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

24 June 2024, 10:00 – 12:30 CEST
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.

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Goals and objectives

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

For questions: www.slido.com  Code: #ESMP-ESS
Send your questions via Slido

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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Shortages management in the EU

Monica Dias, *Head of Supply and Availability of Medicines and Devices*
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.
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.
Coordinating medicine availability in the EU

**EMA/HMA Task Force on availability of authorised medicinal products (TF AAM)**

**POLICY GROUP**

- Operates in:
  - Normal circumstances
- Functions:
  - Supply and availability hub
  - Structural and strategic solutions
  - Development of guidance and policy
- Related activities:
  - EU initiative Joint Action CHESSMEN
  - EC Pharma Strategy
  - EMANS 2025

**Medicine shortages SPOC working party**

**OPERATIONAL GROUP**

- Operates in:
  - Normal circumstances
  - Crisis and preparedness (PHE, ME)
- Functions:
  - 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
- Related activities:
  - EU initiative Joint Action CHESSMEN
  - EC Pharma Strategy
  - EMANS 2025

**Executive steering group on shortages and safety of medicinal products (MSSG)**

**EXECUTIVE GROUP**

- Operates in:
  - Crisis and preparedness (PHE, ME)
- Functions:
  - 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

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

Classified as public by the European Medicines Agency
ESMP in the regulatory landscape

Data collection

- NCA SPOCs
  - Healthcare professionals
  - Patient representative groups
  - Health service ministries
  - Manufacturers
  - Wholesale distributors

- MAH i-SPOCs
  - Preparedness: NAPs
  - Crisis: CAPs and NAPs

Preparedness: NAPs

Crisis: CAPs and NAPs

Regulatory decision-making

- MSSG
- EC

Regulatory coordination

SPOC WP

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# Overview of medicines’ lists

## Union list of critical medicines
- **Available in:** Normal circumstances
- **Purpose:**
  - Help tracking of EU manufacturing capacity
  - Ensure security of supply and availability of critical medicines at EU level
- **Defined by:** EMA / Heads of Medicines Agencies (HMA)
- **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*

## List of medicines to be monitored for MSSG-led crisis preparedness
- **Available in:** Preparedness (PHE, ME)
- **Purpose:**
  - 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
- **Defined by:** Executive steering group on shortages and safety of medicinal products (MSSG)
- **Data submission requirements:**
  - European Shortages Monitoring Platform (ESMP) reporting

## List of critical medicines for a public health emergency/major event
- **Available in:** Crisis (PHE, ME)
- **Purpose:**
  - 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:** Executive steering group on shortages and safety of medicinal products (MSSG)
- **Data submission requirements:**
  - 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

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

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Overview of the European Shortages Monitoring Platform (ESMP)

Sofia Zastavnik, *ESMP Product Owner*
ESMP vision and purpose

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

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

SPOR – substance, product, organisation, referentials management system
IAM- identity access management system
Platform user interfaces (UI)

Platform for NCAs

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

Secure access

Platform for MAHs

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

Open access

Platform for general public

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

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Benefits of establishing ESMP

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

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Data collection in the ESMP

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

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

For questions: www.slido.com  Code: #ESMP-ESS
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
- Shortage impact assessment
- Alternative therapies

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

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

- Shortage information
- Supply and demand of medicines
- Marketing status
- Market share, sales volume and sales forecast
- Manufacturing information including production plan, capacity and alternative sites
- 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.

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

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.

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

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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.

**Data integration**

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

**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: interoperability with national & 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.
Coffee Break

See you in 5’

Send your questions via Slido:

Join at
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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.

For questions: www.slido.com  Code: #ESMP-ESS
High level progress diagram – incremental development

Access Management

MAHs

NCAs

Public

Data collection

MAHs

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

Preparedness

- User interface
- Routine shortage reporting CAPs

NCAs

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

Analysis & Reporting

- Match supply and demand
- iSPOC registration

Shortages Management

- EMA dashboards and reports
- Maintain lists of critical products
- NCA dashboards and reports
- Case management of CAP shortages
- Public webpage

Data Integration

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

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

Feasibility study
Roadmap and MVP agreed
Matching of supply & demand data
i-SPOC registration
MAH submit Marketing status information for CAPs
Reporting of findings & results
Establishment of Critical medicines lists
Security and access management for MAHs

Up to Q4
2023

Q1
Q2
Q3
Q4
2024
2025

MAH Routine Shortage reporting (CAPs)
MAH Crisis submissions (CAPs + NAPs)
NCA MSSG-led preparedness submissions (CAPs + NAPs)
SME user acceptance testing for MAH functionalities
Transition period for MAH reporting
NCA Crisis submissions (CAPs + NAPs)
Public platform go-live

Legend:
 explodes for PMS dependency
 blue for MAH functionalities
 light blue for NCA functionalities
 olive for development completed

For questions: www.slido.com Code: #ESMP-ESS
Stakeholder collaboration in product development

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

- 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

Input, expertise, know-how, suggestions, priorities

NCA & MAH SMEs

Proposals, business requirements, product mock-ups

EMA

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Flow of information: ESMP & PMS

**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.

**Regulatory coordination**
SPOC WP, MSSG, and EC
Measures to prevent, manage and mitigate shortages in EU/EEA, such as exploring MAHs supply capacity and possibility to increase production, regulatory support, etc.

