



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# European Shortages Monitoring Platform (ESMP) Essentials: Industry and Network Reporting Requirements

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Published in July 2024



- 1 Shortage management in the EU**
- 2 Overview of the European Shortages Monitoring Platform (ESMP)**
- 3 Development timeline and dependencies**
- 4 Dependencies: Product data submission required in XEVMPD/PMS**
- 5 ESMP functionalities: platform structure and MAH data elements**
- 6 ESMP functionalities: platform structure and NCA data elements**
- 7 Interoperability**
- 8 Stakeholder engagement**



# 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



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**



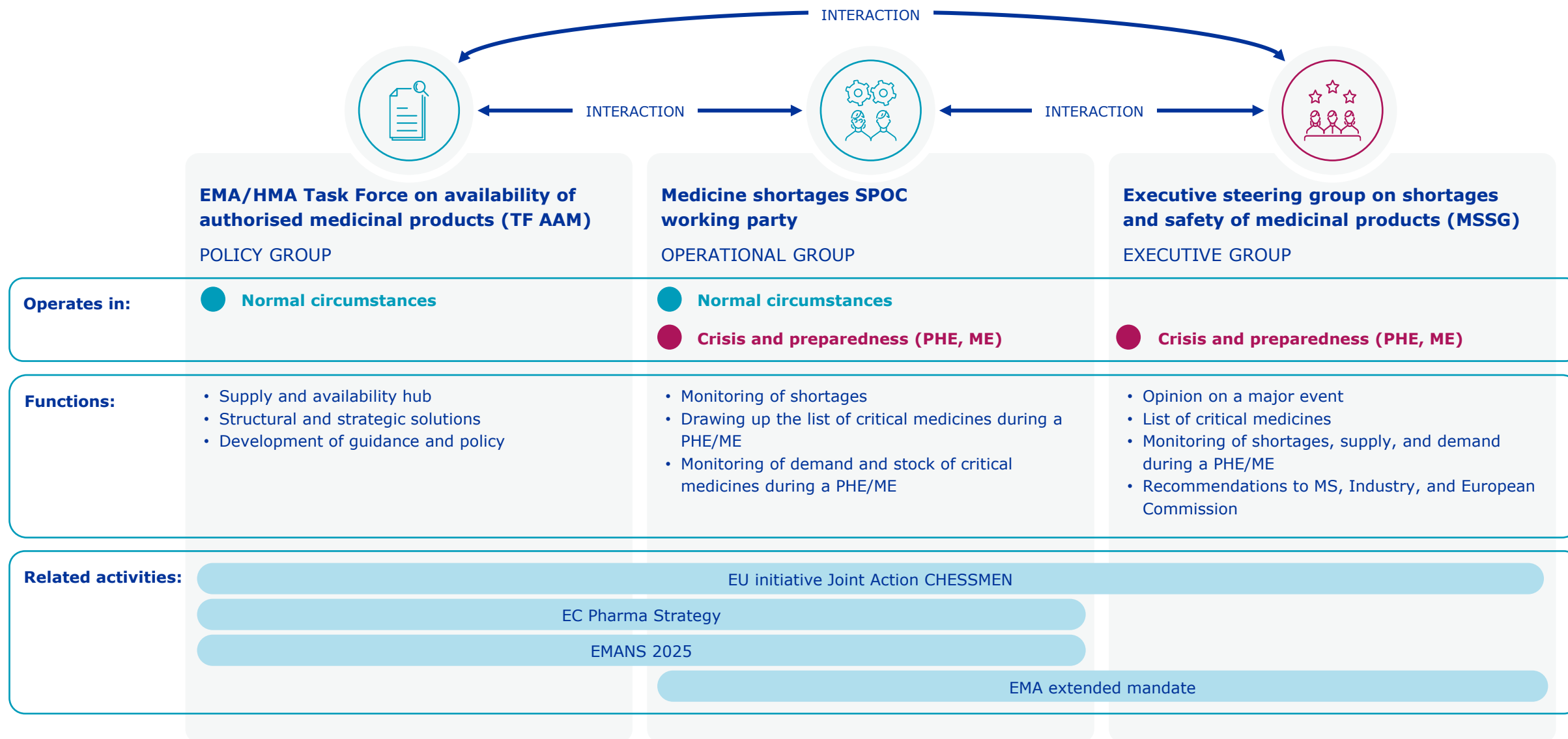
Sets **processes/tools for shortages reporting** and coordinates **responses** of EU countries to shortages of critical medicines during crisis and for monitoring of events which might lead to a crisis situation

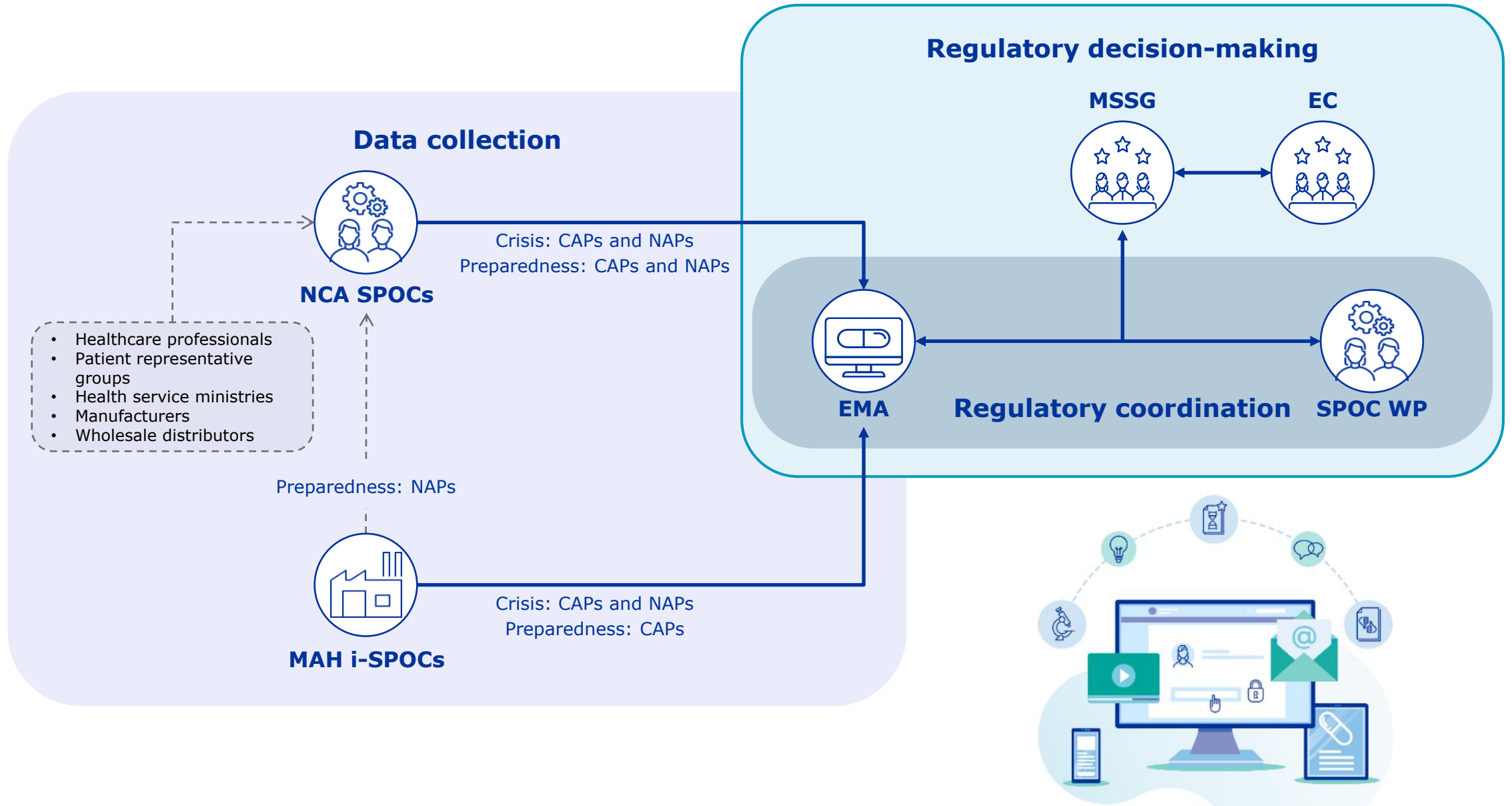


Established the "**Medicines Shortages Steering Group**" (MSSG) supported by the **SPOC Working Party** and a network of contact points from pharmaceutical companies (MAH i-SPOCs)



Foresees the development of the **European Shortages Monitoring Platform** (ESMP) by February 2025





