing up the list of critical medicines during a PHE/ME • Monitoring of demand and stock of critical medicines during a PHE/ME	• Opinion on a major event • List of critical medicines • Monitoring of shortages, supply, and demand during a PHE/ME • Recommendations to MS, Industry, and European Commission
Related activities:	EU initiative Joint Action CHESSMEN EC Pharma Strategy EMANS 2025	EMA extended mandate	

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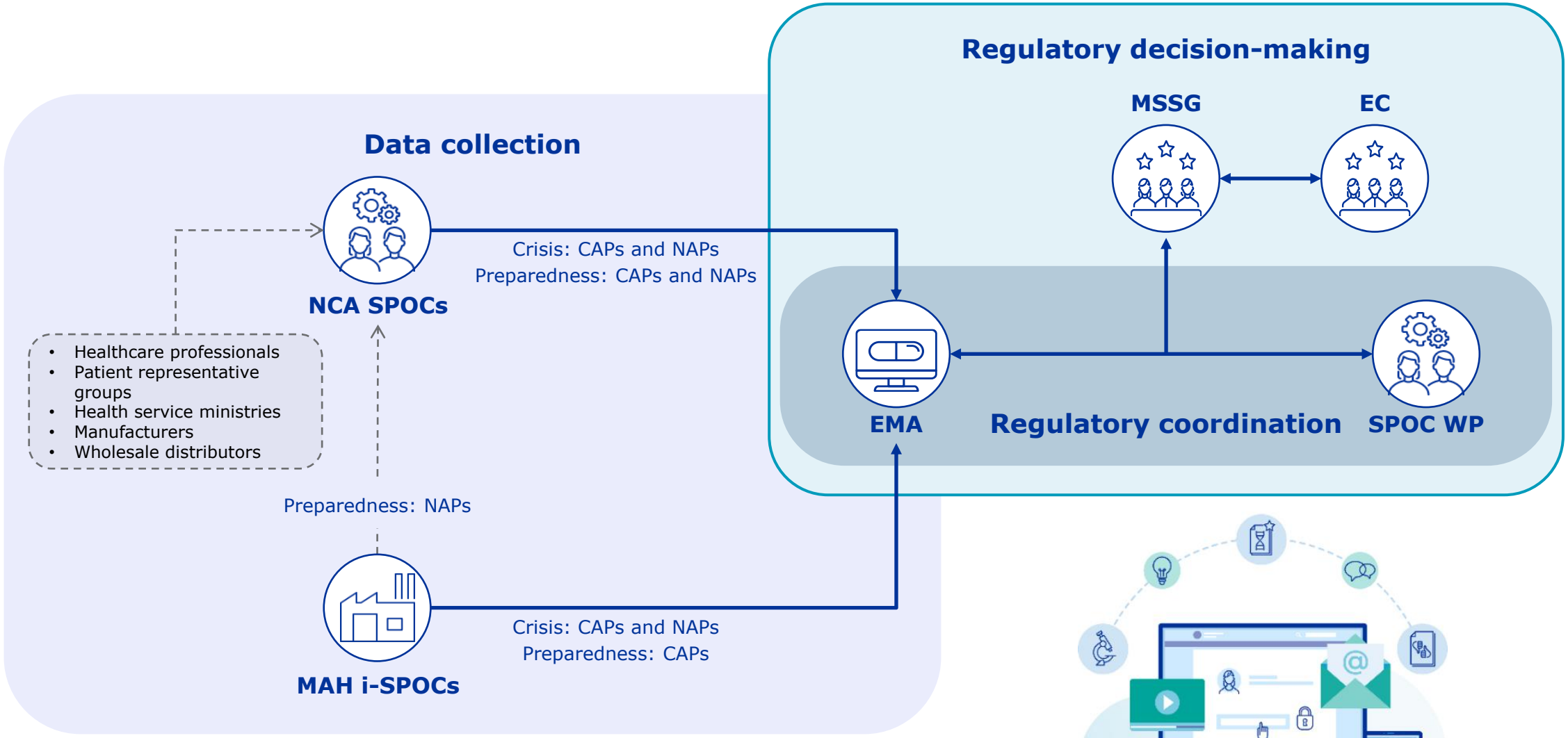
PHE: public health emergency ME: major event MS: member state

ESMP in the regulatory landscape



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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*

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PHE: public health emergency ME: major event

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

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PHE: public health emergency ME: major event

Overview of the European Shortages Monitoring Platform (ESMP)

Sofia Zastavnik, *ESMP Product Owner*

ESMP vision and purpose

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.

PREVENTION

Data collection

- Shortage information
- Supply and demand of medicines
- i-SPOC Registration

MONITORING

Analysis & reporting

- Matching supply & demand
- Reporting findings and results
- Public reports

Shortages management

- Maintain critical medicinal product lists
- Evaluate and manage medicines shortages

MANAGEMENT

Data integration

- EMA data management (SPOR, IAM, IRIS integration)
- Interoperability with NCA and Industry systems

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SPOR – substance, product, organisation, referentials management system
IAM- identity access management system

Platform user interfaces (UI)

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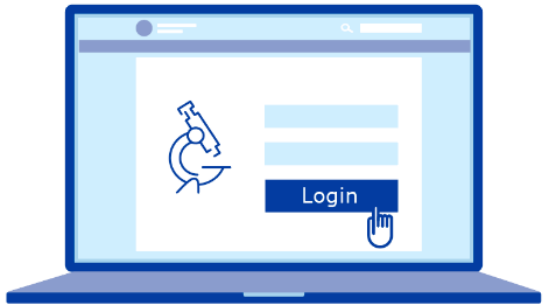
Platform for NCAs

Secure interface for **regulatory authorities** to submit data, retrieve reports and manage shortages

Platform for MAHs



Secure interface for **MAH i-SPOCs** to submit data in scope of reporting requirements

Secure access

Platform for general public

A **public website** where anyone can search for information on critical medicines shortages

Open access

Benefits of establishing ESMP

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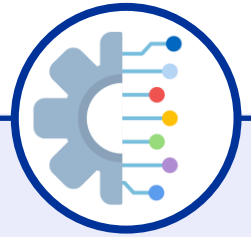
PREVENTION OF SHORTAGES

- Streamlined **reporting of data on shortages** for better prevention, identification and management of them
- **Facilitate medicines availability** during Public Health Emergencies and Major Events



IMPROVEMENT & INTEROPERABILITY

- **User-friendly platform**, designed for **continuous enhancements** and technical improvements
- **Alignment with advancements** in the regulatory and technological spheres
- **Synergies** among different data sources

TRANSPARENCY & COLLABORATION

- **Streamlined collaboration** among different actors
- **Consistent messaging** across stakeholder fora
- **Support** in case of user challenges in the Platform adoption
- **Public access** to information about PHEs/MEs and medicines shortages

Data collection in the ESMP

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Data collection

- Shortage information
- Supply and demand of medicines
- i-SPOC Registration

The ESMP will allow both manual and machine-to-machine submissions of data.