**Data analytics platform**
Matching of supply and demand data

**ESMP**
Packaged medicinal product data (PMS)
Prefilled in ESMP templates/machine-to-machine

Users complete ESMP templates with relevant information per product.

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

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

- New MA eAF (PDF) -> eCTD dossier containing eAF -> Authorised
- MAHs
- EMA
- SIAMED
- XEVMPD

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

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**Actions for MAHs**

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

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

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

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

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

- 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.

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

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**Timeline**

- **Today**
  - MAHs to start submitting packs sizes for ULCM
  - 11/07 PMS webinar on pack size submission

- **Q3 2024**
  - Review CAP and NAP data through PMS API and product UI

- **Q4 2024**
  - Start enriching non-CAPs with manufacturers and structured data on pack sizes

- **Q1 2025**
  - Management of pack sizes directly in PMS

- **Future**
ESMP functionalities: platform structure and data elements

Sofia Zastavnik, ESMP Product Owner
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

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
### 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
- Rapid alert reference number
- Other authorities notified (e.g., other NCAs, EMA), including reference to Quality Defect report

### Additional information

- Reference to related pending regulatory action
- Required NCA actions, if any

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<td>Defined by the MSSG</td>
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**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

**MAH iSPOCs**

**ESMP**
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).
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

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

<table>
<thead>
<tr>
<th>Product information (pre-populated from PMS)</th>
<th>Marketing status details</th>
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</thead>
<tbody>
<tr>
<td>PMS ID (Packaged medicinal product)</td>
<td>Marketing status</td>
</tr>
<tr>
<td>Full product name</td>
<td></td>
</tr>
<tr>
<td>Short product name</td>
<td>Date of planned permanent withdrawal</td>
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<tr>
<td>Active substance</td>
<td>Planned withdrawal comment</td>
</tr>
<tr>
<td>Strength</td>
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<td>Pharmaceutical form</td>
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For questions: www.slido.com  
Code: #ESMP-ESS
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

**Product information**

- 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

**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

---

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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

| Product information (pre-filled from PMS) | | Organisation information (pre-filled from PMS and OMS, currently available only for CAPs) | | Production plan (for API and FDF) | | Production capacity (for API and FDF) |
|-----------------------------------------|---------------------------------|---------------------------------|---------------------------------|---------------------------------|---------------------------------|
| PMS ID (Medicinal product)              | Full product name               | Organisation ID (Manufacturer)  | Manufacturer                     | Operation type ID               | Unit of measurement (kg/units)  |
|                                        | Active substance                |                                 |                                 | Operation type                  | Global monthly production plan - month 1 |
|                                        |                                 | City (Manufacturer)             |                                 | Location ID (Manufacturer)      | Global monthly production plan – month 2 |
|                                        |                                 | Country                        |                                 |                                 | 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 |
|                                        |                                 |                                 |                                 |                                 | Average global monthly production output of previous year |
|                                        |                                 |                                 |                                 |                                 | Peak global monthly production output of previous year |
|                                        |                                 |                                 |                                 |                                 | |

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*Submission of manufacturing information for NAPs currently under refinement, changes possible
Platform view: 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

For questions: www.slido.com  Code: #ESMP-ESS
### Data elements: alternative therapies

<table>
<thead>
<tr>
<th>Product information (pre-filled from PMS)</th>
<th>Invented name*</th>
</tr>
</thead>
<tbody>
<tr>
<td>*for CAPs</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Active substances</td>
</tr>
<tr>
<td></td>
<td>Pharmaceutical form</td>
</tr>
<tr>
<td>Alternative therapies</td>
<td>Alternative substances</td>
</tr>
<tr>
<td></td>
<td>No available alternatives (tick box)</td>
</tr>
</tbody>
</table>

#### 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

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.

<table>
<thead>
<tr>
<th>Demo event</th>
<th>Functionalities showcased</th>
<th>Video recording timestamp</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quarterly system demo - Q2 2024 (26/06/2024)</td>
<td>• Marketing status for nationally authorised products data submission flow for MAHs</td>
<td>Information available after the event</td>
</tr>
<tr>
<td>Quarterly system demo - Q1 2024 (26/03/2024)</td>
<td>• 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</td>
<td>03:01:45</td>
</tr>
<tr>
<td>Quarterly system demo - Q3 2023 (21/09/2023)</td>
<td>• Template download for marketing authorisation (MAH) holderbulk submission of shortages • Submission of alternative substances • Embedding marketing status for centrally authorised products • Data analytics platform</td>
<td>00:26:24</td>
</tr>
<tr>
<td>Quarterly system demo - Q1 2023 (22/03/2021)</td>
<td>Data elements and upload for MAH bulk submission of shortage Information</td>
<td>2:17:20</td>
</tr>
<tr>
<td>Quarterly system demo - Q3 2022 (28/09/2022)</td>
<td>MAH submission of individual shortages</td>
<td>1:08:53</td>
</tr>
</tbody>
</table>