## 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





	Routine shortage reporting	MSSG-led preparedness	Crisis
<b>Available in:</b>	● Normal circumstances	● Preparedness (PHE, ME)	● Crisis (PHE, ME)
<b>Purpose:</b>	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
<b>Submission trigger:</b>	Potential or actual shortage of a marketing authorisation holders' product	MSSG announcement of preparedness exercise	EC recognition of a PHE/ME
<b>Products in scope:</b>	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)
<b>Frequency of reporting:</b>	As required, updated when new relevant information is available	Defined by the MSSG	Defined by the MSSG



## MSSG-led preparedness

## Crisis

**Available in:**

● Preparedness (PHE, ME)

● Crisis (PHE, ME)

**Purpose:**

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:**

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



# Overview of the European Shortages Monitoring Platform (ESMP)

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## 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

## MANAGEMENT



### Shortages management

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



### Data integration

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

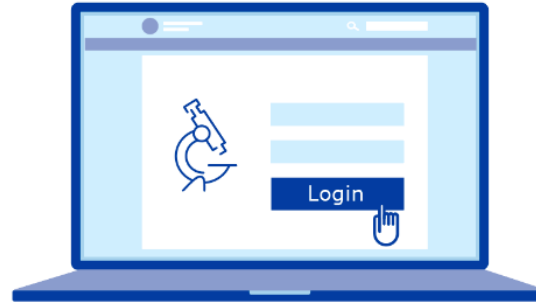
Platform for NCAs



Platform for MAHs



Platform for  
general public



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

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

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

Secure access

Open access



## 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

- 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
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											



NCA SPOCs



ESMP



MAH i-SPOCs

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

- 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**

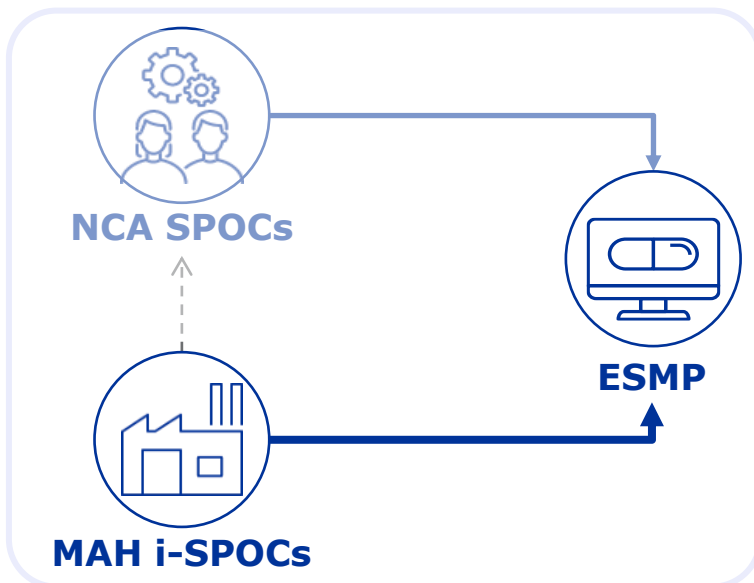
Submissions are **triggered by a potential or actual shortage** and MAHs need to keep the **entries up-to-date**, including the latest information.

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 or major event.

- **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 collection

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

In **normal circumstances**, NCAs will submit routine reporting of critical shortages via the current process of free text notifications and triggering questionnaires to other SPOCs.

- **Marketing status, shortage details, alternative therapies, further actions**

Submissions are **triggered by external events** and **frequency** of reporting is **as needed**.

During an **MSSG-led preparedness exercise**, NCAs submit data on a subset of nationally and centrally authorised products in scope of a critical medicines list.

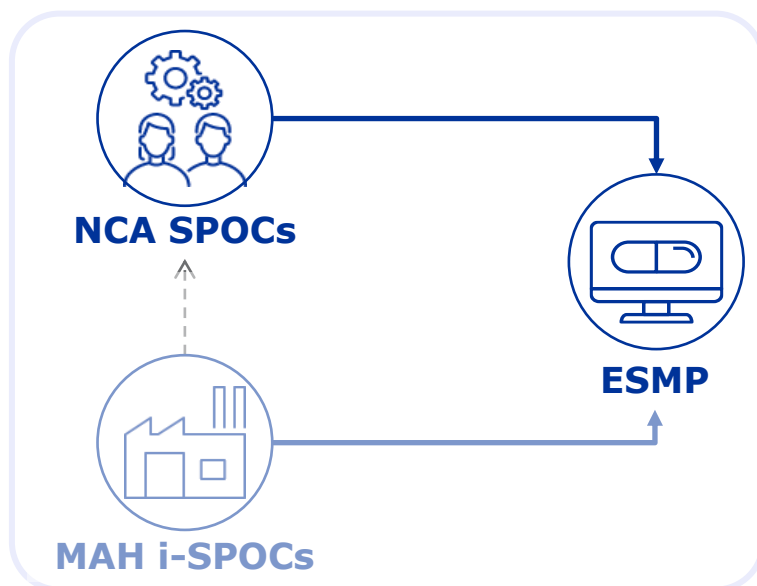
- **Estimated member state demand** for a period of six months

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

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

- **Stock and supply** including historical consumption, volume of sales, planned minimum stock, hospital, community pharmacy, wholesale distributor stocks and strategic reserve
- **Patient estimation** including vaccination needs, hospital and ICU patient-days for the following six-month period
- **Medicine usage** including average daily dose and proportion of estimated patients to be receiving the medicine in hospitals and ICU

Submissions are **triggered by external events** and **frequency** of reporting is **defined by the MSSG**.

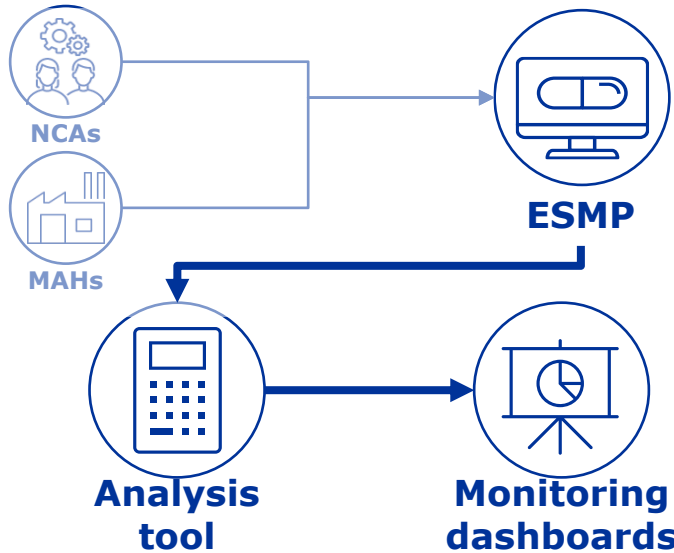
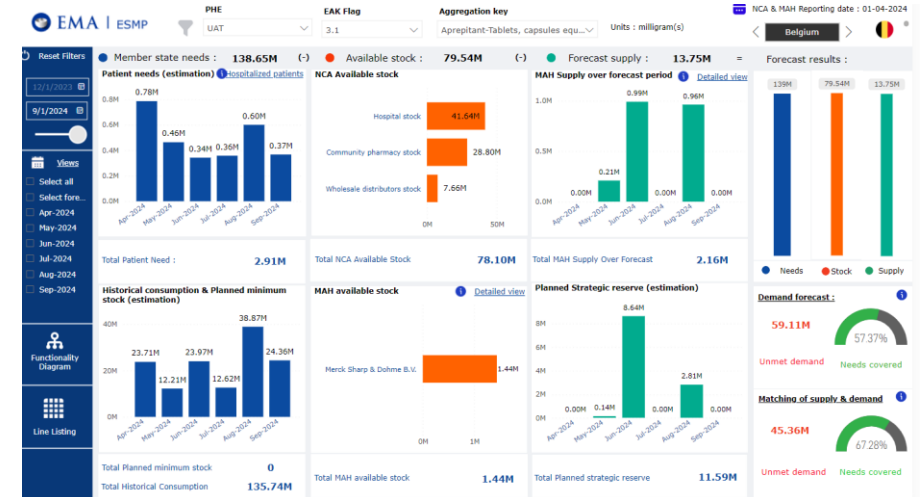




## Analysis & reporting

- 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



## 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



NCA SPOCs



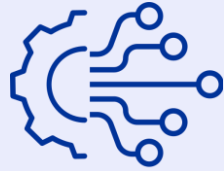
ESMP



MAH i-SPOCs

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

Case Title	Customer	Process Type	Case Subject	Sub-Status	EMA Assist...	Case Folder	Submitte...	Priority	Notification	Modified On	Resoluti
EMA/SH/5000078...	Bristol-Myers Squibb Pharma Eeig	Crisis	Baradude - B...	Under Eval...	Sofia Zastav...	https://euem...	16/02/2024	Normal	21/02/2024 - ...	27/02/2024 13...	
EMA/SH/5000078...	H. Lundbeck A/S	Crisis	Vyepti - H. L...	Completed	ESMP - Shor...	https://euem...	14/02/2024	Normal		06/03/2024 12...	
EMA/SH/5000075...	UAT ORG (ORG-200036100)	Preparedness	Silentium - U...	Completed	Bhavesh Raj...	https://euem...	04/02/2024	Normal		22/02/2024 13...	
EMA/SH/5000074...	Roche Registration GmbH	Crisis	RoActemra - ...	Submitted	ESMP - Shor...	https://euem...	31/01/2024	Normal		22/03/2024 09...	
EMA/SH/5000073...	UAT ORG (ORG-200036099)	Preparedness	Qwerty - UA...	Submitted	ESMP - Shor...	https://euem...	31/01/2024	Normal		22/03/2024 09...	
EMA/SH/5000078...	H. Lundbeck A/S	Preparedness	Brintellix - H...	Submitted	ESMP - Shor...	https://euem...	31/01/2024	Normal	22/03/2024 - ...	22/03/2024 15...	