- **Tabular submission of data** will be available through excel templates via the ESMP User Interface
- **Machine-to-machine submissions** will be available through interoperability between national and industry systems

	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
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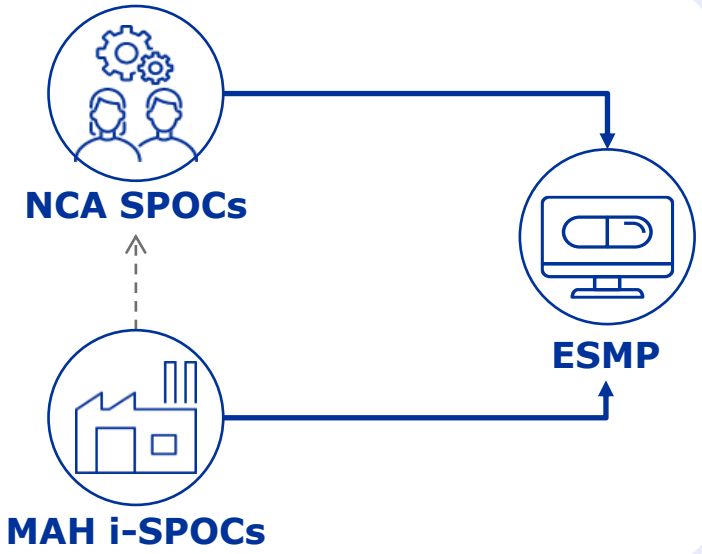

Users are required to submit data through the ESMP in **three different instances**: **crisis, MSSG-led preparedness**, and **routine shortage** reporting.

- **National competent authorities** provide data on national demand, stock and supply levels, patient estimation, and medicine usage
- **Marketing authorisation holders** provide data on medicine availability, forecast of supply, alternative therapies, marketing status, manufacturing details, and production plans

Data collection in the ESMP: MAH submissions

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Data collection

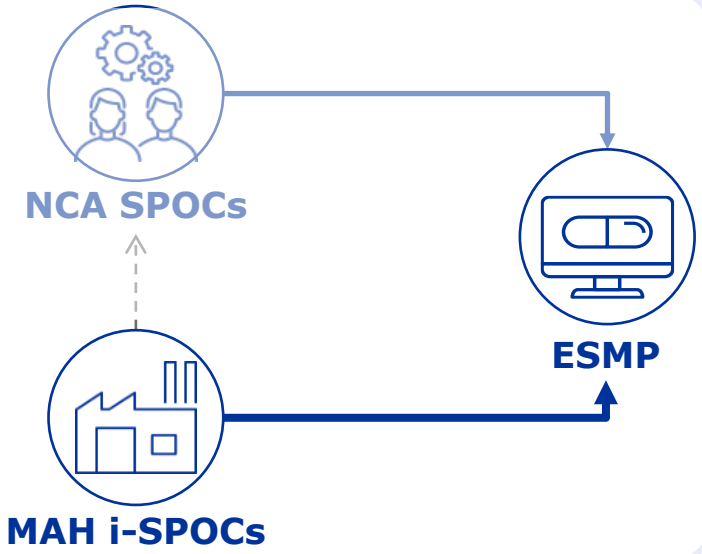
- Shortage information
- Supply and demand of medicines
- i-SPOC Registration

In **normal circumstances**, MAHs will report shortages of centrally authorised products.

- **Shortage information**
- **Shortage prevention and mitigation plans**
- **Shortage impact assessment**
- **Alternative therapies**

Submissions are triggered by a potential or actual shortage and MAHs need to keep the entries up-to-date, including the latest information.

During an **MSSG-led preparedness exercise**, MAHs follow the same submission process as during a crisis situation for a subset of products subject to close monitoring.



In a **crisis situation**, MAHs submit data on nationally and centrally authorised products in scope of a critical medicines list for a particular public health emergency.

- **Shortage information**
- **Shortage prevention and mitigation plans**
- **Marketing status**
- **Market share, sales volume** and **sales forecast**
- **Manufacturing information** including production plan, capacity and alternative sites
- **Alternative therapies**

Submissions are triggered by an MSSG announcement and frequency of reporting is defined by the MSSG.

Data analysis and reporting

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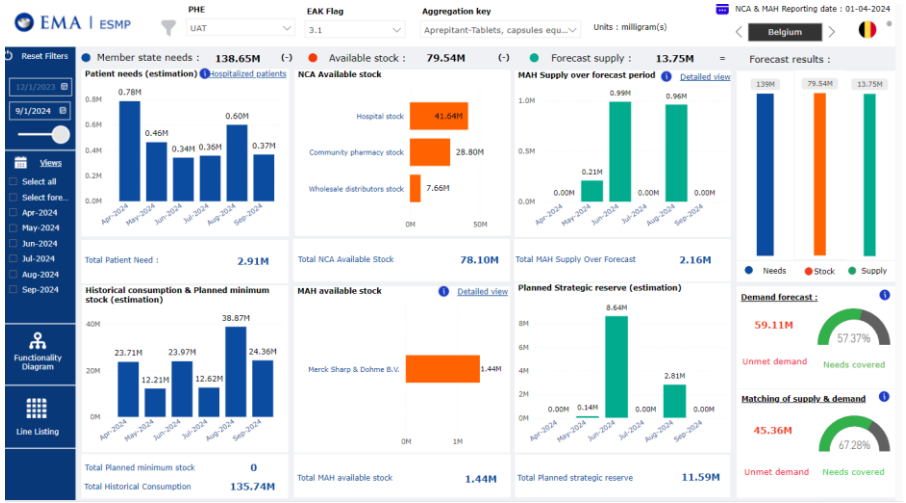
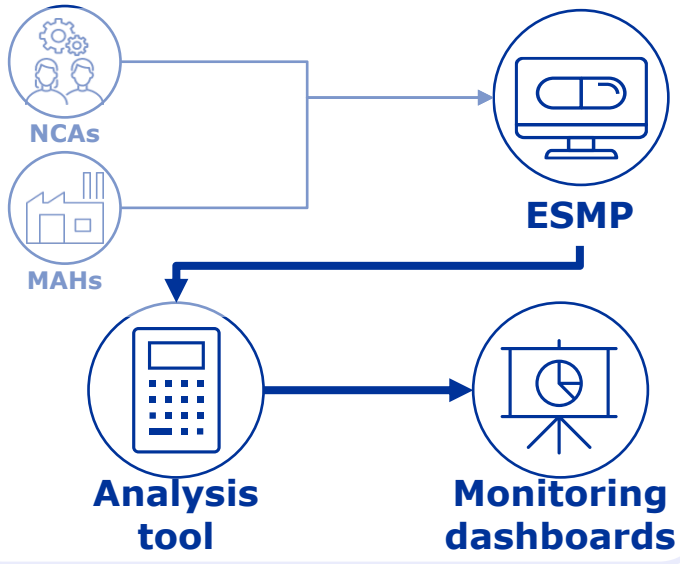
Analysis & reporting

- Matching supply & demand
- Reporting findings and results
- Public reports

Following NCA and MAH submissions through the ESMP, the underlying data analytics platform will **match information on the supply and demand** of medicinal products in scope of reporting requirements through a tool for automated analysis, visualisation, and monitoring.





- **Centralised PHE dashboards** to structure data and allow a deep understanding of the supply and demand of critical products across the EU/EEA
- **Country-specific monitoring dashboards** to allow the structured visualization of supply and demand data in each member state

Management of shortages via ESMP

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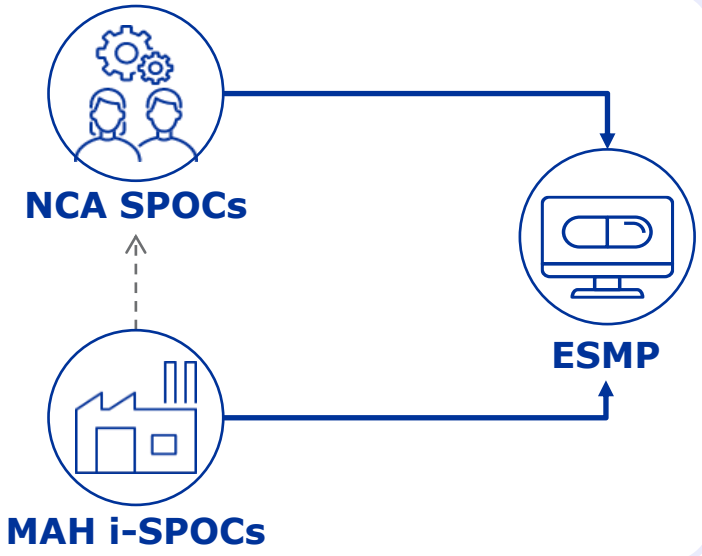
Shortages management