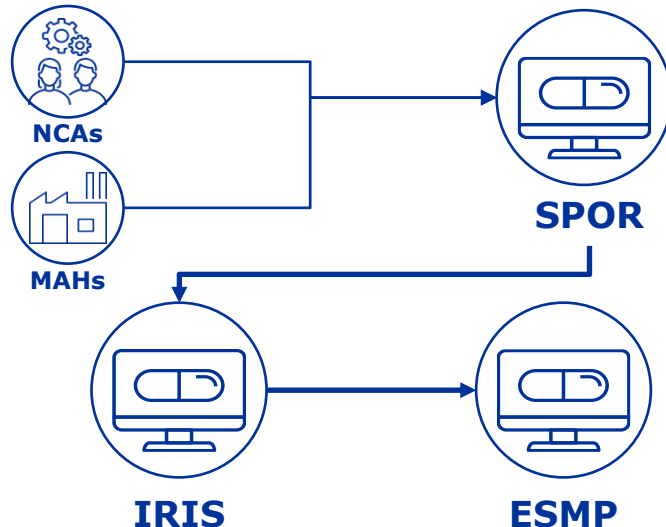
## Data integration

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

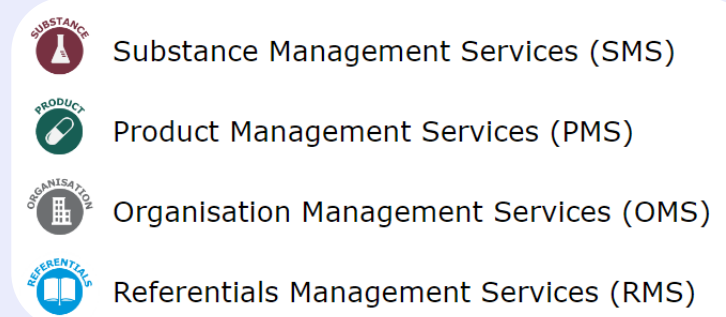
Integration with EMA data management services facilitates the reliable **exchange of information** in a robust and consistent manner by providing master data and a common language used across the EU/EEA.

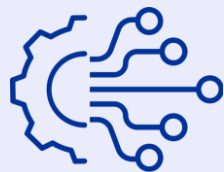
ESMP is integrated with the EMA **Account Management Portal (IAM)**, a secure online platform for requesting and managing access to EMA applications. Integration with **SPOR** also allows ESMP to retrieve harmonised data on data such as product and referentials master data.

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





## 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.

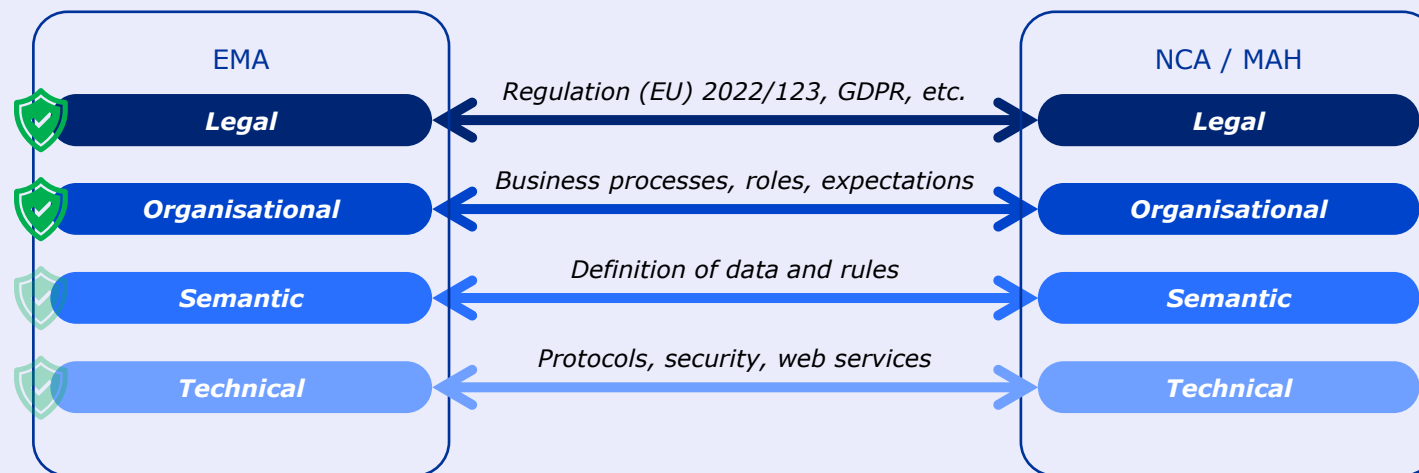
It allows to establish direct links to data across national and industry databases, enabling seamless **machine-to-machine data exchange**, harnessing existing data on the supply chain of products.

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



NCA/MAH system

ESMP





# Development timeline and dependencies

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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.



## Access Management

MAHs

NCA's

Public

### Data collection

#### MAHs

##### Crisis / MSSG-led preparedness

User Interface

Alternative Therapies

Overview of critical medicines

Marketing status NAPs

Marketing status CAPs

Manufacturing details, production plan CAPs

Availability of medicines

Production plan NAPs

##### Preparedness

User interface

Routine shortage reporting CAPs

#### NCA's

##### Crisis

User interface

Stock and supply

Patient estimation

Medicine usage

##### MSSG-led preparedness

User interface

National demand

### 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

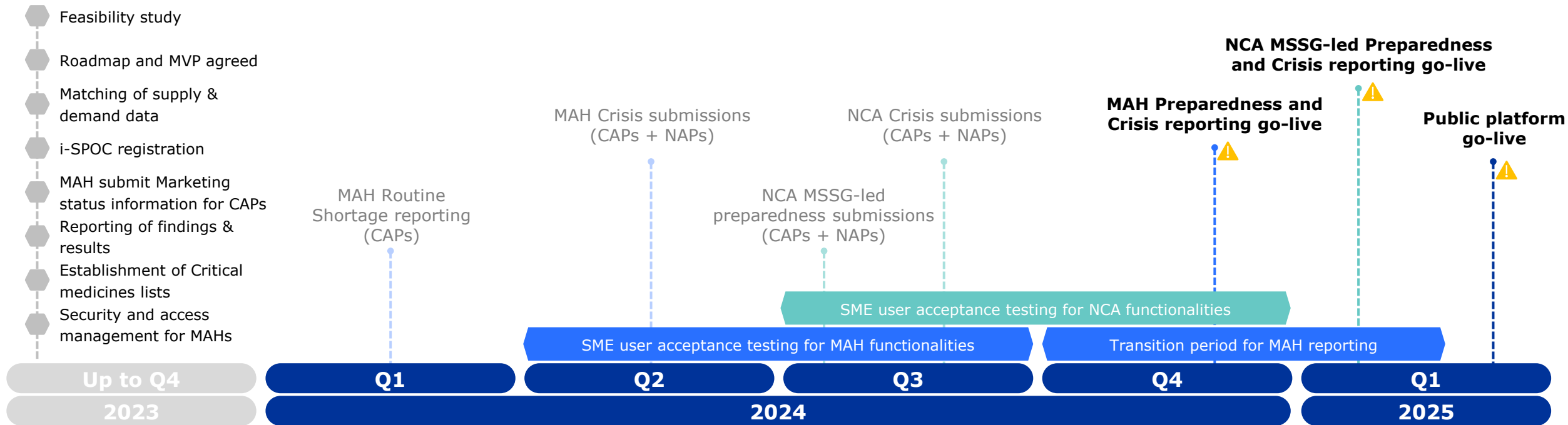
PMS integration (NAPs)

Interoperability

Completed
  In Progress
  Not Started



# Development timeline



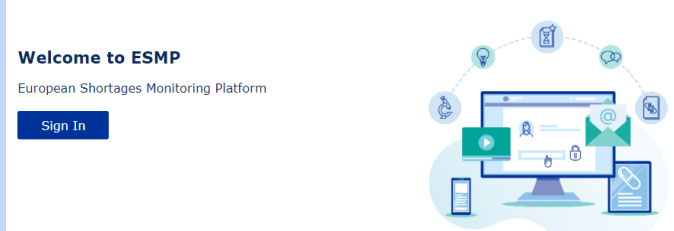


## Member State data systems

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](#)

### ESMP

#### 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 product)	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
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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

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

## 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

The screenshot displays a dashboard with several key metrics and charts:

- Member state needs:** 138,65M
- Available stock:** 79,54M
- Forecast supply:** 13,75M
- Member state needs (bar chart):** Shows demand across various member states.
- Community pharmacy stock (bar chart):** Shows stock levels in pharmacies.
- Wholesale distributors stock (bar chart):** Shows stock levels in wholesalers.
- Historical consumption & Planned minimum stock (bar chart):** Compares past usage with required minimum stock.
- Forecast results (bar chart):** Shows supply vs demand over time.
- Planned Strategic reserve (bar chart):** Shows reserve levels.
- Decreased forecast (gauge):** 59,11M (27,27%)
- Matches of supply & demand (gauge):** 45,36M (32,28%)

Matching of supply and demand data

## Prevent, monitor and manage shortages

26

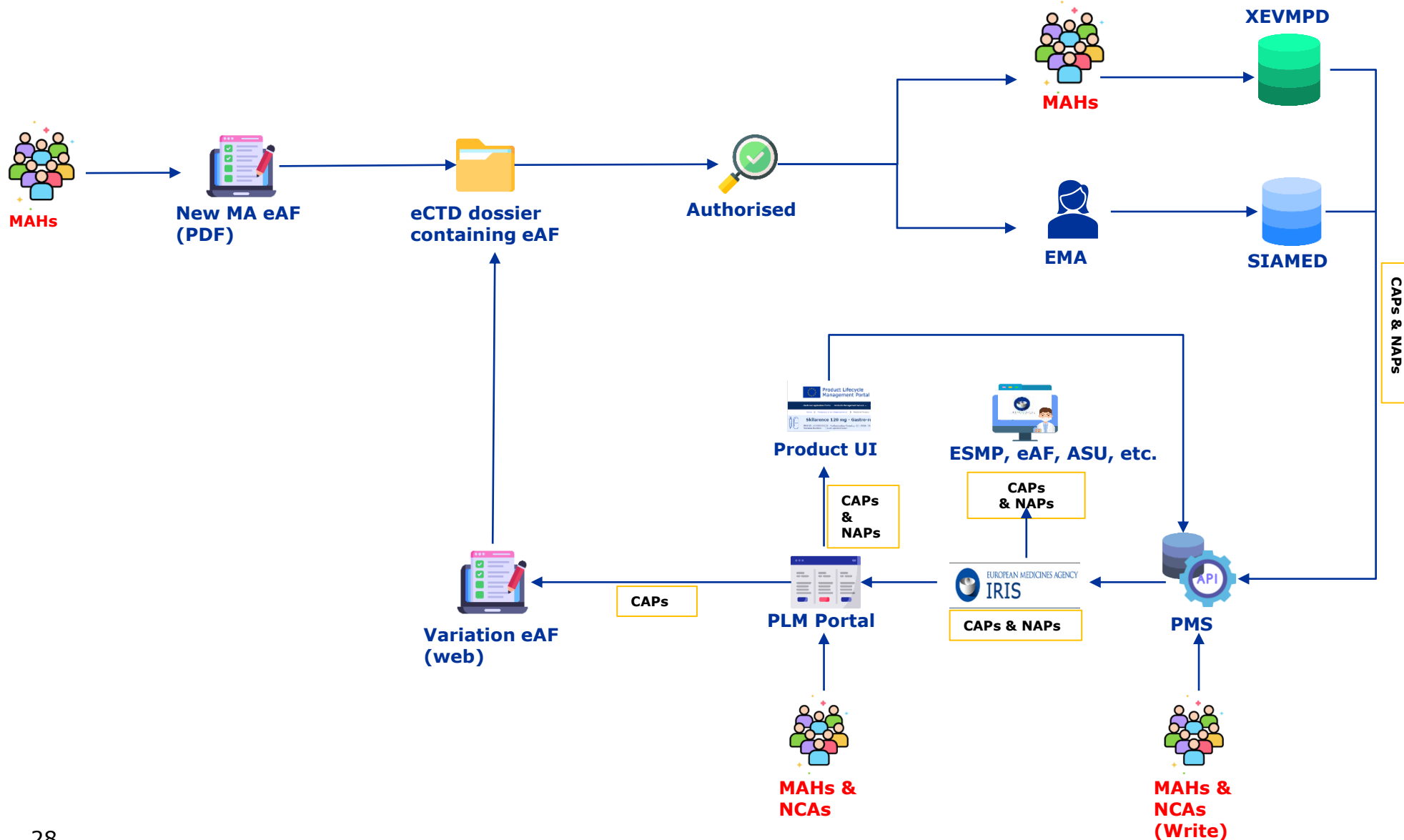
Classified as public by the European Medicines Agency



## ESMP dependencies: Product data submission required in XEVMPD/PMS

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# Data process flow: from XEVMPD to other systems

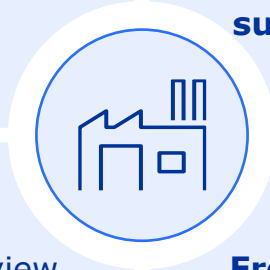


**From XEVMPD to PMS, used in ESMP**

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

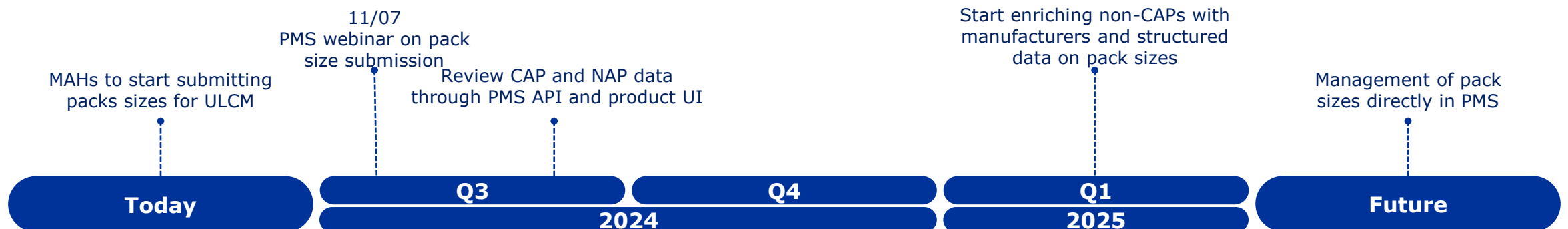
Make sure **authorised pack sizes** for products under the **Union List of Critical Medicines** are submitted to XEVMPD before **February 2025**

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.





# ESMP functionalities: platform structure and MAH data elements

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Technical details and rules of data elements to be reported via ESMP are illustrated in the **ESMP implementation guide for MAHs** which is published on the [ESMP webpage](#).

## Routine shortage reporting

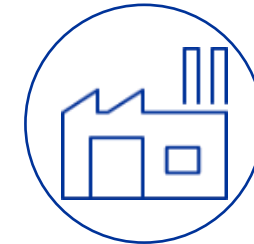
Monitoring of actual or potential shortages that can lead to a public health emergency or major event