- Maintain critical medicinal product lists
- Evaluate and manage medicines shortages

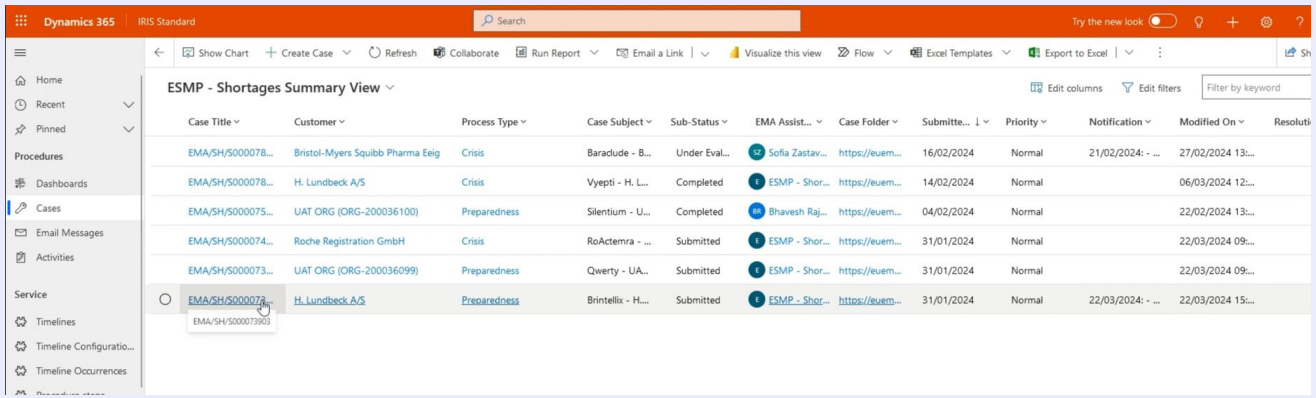
Creating and continuously updating lists of critical medicinal products, as defined by the MSSG, is essential for crisis preparedness and management. These lists specify the **categories of medicinal products that need close monitoring**. Those categories are mapped to specific medicinal products identified in PMS, and this information is incorporated and used by ESMP for effective data collection, analysis, and management.

List of products in scope of MSSG-led preparedness reporting

List of critical medicines for a public health emergency/major event



The *case management* functionality allows EMA staff to **triage, evaluate, and manage shortage cases** reported via the ESMP through an integrated and automated system.



Data integration: EMA data management systems

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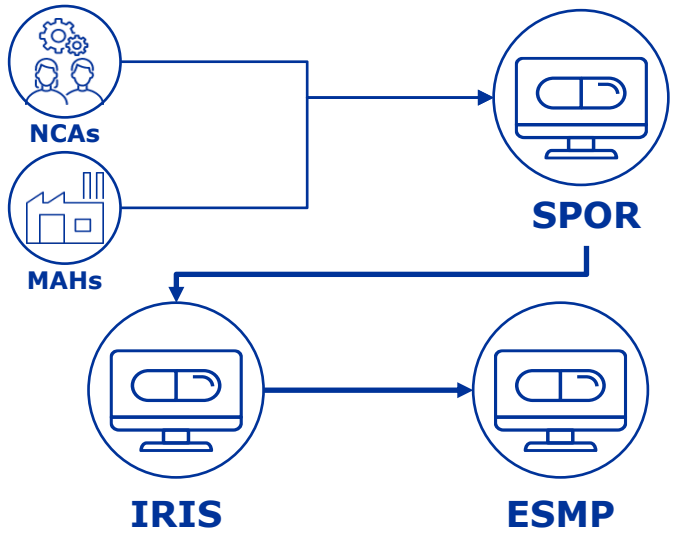
Data integration

- **EMA data management (SPOR, IAM, IRIS integration)**
- Interoperability with NCA and Industry systems

Integration with EMA data management services facilitates the reliable **exchange of information** in a robust and consistent manner by providing master data and a common language used across the EU/EEA.

ESMP is integrated with the EMA **Account Management Portal (IAM)**, a secure online platform for requesting and managing access to EMA applications. Integration with **SPOR** also allows ESMP to retrieve harmonised data on data such as product and referentials master data.

Data reported through **IRIS** on the **marketing status of CAPs** is also integrated in the ESMP platform.



- User account management (IAM)
- SPOR integration: ESMP will be integrated with PMS, RMS, SMS and OMS, retrieving information to pre-populate reporting templates and facilitate data collection, analysis, and management
- Marketing status for CAPs in IRIS

Substance Management Services (SMS)

Product Management Services (PMS)

Organisation Management Services (OMS)

Referentials Management Services (RMS)

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Data integration: interoperability with national & industry systems

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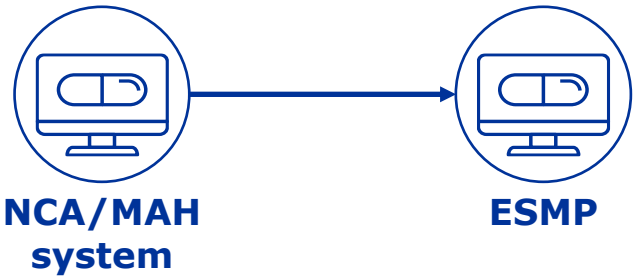
Data integration

- EMA data management (SPOR, IAM, IRIS integration)
- **Interoperability with NCA and Industry systems**

Interoperability is defined as the ability of organisations to interact towards mutually beneficial goals, involving the **sharing of information and knowledge** by means of the exchange of data between their ICT systems.

It allows to establish direct links to data across national and industry databases, enabling seamless **machine-to-machine data exchange**, harnessing existing data on the supply chain of products.

Note: a pre-requisite for achieving interoperability is the mapping of PMS identifiers with product identifiers held in industry and national product systems.



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Coffee Break

See you in 5’

Send your questions via Slido:

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Development timeline and dependencies

Sofia Zastavnik, *ESMP Product Owner*

Building the ESMP: Agile way of working

EMA is developing the ESMP in line with the **Scaled Agile Framework** (SAFe). Following an Agile approach means that new products like the ESMP will start with basic features (minimum viable product) and EMA will gradually add more over time.

The Network and Industry stakeholders are part of the Agile product teams participating directly in the delivery of the Network Portfolio.

INCREMENTAL DEVELOPMENT

Features of the ESMP will be released gradually towards a **minimum viable product** (MVP), to be delivered in line with the requirements in the Regulation 2022/123.

Following February 2025, the platform will evolve through consistent **enhancements** and **improvements**.

STAKEHOLDER COLLABORATION

EMA maintains regular and close interactions with both Industry and Network stakeholders, to **understand their needs**, **share information**, **align on priorities**, and **leverage insights and know-how** from our stakeholders.

INTERCONNECTION WITHIN VALUE STREAMS

The ESMP is part of the EMA Network Portfolio, which is organized in value streams. Products within value streams can be interconnected and complementary, aiming towards a vision of **bringing comprehensive value** to health and patients across the EU/EEA.