**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



**MAH iSPOCs**



**ESMP**





## ● Normal circumstances

EMA | ESMP



### ➤ 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

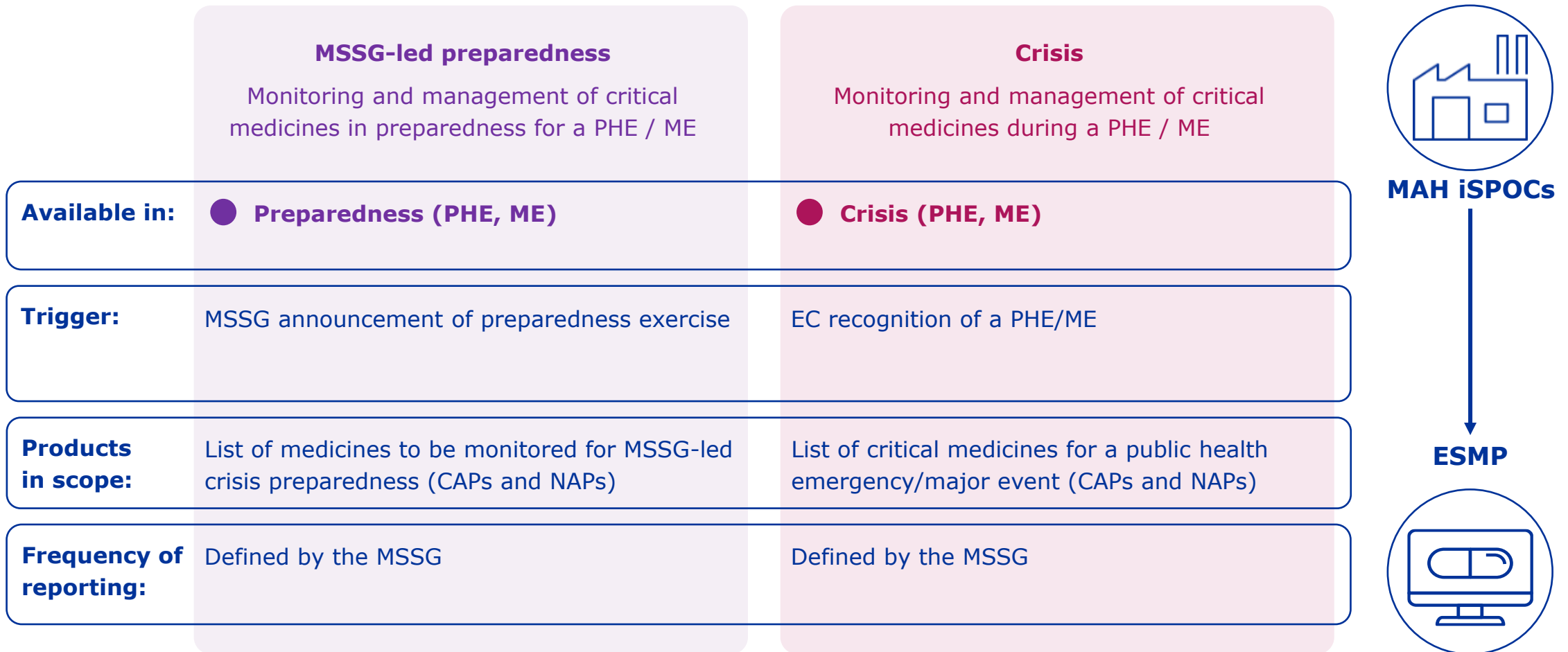




**● Normal circumstances**

<b>Product information</b> <i>(pre-populated from PMS and IRIS)</i>	<i>PMS ID (Packaged medicinal product)</i>
	<i>Full product name</i>
	<i>Short product name</i>
	<i>Active substance</i>
	<i>Strength</i>
	<i>Pharmaceutical form</i>
	<i>Pack size</i>
	<i>Packaging</i>
	<i>PCID</i>
	<i>Country of authorisation</i>
<i>Marketing status</i>	
<b>Shortage information</b>	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	

<b>Prevention and mitigation plans</b>	Shortage prevention and mitigation plans
	Shortage prevention and mitigation plans – ongoing and planned steps
<b>Impact assessment</b>	Affected population estimate
	Market share
	Shortage impact risk assessment
	Shortage impact risk assessment – additional information
<b>Potential alternatives therapies</b>	Alternatives therapies available ? (yes/no)
	Alternative therapies
<b>Additional information</b>	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





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

EMA | ESMP



## 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)



● Preparedness (PHE, ME)

● Crisis (PHE, ME)

EMA | ESMP



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



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

EMA | ESMP



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



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

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



● Preparedness (PHE, ME)

● Crisis (PHE, ME)

EMA | ESMP



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



● Preparedness (PHE, ME)

● Crisis (PHE, ME)

<b>Product information</b> <i>(pre-populated from PMS and IRIS)</i>	<i>PMS ID (Packaged medicinal product)</i>
	<i>Full product name</i>
	<i>Short product name</i>
	<i>Active substance</i>
	<i>Strength</i>
	<i>Pharmaceutical form</i>
	<i>Pack size</i>
	<i>Packaging</i>
	<i>PCID</i>
	<i>Country of authorisation</i>
<b>Shortage information</b>	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
Root cause of the shortage – additional information	
<b>Shortage prevention and mitigation plans</b>	Shortage prevention and mitigation plans
	Shortage prevention and mitigation plans – ongoing and planned steps

<b>Market share</b>	Market share
	Market share – additional information
<b>Shares volume and forecast</b>	Sales volume
	Sales volume – pre-PHE/ME
	Sales forecast – month 1
	Sales forecast – month 2
	Sales forecast – month 3
	Sales forecast – month 4
	Sales forecast – month 5
Sales forecast – month 6	
<b>Supply forecast</b>	Additional information on sales volume
	Supply forecast – month 1
	Supply forecast – month 2
	Supply forecast – month 3
	Supply forecast – month 4
	Supply forecast – month 5
	Supply forecast – month 6
Supply forecast – additional information	
<b>Stock information</b>	Available stock
	Desired safety stock
	Stocks – additional information





● Preparedness (PHE, ME)

● Crisis (PHE, ME)

EMA | ESMP



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**



● Preparedness (PHE, ME)

● Crisis (PHE, ME)

<b>Product information</b> <i>(pre-filled from PMS)</i>	<i>PMS ID (Medicinal product)</i>
	<i>Full product name</i>
	<i>Active substance</i>
<b>Representative product</b>	Representative product
<b>Organisation information</b> <i>(pre-filled from PMS and OMS, currently available only for CAPs)</i>	<i>Operation type ID</i>
	<i>Operation type</i>
	<i>ORG-ID (Manufacturer)</i>
	<i>Manufacturer</i>
	<i>LOC-ID (Manufacturer)</i>
	<i>City (Manufacturer)</i>
	<i>Country (Manufacturer)</i>
<b>Manufacturing details</b>	Manufacturing site status
	Is the site a contract manufacturer?
<b>Alternative sites</b>	Alternative site LOC-ID
	Alternative site Country

<b>Production capacity</b> <i>(for API and FDF)</i>	Unit of measurement
	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
	Global monthly production plan - additional information
	Average global monthly production output of previous year
	Peak global monthly production output of previous year



● Preparedness (PHE, ME)

● Crisis (PHE, ME)

EMA | ESMP



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



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

<b>Product information</b> (pre-filled from PMS)  *for CAPs	<i>Invented name*</i>
	<i>Active substances</i>
	<i>Pharmaceutical form</i>
<b>Alternative therapies</b>	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



# ESMP functionalities: platform structure and NCA data elements

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Technical details and rules of data elements to be reported via ESMP are illustrated in the **ESMP implementation guide for NCAs** which is published on the [ESMP webpage](#).



## Critical 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 medicinal product for which there is no appropriate alternative available on the market in the NCA's Member State

**Products in scope:** All products

**Frequency of reporting:** As required, updated when new relevant information is available



**NCA SPOCs**



**ESMP**



## MSSG-led preparedness

Monitoring and management of critical medicines in preparedness for a PHE / ME

**Available in:** ● Preparedness (PHE, ME)

**Trigger:** MSSG announcement of preparedness exercise

**Products in scope:** List of medicines to be monitored for MSSG-led crisis preparedness (CAPs and NAPs) authorised in the NCA's Member State

**Frequency of reporting:** Defined by the MSSG



**NCA SPOCs**



**ESMP**





## ● Preparedness (PHE, ME)

EMA | ESMP



### ➤ National demand



The national demand feature applies to MSSG-led preparedness reporting situations. For each packaged medicinal product, national competent authorities (NCAs) will be requested to report information about the **estimated number of units** of the medicinal product **needed to treat patients for a six months** forecast period.





● Preparedness (PHE, ME)

<b>Product information</b> <i>pre-populated from PMS</i>	<i>PMS ID (Medicinal product)</i>
	<i>Full product name</i>
	<i>Short product name</i>
	<i>MAH</i>
	<i>Active substance</i>
	<i>Active substance strength</i>
	<i>Pharmaceutical form</i>
	<i>Units of presentation</i>
<b>Demand forecast</b>	Demand forecast Month 1
	Demand forecast Month 2
	Demand forecast Month 3
	Demand forecast Month 4
	Demand forecast Month 5
	Demand forecast Month 6

**Crisis**  
Monitoring and management of critical medicines during a PHE / ME

<b>Available in:</b>	● <b>Crisis (PHE, ME)</b>
<b>Trigger:</b>	EC recognition of a PHE/ME
<b>Products in scope:</b>	List of critical medicines for a public health emergency/major event (CAPs and NAPs) authorised in the NCA's Member State
<b>Frequency of reporting:</b>	Defined by the MSSG



**NCA SPOCs**



**ESMP**





## ● Crisis (PHE, ME)

EMA | ESMP



### ➤ Stock and supply

Patient estimation

Medicine usage



The stock and supply feature is activated in crisis conditions. In this eventuality, national competent authorities (NCAs) will be requested to report for each packaged medicinal product details about **member state available stock**, reflecting stocks from various stakeholders such as hospitals, pharmacies, and wholesale distributors. NCAs are also required to report information on (planned) strategic reserves and minimum stock. NCAs will report information also about **historical consumption** and **volume of prescriptions**.



● **Crisis (PHE, ME)**

<b>Product information</b> <i>pre-populated from PMS</i>	<i>PMS ID (Packaged medicinal product)</i>
	<i>Full product name</i>
	<i>Short product name</i>
	<i>Marketing Authorisation Holder (MAH)</i>
	<i>Active substance</i>
	<i>Strength</i>
	<i>Pharmaceutical form</i>
	<i>Pack size</i>
	<i>Packaging</i>
<b>MS available stock</b>	Current hospital stock
	Current community pharmacy stock
	Current wholesale distributors stock
	Current strategic reserve
<b>Planned minimum stock</b>	Planned minimum stock

<b>Planned strategic reserve</b>	Planned strategic reserve Month 1
	Planned strategic reserve Month 2
	Planned strategic reserve Month 3
	Planned strategic reserve Month 4
	Planned strategic reserve Month 5
	Planned strategic reserve Month 6
<b>Historical consumption (non-PHE/ME need)</b>	Historical consumption non-PHE/ME need Month 1
	Historical consumption non-PHE/ME need Month 2
	Historical consumption non-PHE/ME need Month 3
	Historical consumption non-PHE/ME need Month 4
	Historical consumption non-PHE/ME need Month 5
	Historical consumption non-PHE/ME need Month 6
<b>Historical volume of prescriptions</b>	Historical volume of prescriptions Month 1
	Historical volume of prescriptions Month 2
	Historical volume of prescriptions Month 3
	Historical volume of prescriptions Month 4
	Historical volume of prescriptions Month 5
	Historical volume of prescriptions Month 6



● Crisis (PHE, ME)

EMA | ESMP



Stock and supply

➤ **Patient estimation**

Medicine usage



The patient estimation feature applies in crisis situations with the aim to collect details about the **estimated number of patients for vaccination, hospitalised patients-days, and intensive care unit (ICU) patient-days.**



**Crisis (PHE, ME)**

<b>Vaccination - estimated total number of patients</b>	Month 1
	Month 2
	Month 3
	Month 4
	Month 5
	Month 6
	PHE/ME RMS ID
<b>Hospital - estimated total number of hospitalised patient- days</b>	Month 1
	Month 2
	Month 3
	Month 4
	Month 5
	Month 6
	PHE/ME RMS ID
<b>ICU - estimated total number of ICU patient-days</b>	Month 1
	Month 2
	Month 3
	Month 4
	Month 5
	Month 6
	PHE/ME RMS ID



## ● Crisis (PHE, ME)

EMA | ESMP



Stock and supply

Patient estimation

➤ **Medicine usage**



The medicine usage feature is needed during crisis situations to gather information regarding the amounts of critical medicines (expressed as active substances and pharmaceutical forms) expected to be used. Based on historical data on medicine usage, NCAs can provide ESMP with **estimate average data** for the usage of medicines in hospitals and Intensive Care Units (ICU).



● **Crisis (PHE, ME)**

<b>Medicine information</b>	Active substance SMS ID
	Active substances
	Pharmaceutical dose form RMS ID
	Pharmaceutical dose forms
<b>Hospital medicine usage</b>	Average daily dose of medicine per adult patient - hospital (mg/patient-day)
	Proportion of estimated patients receiving the medicine - hospital
<b>ICU medicine usage</b>	Average daily dose of medicine per adult patient - ICU (mg/patient-day)
	Proportion of estimated patients receiving the medicine - ICU





# Interoperability

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## Recital (20)

*"In order to facilitate the coordination role of the Agency, the **interoperability of data** with existing Member States' IT platforms for monitoring shortages and other systems, as appropriate, is essential to allow the sharing of relevant information with the ESMP, which should be managed by the Agency."*

## Article 9(1)

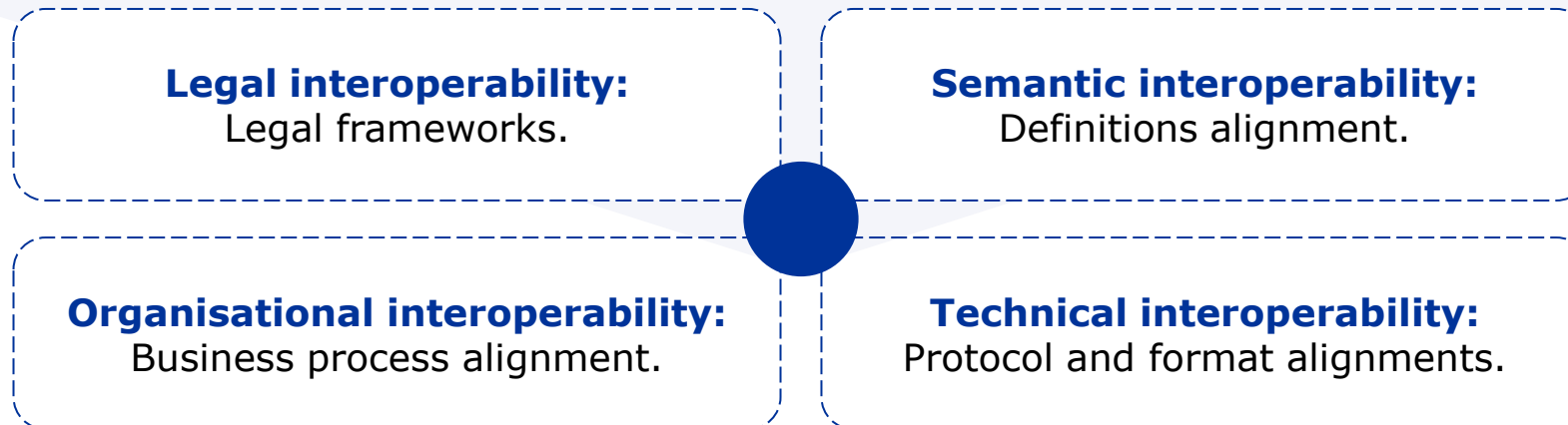
*Working methods and provision of information on medicinal products:*

*(c) develop streamlined IT monitoring and reporting systems, in coordination with the relevant national competent authorities, that facilitate **interoperability** with other existing IT systems and IT systems under development until the ESMP is fully functional, on the basis of data fields that are harmonised across Member States;*

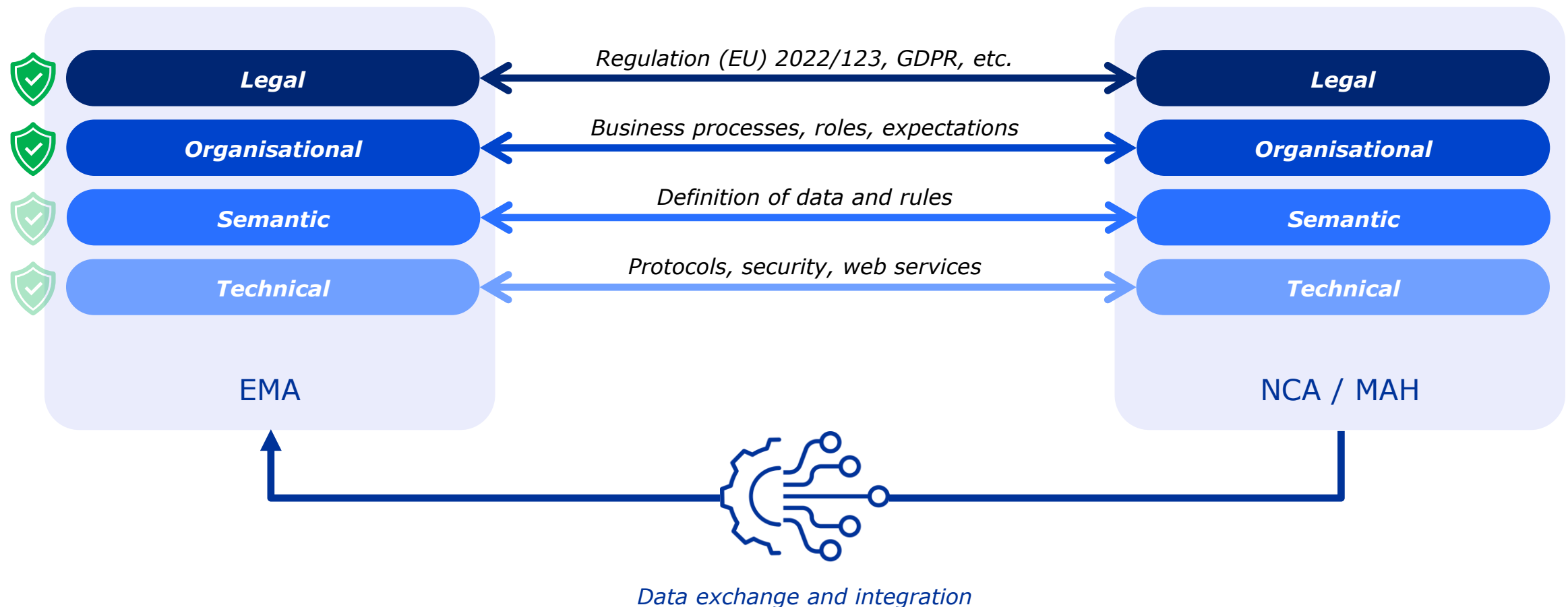


The EIF represents a **commonly agreed approach to the delivery of European public services in an interoperable manner**. It defines basic interoperability guidelines in the form of common principles, models and recommendations. For the purpose of the EIF, interoperability is defined as:

*"the **ability of organisations to interact** towards mutually beneficial goals, involving the **sharing of information and knowledge** between these organisations, through the business processes they support, by means of the **exchange of data between their ICT systems**."*

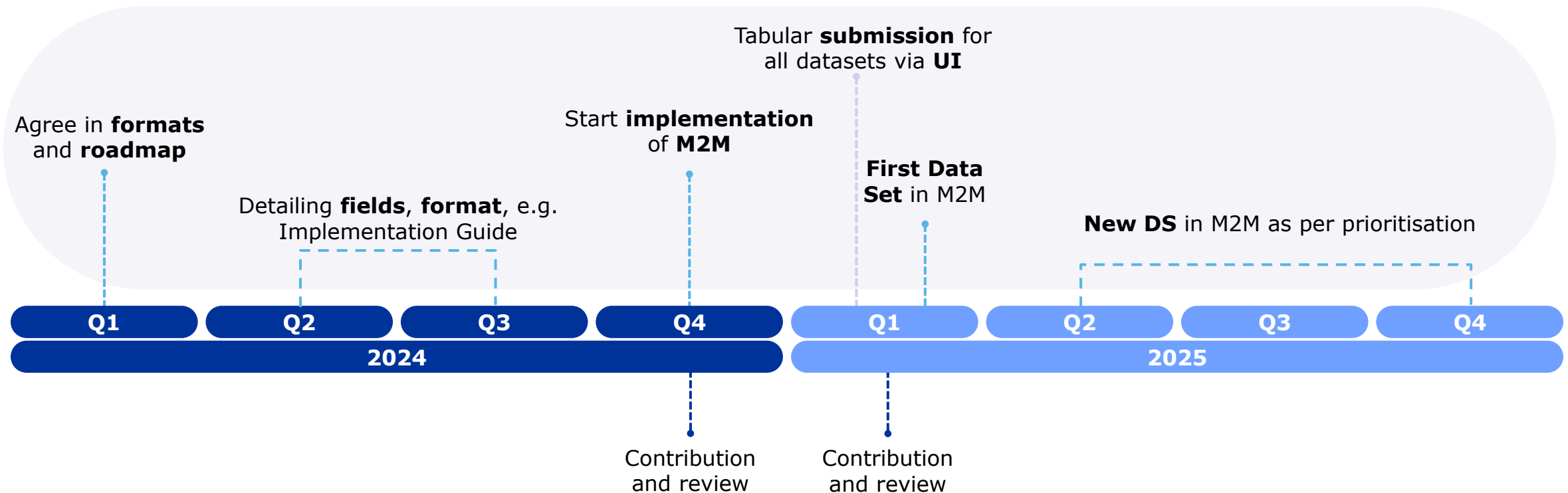


Interoperability is defined as the **ability of organisations to interact towards mutually beneficial goals**, involving the **sharing of information and knowledge** between these organisations, through the business processes they support, by means of the exchange of data between their ICT systems.



## Machine to Machine (M2M) solution

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





# Stakeholder engagement

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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*



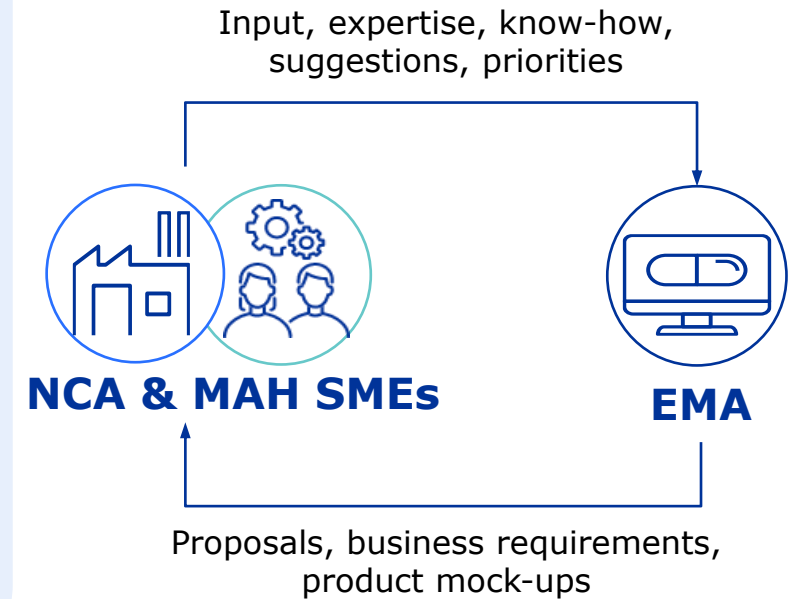
- Supporting the **definition and development** of the minimum viable product (MVP)
- Providing **recommendations** and supporting **consistent enhancements** to the ESMP



- 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

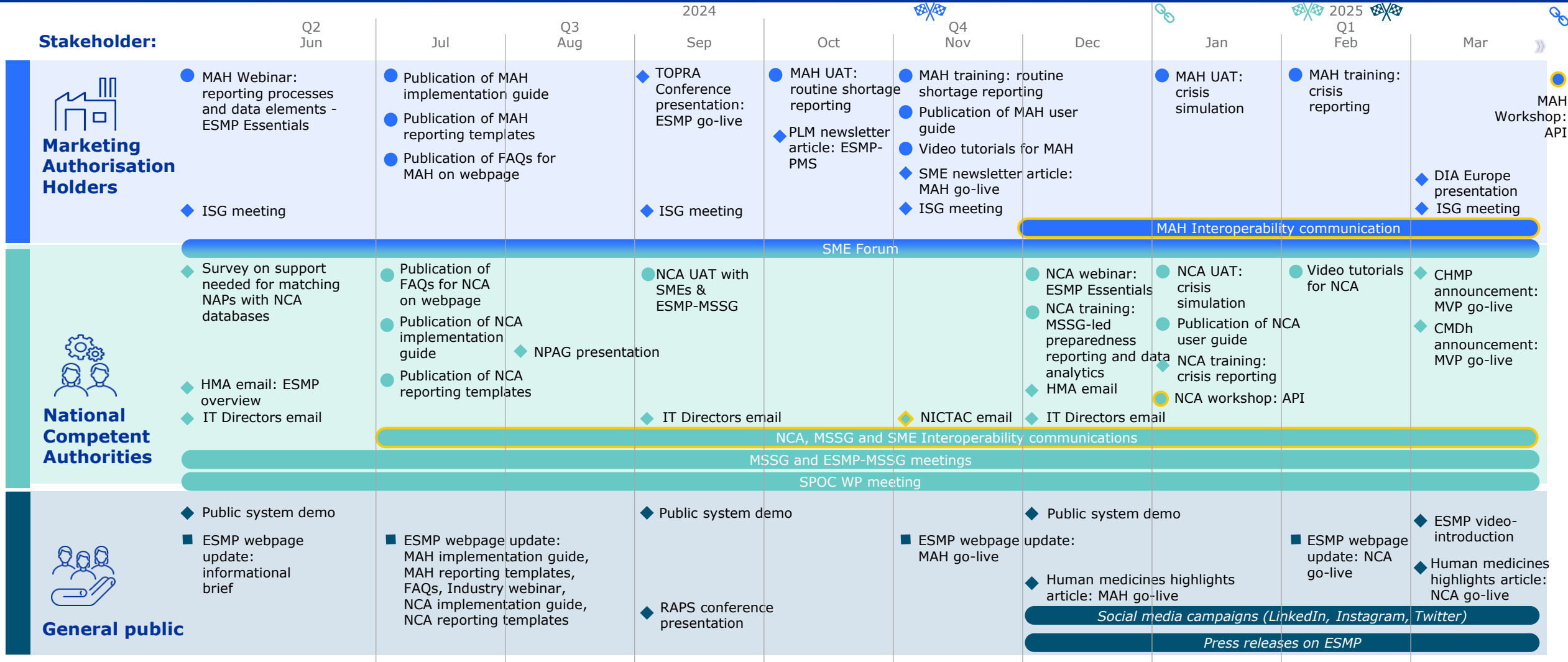
SMEs: Subject Matter Experts  
ESMP-MSSG WG: ESMP-MSSG Working Group

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

# ESMP communication plan



**Legend:** ● Training materials/activities    ◆ Communication and engagement activities    ■ ESMP webpage update    ● MAH    ● NCA    ● General public    🔗 API    🚩 Go-live