High level progress diagram – incremental development

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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

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PMS : Product Management Services
RMS : References Management Services

Development timeline

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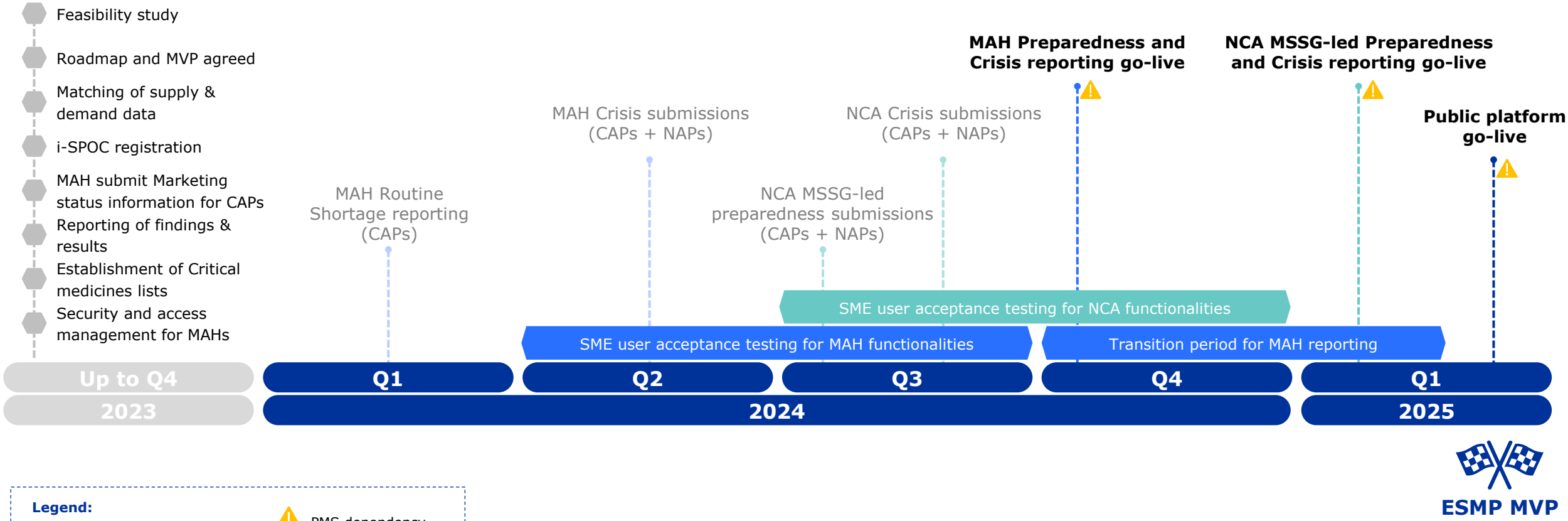

Legend:

- Public delivery
- Development completed
- PMS dependency
- MAH functionalities
- NCA functionalities

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Stakeholder collaboration in product development

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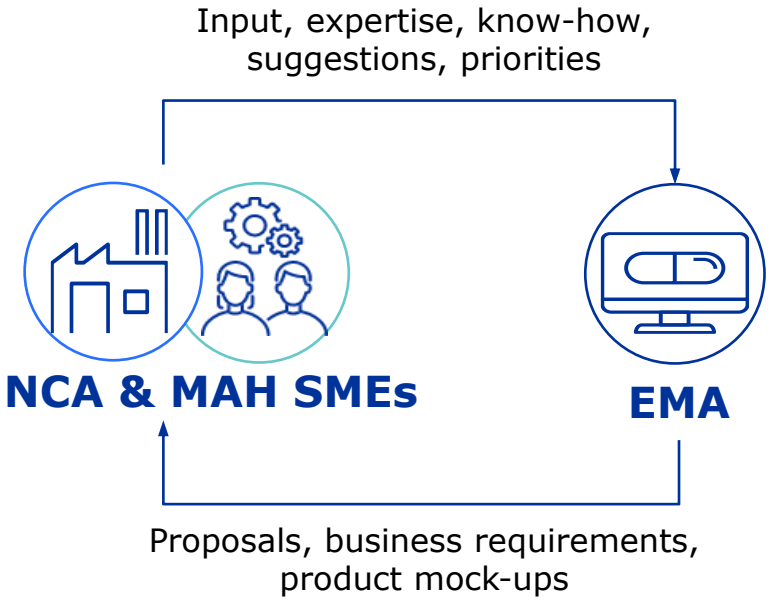
Role of subject matter experts (SMEs) as part of the Agile team

Bi-weekly SME Forum | User Acceptance Testing | Ad hoc consultation *e.g. Interoperability*

- Supporting the **definition and development** of the minimum viable product (MVP)
- Providing **recommendations** and supporting **consistent enhancements** to the ESMP
- Provide **expert input on the subject matter** of the ESMP
- Collaborate in the formulation of **business requirements** to support the development of features
- Support Product Owners with **insights on behalf of industry stakeholder groups** to inform prioritisation of features



Channels of communication and receiving input/feedback on the development of the ESMP

Monthly SPOC WP meetings | MSSG meetings | Monthly ESMP-MSSG WG meetings | Quarterly System Demos | Quarterly NPAG & NICTAC meetings | IT Directors meetings

EMA-Industry bilaterals | Bi-annual Strategic Portfolio review | Quarterly ISG meetings | Quarterly System Demos

SMEs: Subject Matter Experts
ESMP-MSSG WG: ESMP-MSSG Working Group

SPOC WP: Single Points of Contact Working Party
NPAG: Network Portfolio Advisory Group

MSSG: Executive Steering Group on Shortages of Medicinal Products
NICTAC: Network ICT Advisory Committee

Network
Industry

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Flow of information: ESMP & PMS

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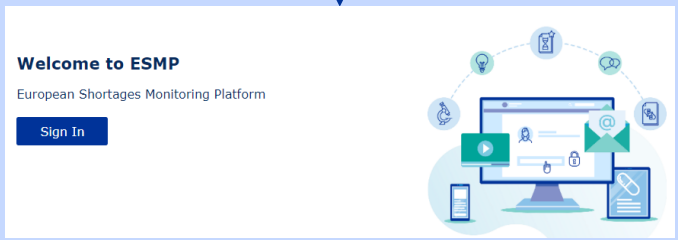
Member State data systems

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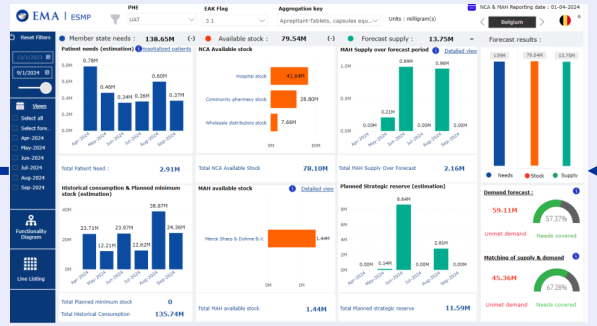
Users **complete ESMP templates** with relevant information per product

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.