Please note: the presented timings may be subject to change. Specific dates will be confirmed closer to each deadline. Yellow initiatives represent Interoperability related ones

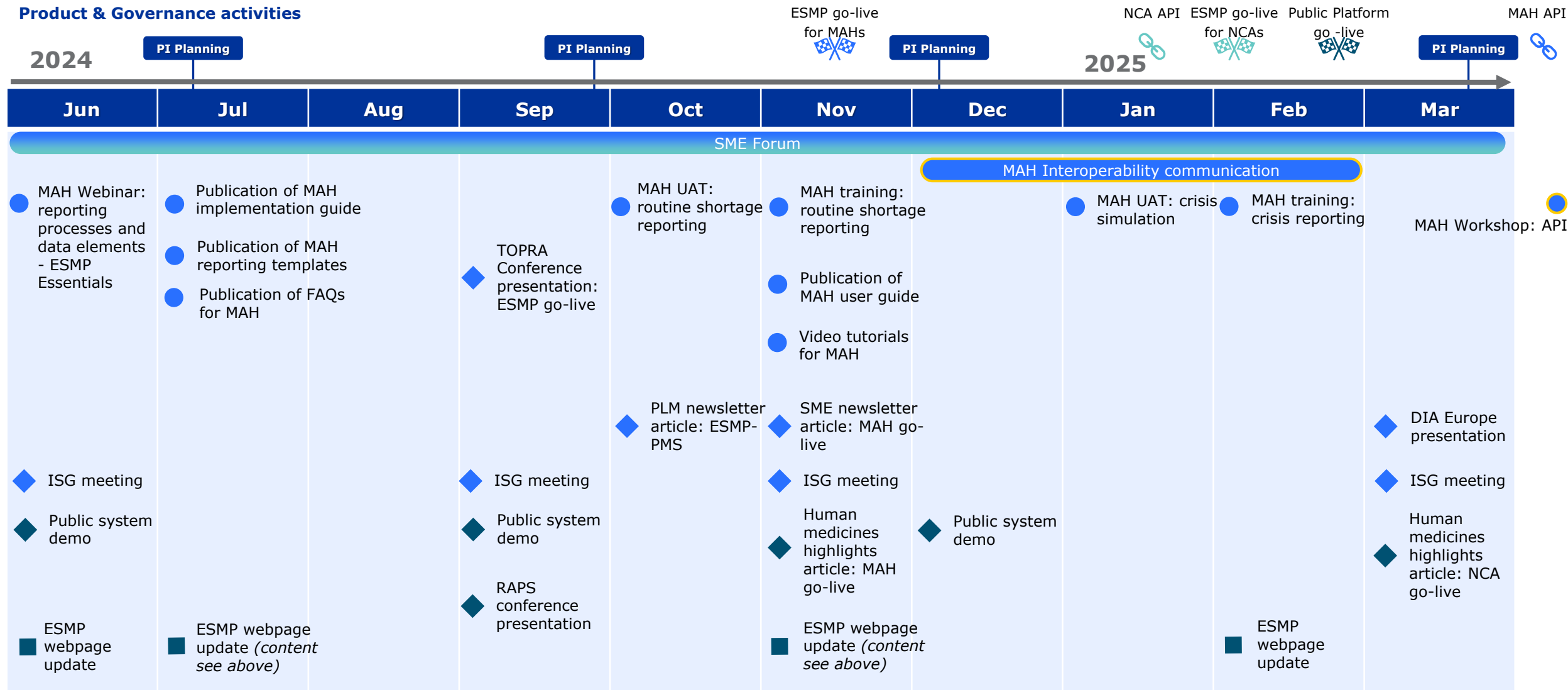


# ESMP communication plan: focus on MAHs



EUROPEAN MEDICINES AGENCY

## Product & Governance activities



**Legend:** ● Training materials/activities    ◆ Communication and engagement activities    ■ ESMP webpage update    ● MAH    ● NCA    ● General public    🔗 API    🚩 Go-live

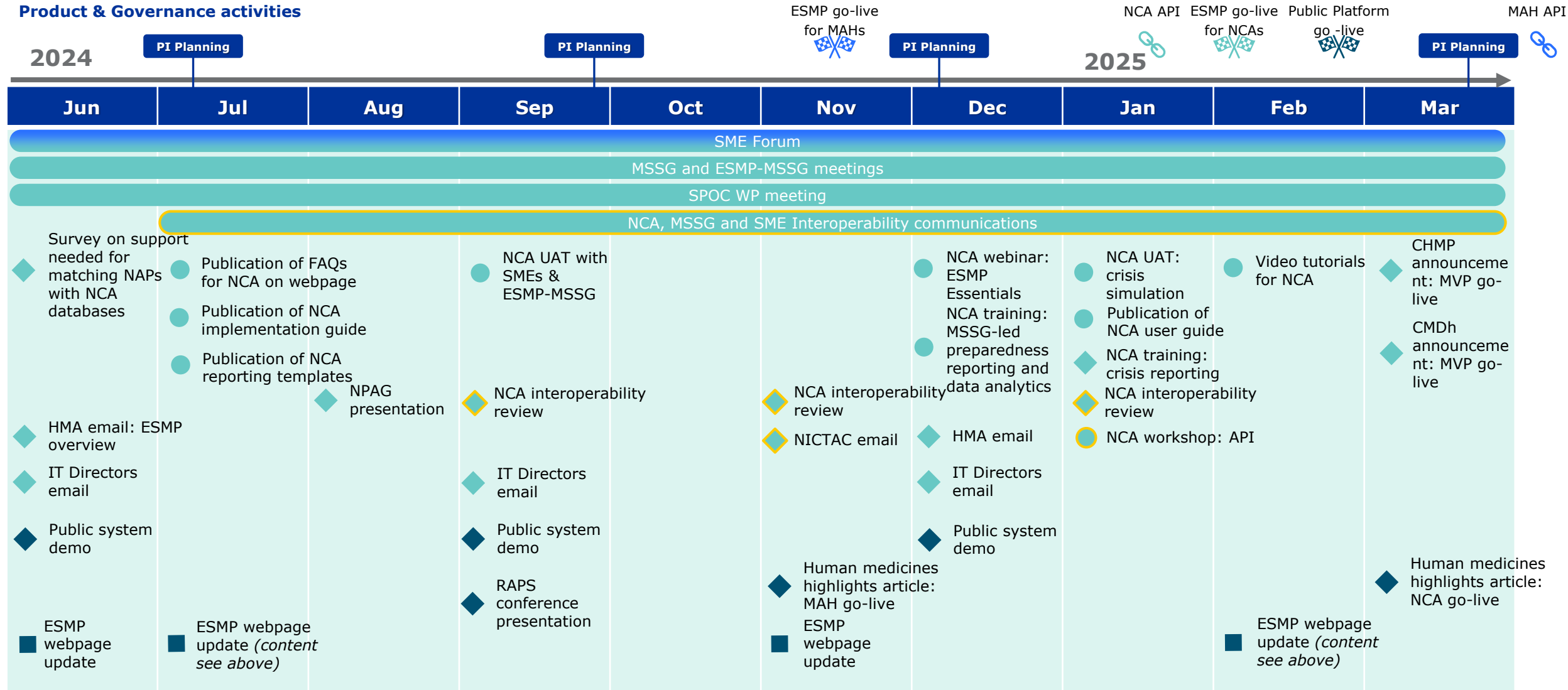
Please note: the presented timings may be subject to change. Specific dates will be confirmed closer to each deadline. Yellow initiatives represent Interoperability related ones.

# ESMP communication plan: focus on NCAs



EUROPEAN MEDICINES AGENCY

## Product & Governance activities



**Legend:** ● Training materials/activities ● Communication and engagement activities ■ ESMP webpage update ● MAH ● NCA ● General public 🔗 API 🇪🇺 🇬🇧 🇮🇹 🇪🇸 🇫🇷 🇩🇪 🇬🇰 🇮🇪 🇮🇸 🇯🇪 🇱🇻 🇻🇪 🇽🇰 🇾🇪 🇿🇪 Go-live

Please note: the presented timings may be subject to change. Specific dates will be confirmed closer to each deadline. Yellow initiatives represent Interoperability related ones.



## ESMP webpage

Click [here](#)

- **Additional information** regarding ESMP (e.g., high-level information on the role of the platform, development and milestones)
- **MAH and NCA implementation guides and templates**, to provide clarifications regarding requirements
- **FAQs** document to illustrate answers to frequently asked questions gathered
- **Events** deep-dive to keep stakeholders updated on past and upcoming meetings



## EMA availability page

Click [here](#)

- **Good practices for industry for the prevention of human medicinal product shortages** to provide recommendations and clarifications
- Information regarding **i-SPOCs** for human medicines and their **registration**



## Further information

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For questions on the ESMP, please consult the FAQs on the [ESMP webpage](#) or [Send a question to the European Medicines Agency](#).

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