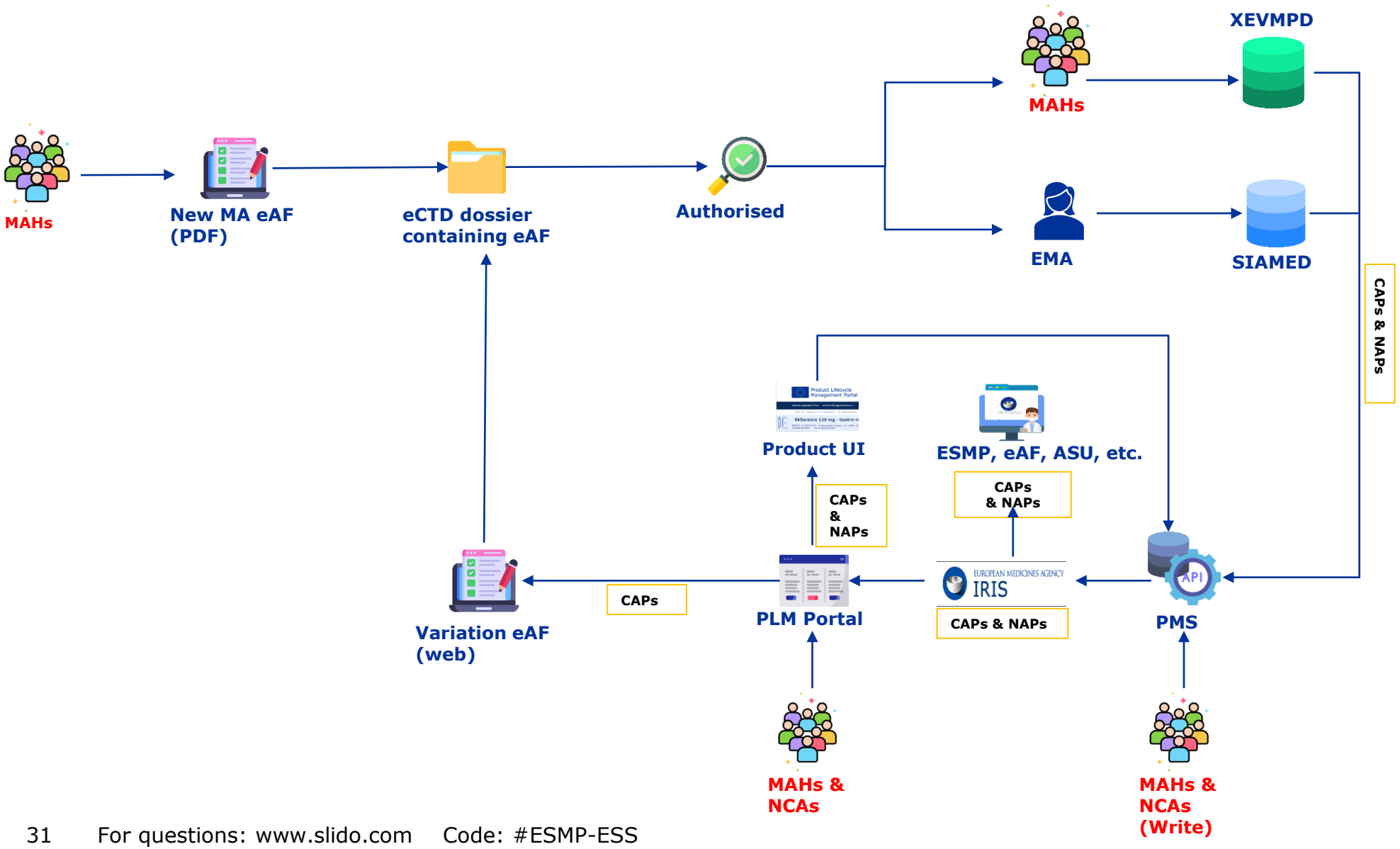
Prevent, monitor and manage shortages

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

ESMP dependencies: Product data submission required in XEVMPD/PMS

Marcos Fernandez Gomez, *PMS Product Owner*

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

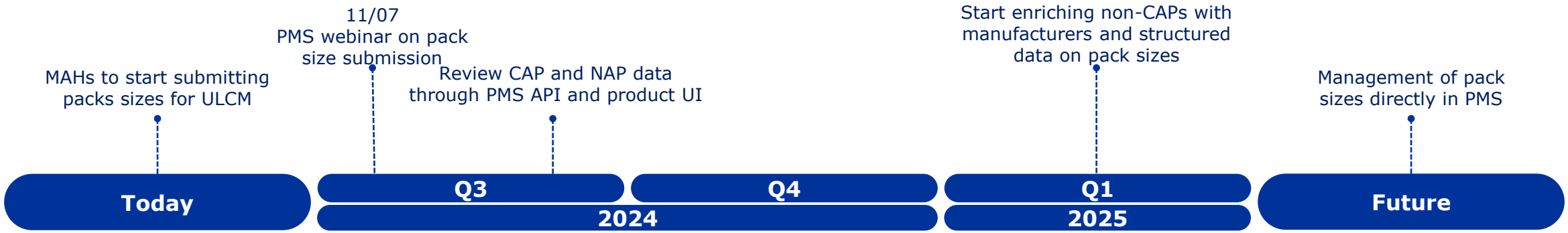
Make sure **authorised pack sizes** for products under the **Union List of Critical Medicines** are submitted to XEVMPD before **February 2025**

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**

*PMS Team will host a **webinar on 11th July** to provide information on pack size submission to XEVMPD*

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.



ESMP functionalities: platform structure and data elements

Sofia Zastavnik, *ESMP Product Owner*

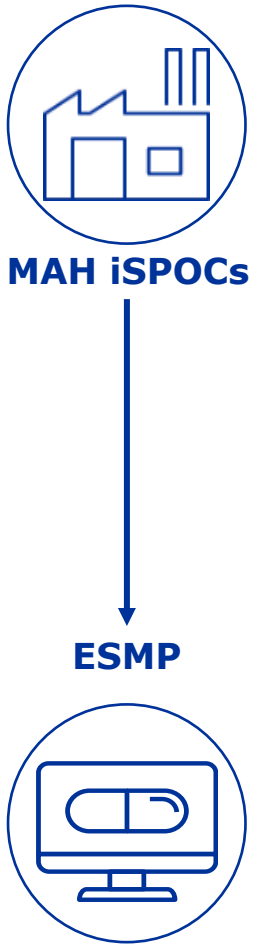
MAH routine shortage reporting via ESMP

EUROPEAN MEDICINES AGENCY

Routine shortage reporting

Monitoring of actual or potential shortages that can lead to a public health emergency or major event

Available in:	● **Normal circumstances**
Trigger:	Potential or actual shortage of a marketing authorisation holders' product
Products in scope:	All centrally authorised products (CAPs)
Frequency of reporting:	As required, updated when new relevant information is available



Platform view: routine shortage reporting

EUROPEAN MEDICINES AGENCY

Normal circumstances

Routine shortage reporting

During normal circumstances **MAHs** for **CAPs** are required to routinely report information on **potential or actual shortages** of medicinal products to EMA through the ESMP

To perform routine shortage submissions, MAHs will:

1) **Select relevant products** under their product portfolio
2) **Download a reporting template** pre-filled with the relevant product information
3) **Compile and submit** relevant information
4) **Perform updates** to keep information current

Data elements: routine shortage reporting

EUROPEAN MEDICINES AGENCY

Normal circumstances

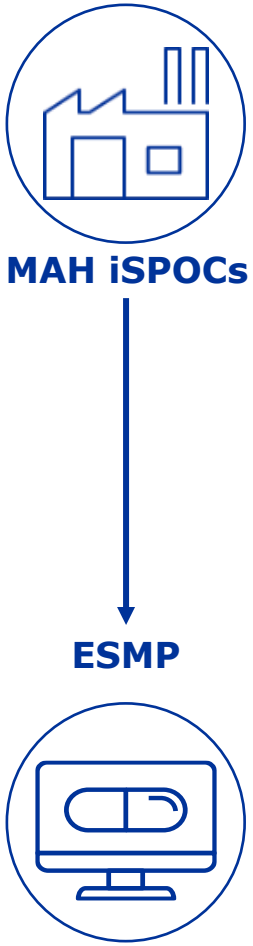
Product information *(pre-populated from PMS and IRIS)*	*PMS ID (Packaged medicinal product)*
	Full product name
	Short product name
	Active substance
	Strength
	Pharmaceutical form
	Pack size
	Packaging
	PCID
	Country of authorisation
	Marketing status
Shortage information	Shortage status
	Shortage start date or expected start date
	Shortage end date or expected end date
	Point in supply chain at which disruption occurs
	Root cause of the shortage
	Countries in which manufacturing issues occur
	Countries in which increased demand occurs
	Countries in which distribution issues occur
	Additional information on the root cause of the shortage

Prevention and mitigation plans	Shortage prevention and mitigation plans
	Shortage prevention and mitigation plans – ongoing and planned steps
Impact assessment	Affected population estimate
	Market share
	Shortage impact risk assessment
	Shortage impact risk assessment – additional information
Potential alternatives therapies	Alternatives available (yes/no)
	Alternative therapies
Additional information	Rapid alert reference number
	Other authorities notified (e.g., other NCAs, EMA), including reference to Quality Defect report
	Reference to related pending regulatory action
	Required NCA actions, if any

MAH MSSG-led preparedness and crisis reporting via ESMP

EUROPEAN MEDICINES AGENCY

	MSSG-led preparedness Monitoring and management of critical medicines in preparedness for a PHE / ME	**Crisis** Monitoring and management of critical medicines during a PHE / ME
Available in:	● **Preparedness (PHE, ME)**	● **Crisis (PHE, ME)**
Trigger:	MSSG announcement of preparedness exercise	EC recognition of a PHE/ME
Products in scope:	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:	Defined by the MSSG	Defined by the MSSG



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PHE: public health emergency ME: major event

Platform view: my critical medicines

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- **Preparedness (PHE, ME)**
- **Crisis (PHE, ME)**

- **My critical medicines**
- Marketing status CAPs
- Marketing status NAPs
- Availability information
- Manufacturing information
- Alternative therapies

The ESMP shows all the medicines in the MAH's product portfolio that have been marked as **critical for a particular crisis or MSSG-led preparedness exercise**, together with their marketing status

MAHs will be able to obtain a comprehensive overview of the **scope of reporting** and **marketing status** to ensure previously reported data is **up-to-date** (primarily the data on marketing status of CAPs coming from IRIS)

Platform view: marketing status CAPs

EUROPEAN MEDICINES AGENCY

- **Preparedness (PHE, ME)**
- **Crisis (PHE, ME)**

My critical medicines

› **Marketing status CAPs**

Marketing status NAPs

Availability information

Manufacturing information

Alternative therapies

For CAPs, marketing status details are pre-populated from the **IRIS platform**. To modify this information, changes must be made **directly in IRIS**, which will then be **automatically updated** in the ESMP

To update the marketing status for CAPs, the users will be able to access the relevant **IRIS platform page** directly from the ESMP

Platform view: marketing status NAPs

EUROPEAN MEDICINES AGENCY

- **Preparedness (PHE, ME)**
- **Crisis (PHE, ME)**

- My critical medicines
- Marketing status CAPs
- **Marketing status NAPs**
- Availability information
- Manufacturing information
- Alternative therapies

For the relevant **NAPs** in the scope of reporting requirements the platform will enable the MAHs to **submit the marketing status** data and show the data **previously submitted through the ESMP**, if applicable

To perform this submission, MAHs will:

1) **Download a reporting template** pre-filled with the relevant NAP product information
2) **Compile and submit** relevant information
3) **Perform updates** to keep information current

Data elements: marketing status NAPs

EUROPEAN MEDICINES AGENCY

- **Preparedness (PHE, ME)**
- **Crisis (PHE, ME)**

Product information (pre-populated from PMS)	*PMS ID (Packaged medicinal product)*
	Full product name
	Short product name
	Active substance
	Strength
	Pharmaceutical form
	Pack size
	Packaging
	PCID
	Country of authorisation
Marketing status details	Marketing status
	Date of planned permanent withdrawal
	Planned withdrawal comment

Platform view: availability information

EUROPEAN MEDICINES AGENCY

- **Preparedness (PHE, ME)**
- **Crisis (PHE, ME)**

- My critical medicines
- Marketing status CAPs
- Marketing status NAPs
- **Availability information**
- Manufacturing information
- Alternative therapies

During a crisis or upon request of the MSSG, MAHs **are required to report** information about shortages, sales volumes, forecasts of sales and supply and other information for medicines in scope of a specific list of critical medicines for the respective situation

To perform this data submission, MAHs will:

1) **Download a reporting template** pre-filled with the relevant CAP & NAP product information
2) **Compile and submit** relevant information
3) **Perform updates** to keep information current at a **frequency defined by the MSSG**

Data elements: availability information

EUROPEAN MEDICINES AGENCY

Product information *(pre-populated from PMS and IRIS)*	*PMS ID (Packaged medicinal product)*
	Full product name
	Short product name
	Active substance
	Strength
	Pharmaceutical form
	Pack size
	Packaging
	PCID
	Country of authorisation
	Marketing status
Shortage information	Shortage status
	Shortage start date or expected start date
	Shortage end date or expected end date
	Point in supply chain at which disruption occurs
	Root cause of the shortage
	Countries in which manufacturing issues occur
	Countries in which increased demand occurs
	Countries in which distribution issues occur
	Additional information on the root cause of the shortage
Shortage prevention and mitigation plans	Shortage prevention and mitigation plans
	Shortage prevention and mitigation plans – ongoing and planned steps

● **Preparedness (PHE, ME)**

● **Crisis (PHE, ME)**

Market share	Market share
	Additional information on market share
Sales volume	Sales volume
	Sales volume – pre-PHE/ME
	Additional information on sales volume
Forecast of sales and supply	Sales forecast – month 1
	Sales forecast – month 2
	Sales forecast – month 3
	Sales forecast – month 4
	Sales forecast – month 5
	Sales forecast – month 6
	Supply forecast – month 1
	Supply forecast – month 2
	Supply forecast – month 3
	Supply forecast – month 4
	Supply forecast – month 5
	Supply forecast – month 6
Stock information	Available stock
	Desired safety stock
	Additional information on stocks

Platform view: manufacturing information

EUROPEAN MEDICINES AGENCY

- **Preparedness (PHE, ME)**
- **Crisis (PHE, ME)**

My critical medicines

Marketing status CAPs

Marketing status NAPs

Availability information

› Manufacturing information

Alternative therapies

For medicinal products subject to crisis/MSSG-led preparedness monitoring through the ESMP MAHs need to report on **manufacturing methods** (own factory or subcontracted), **production plans** and **production capacity** (average and peak outputs) for the active substances and final dose form

To perform this data submission, MAHs will:

1) **Download a reporting template** pre-filled with the relevant CAP & NAP product information
   - **CAPs will be listed** alongside their manufacturing sites for all stages of production (data available in PMS)
   - **for NAPs** information on manufacturing sites will be integrated into the ESMP once this data is submitted in PMS
2) **Compile and submit** relevant information
3) **Perform updates** to keep information current at a **frequency defined by the MSSG**

Data elements: manufacturing information

EUROPEAN MEDICINES AGENCY

● **Preparedness (PHE, ME)**

● **Crisis (PHE, ME)**

Product information *(pre-filled from PMS)*	*PMS ID (Medicinal product)*
	Full product name
	Active substance
Organisation information *(pre-filled from PMS and OMS, currently available only for CAPs)*	*Organisation ID (Manufacturer)*
	Manufacturer
	Operation type ID
	Operation type
	Location ID (Manufacturer)
	City
	Country
Manufacturing details	Manufacturing site status (active/backup)
	Is the site a contract manufacturer? (yes/no)
Alternative sites	Alternative site Location ID
	Alternative site Country

	Unit of measurement (kg/units)
Production plan *(for API and FDF)*	Global monthly production plan - month 1
	Global monthly production plan – month 2
	Global monthly production plan – month 3
	Global monthly production plan – month 4
	Global monthly production plan – month 5
	Global monthly production plan – month 6
	Additional information on the production plan
Production capacity *(for API and FDF)*	Average global monthly production output of previous year
	Peak global monthly production output of previous year

*submission of manufacturing information for NAPs currently under refinement, changes possible

Platform view: alternative therapies

EUROPEAN MEDICINES AGENCY

- **Preparedness (PHE, ME)**
- **Crisis (PHE, ME)**

My critical medicines

Marketing status CAPs

Marketing status NAPs

Availability information

Manufacturing information

Alternative therapies

MAHs must report alternative therapies for medicinal products subject to crisis/MSSG-led preparedness monitoring through the ESMP. **All active substances and compositions** that can be considered as therapeutic alternatives should be listed

The data is inserted directly in the ESMP **webform**:

- **CAPs** are grouped by short name, active substance and pharmaceutical form
- **NAPs** are grouped by active substance and pharmaceutical form

Data elements: alternative therapies

EUROPEAN MEDICINES AGENCY

- **Preparedness (PHE, ME)**
- **Crisis (PHE, ME)**

Product information *(pre-filled from PMS)* **for CAPs*	*Invented name**
	Active substances
	Pharmaceutical form
Alternative therapies	Alternative substances
	No available alternatives (tick box)

Webform – alternative substances

- The webform will present the active substances and combinations of active substances of valid products authorized in the EU/EEA
- Users to choose one or multiple active substance compositions that could be considered therapeutic alternatives to the product in question
- "No available alternatives" option can be selected, as required

Stay up-to-date: Quarterly system demo & webpage

EUROPEAN MEDICINES AGENCY

Quarterly system demo

- All features are demonstrated in EMA's public quarterly system demos when the development and testing is completed
- All previous ESMP system demos are recorded and available on the ESMP website, alongside the list of features demonstrated in each event

ESMP webpage

- Primary access point for all available information related to the ESMP and a comprehensive and updated knowledge repository
- Overview of the ESMP, its regulatory context and the expected impact of implementation
- Updates on the development including information on milestones, and availability of relevant resources
- Access to all ESMP references in one place, including links to event pages, recordings, and technical guidance
- To be regularly updated with fresh additional content

Events

Throughout 2024 and 2025, EMA will organise events to familiarise relevant stakeholders with the platform:

- European Shortages Monitoring Platform Essentials and Industry Reporting Requirements (24/06/2024)

EMA carries out **public system demonstrations** - or demos - to inform and involve stakeholders in the development of the European Shortages Monitoring Platform (ESMP).

Information on these demos is available in the table below. Demo video recordings are available by visiting the event pages linked in the table.

Demo event	Functionalities showcased	Video recording timestamp
Quarterly system demo - Q2 2024 (26/06/2024)	• Marketing status for nationally authorised products data submission flow for MAHs • Manufacturing information for centrally authorised products data submission flow for MAHs	Information available after the event
Quarterly system demo - Q1 2024 (26/03/2024)	• User interface design • MAH routine reporting of shortages of centrally authorised products • Portal for EMA case management of shortages • Public health emergency monitoring dashboards for member states	03:01:45
Quarterly system demo - Q3 2023 (21/09/2023)	• Template download for marketing authorisation (MAH) holder bulk submission of shortages • Submission of alternative substances • Embedding marketing status for centrally authorised products • Data analytics platform	00:26:24
Quarterly system demo - Q1 2023 (22/03/2023)	Data elements and upload for MAH bulk submission of shortage information	2:17:20
Quarterly system demo - Q3 2022 (28/09/2022)	MAH submission of individual shortages	1:08:53

https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/medicine-shortages-availability-issues/european-shortages-monitoring-platform

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

Next steps

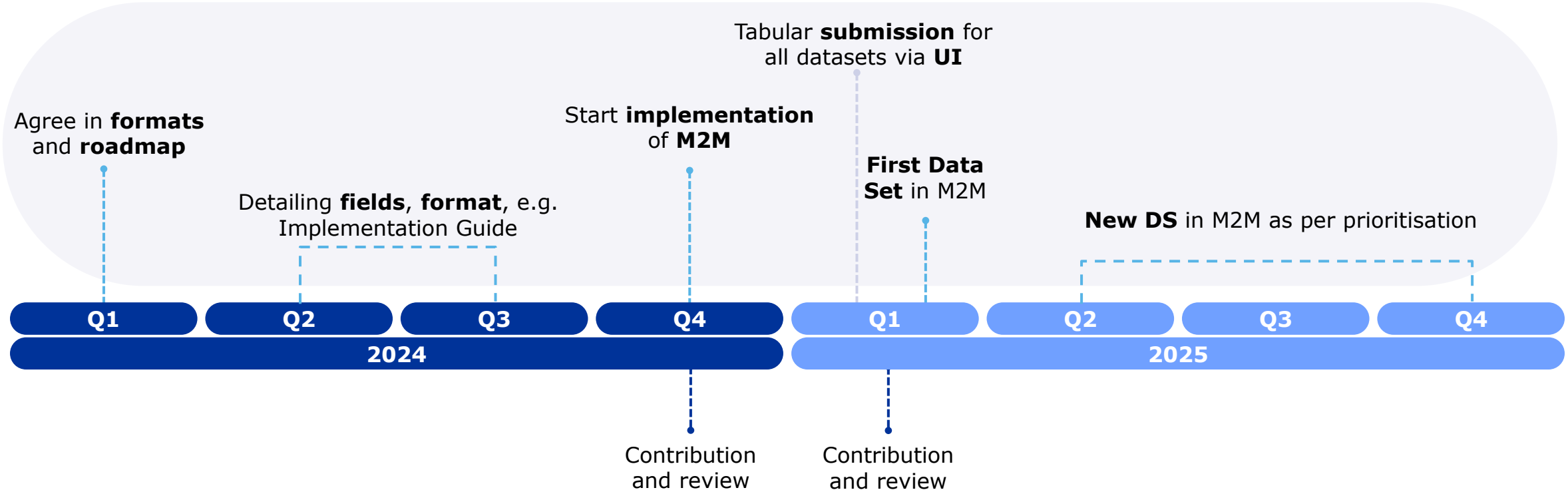
Pedro Pina Ferreira, *Monitoring VS Owner*

Interoperability implementation roadmap

EUROPEAN MEDICINES AGENCY

Machine to Machine (M2M) solution

Solution for MVP - Excel via UI (small exceptions via web form e.g. alternative therapies)



ESMP communication plan

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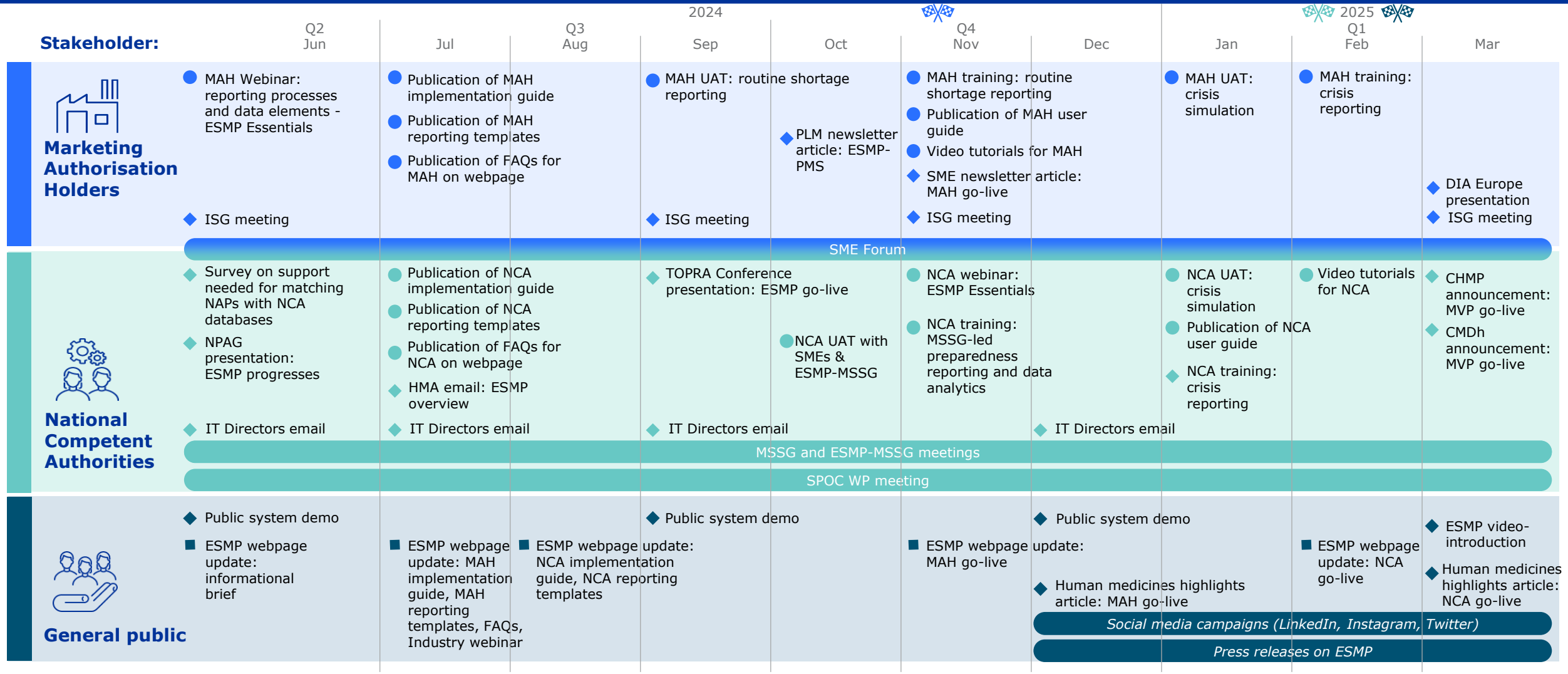

Legend: Training materials/activities; Communication and engagement activities; ESMP webpage update; MAH; NCA; General public; Go-live

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

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

ESMP communication plan: focus on MAHs

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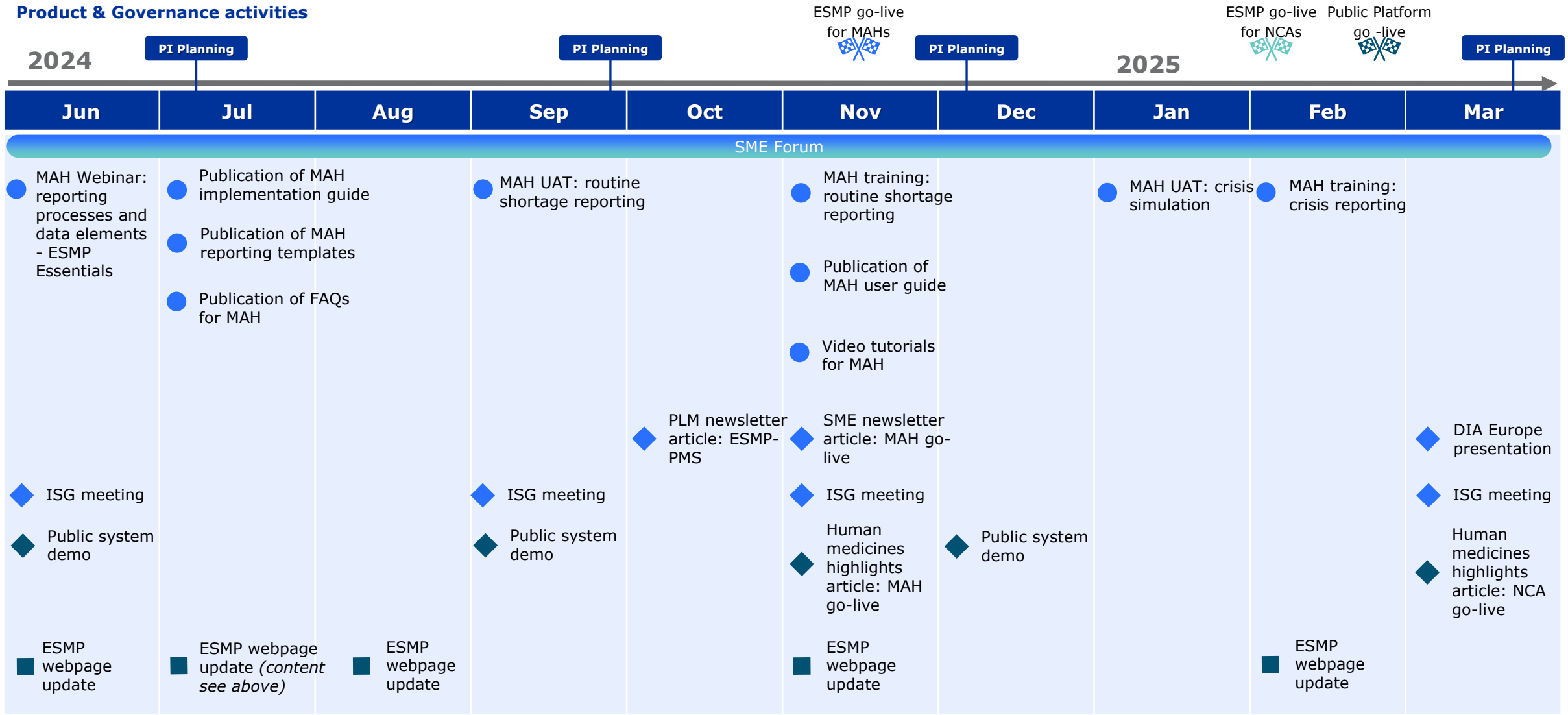

Legend: Training materials/activities; Communication and engagement activities; ESMP webpage update; MAH; NCA; General public; Go-live

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

Main upcoming events

Legend: MAH NCA General public

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

Send your questions via Slido

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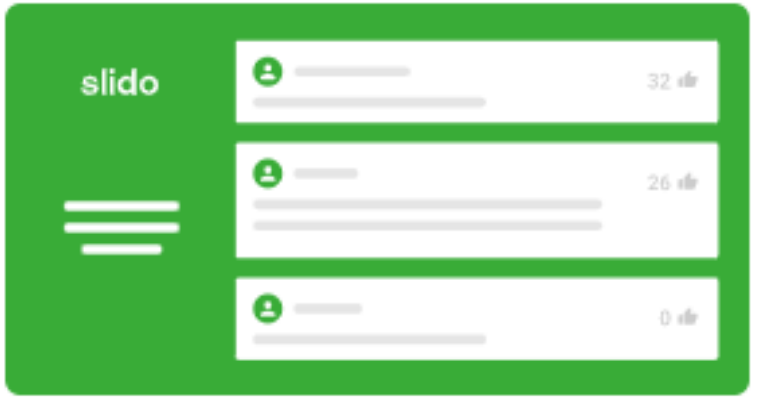
#ESMP-ESS

1. Join via the QR code or link

2. Send or upvote the questions you want to hear answered



3. Questions will be shown on the screen and managed live in the Q&A session

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Audience Q&A Session

ⓘ Start presenting to display the audience questions on this slide.

Wrap up

Thank you for your participation! Today we covered…

1. an introduction to the **regulatory landscape** in shortages management in the EU/EEA
2. the **ESMP vision, objectives, benefits** and components
3. information on each specific platform **functionalities and data** in scope of reporting requirements
4. the list of the **upcoming initiatives** and planned communications for 2024 and early 2025
5. participants **questions**, concerns and feedback

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

Your feedback matters

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- Please spare **a few minutes to complete the survey** in Slido, sharing your feedback on today's event.
- **Your input will guide us in tailoring next sessions** to better meet your needs and preferences.

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