Next steps

Pedro Pina Ferreira, Monitoring VS Owner
## Interoperability implementation roadmap

### Machine to Machine (M2M) solution

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

<table>
<thead>
<tr>
<th>Quarter</th>
<th>Activity</th>
<th>Timeline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1</td>
<td>Agree in formats and roadmap</td>
<td>2024</td>
</tr>
<tr>
<td>Q2</td>
<td>Detailing fields, format, e.g. Implementation Guide</td>
<td>2024</td>
</tr>
<tr>
<td>Q3</td>
<td>Start implementation of M2M</td>
<td>2024</td>
</tr>
<tr>
<td>Q4</td>
<td>Tabular submission for all datasets via UI</td>
<td>2024</td>
</tr>
<tr>
<td>Q1</td>
<td>First Data Set in M2M</td>
<td>2024</td>
</tr>
<tr>
<td>Q2</td>
<td>New DS in M2M as per prioritisation</td>
<td>2024</td>
</tr>
<tr>
<td>Q3</td>
<td>Contribution and review</td>
<td>2025</td>
</tr>
<tr>
<td>Q4</td>
<td>Contribution and review</td>
<td>2025</td>
</tr>
</tbody>
</table>

For questions: [www.slido.com](http://www.slido.com) Code: #ESMP-ESS
## ESMP communication plan

<table>
<thead>
<tr>
<th>Stakeholder:</th>
<th>Q2</th>
<th>Q3</th>
<th>2024</th>
<th>Q4</th>
<th>2025</th>
<th>2026</th>
<th>2027</th>
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</thead>
<tbody>
<tr>
<td><strong>Marketing Authorisation Holders</strong></td>
<td><strong>MAH Webinar:</strong> reporting processes and data elements - ESMP Essentials</td>
<td><strong>Publication of MAH implementation guide</strong></td>
<td><strong>MAH UAT:</strong> routine reporting</td>
<td><strong>MAH training:</strong> routine reporting</td>
<td><strong>MAH UAT:</strong> crisis simulation</td>
<td><strong>MAH training:</strong> crisis reporting</td>
<td><strong>DIA Europe presentation</strong></td>
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<tr>
<td></td>
<td><strong>Publication of MAH implementation guide</strong></td>
<td><strong>Publication of MAH reporting templates</strong></td>
<td><strong>PLM newsletter article:</strong> ESMP-PMS</td>
<td><strong>Publication of MAH user guide</strong></td>
<td><strong>Video tutorials for MAH</strong></td>
<td><strong>ESMP video-introduction</strong></td>
<td><strong>ESMP video-introduction</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Publication of FAQs for MAH on webpage</strong></td>
<td><strong>ISG meeting</strong></td>
<td><strong>MAH training:</strong> crisis simulation</td>
<td><strong>SME newsletter article:</strong> MAH go-live</td>
<td><strong>ISG meeting</strong></td>
<td><strong>Public system demo</strong></td>
<td><strong>Human medicines highlights article:</strong> NCA go-live</td>
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<tr>
<td></td>
<td><strong>ISG meeting</strong></td>
<td></td>
<td><strong>Publication of FAQs for MAH on webpage</strong></td>
<td><strong>ISG meeting</strong></td>
<td></td>
<td><strong>Publication of NCA implementation guide</strong></td>
<td><strong>ESMP video-introduction</strong></td>
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<td></td>
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<td><strong>ISG meeting</strong></td>
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<td><strong>ESMP video-introduction</strong></td>
</tr>
<tr>
<td><strong>National Competent Authorities</strong></td>
<td><strong>Survey on support needed for matching NAPs with NCA databases</strong></td>
<td><strong>Publication of NCA implementation guide</strong></td>
<td><strong>TOPRA Conference presentation:</strong> ESMP go-live</td>
<td><strong>NCA webinar:</strong> ESMP Essentials</td>
<td><strong>NCA UAT:</strong> crisis simulation</td>
<td><strong>Video tutorials for NCA</strong></td>
<td><strong>Human medicines highlights article:</strong> NCA go-live</td>
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<td></td>
<td><strong>NPAG presentation:</strong> ESMP progresses</td>
<td><strong>Publication of NCA reporting templates</strong></td>
<td><strong>NCA UAT with SMES &amp; ESMP-MSSG</strong></td>
<td><strong>NCA training:</strong> MSSG-led preparedness reporting and data analytics</td>
<td><strong>NCA UAT:</strong> crisis simulation</td>
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<td><strong>IT Directors email</strong></td>
<td><strong>Publication of FAQs for NCA on webpage</strong></td>
<td><strong>HMA email:</strong> ESMP overview</td>
<td><strong>NCA training:</strong> crisis reporting</td>
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<td><strong>IT Directors email</strong></td>
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<tr>
<td><strong>General public</strong></td>
<td><strong>Public system demo</strong></td>
<td><strong>ESMP webpage update:</strong> informational brief</td>
<td><strong>ESMP webpage update:</strong> MAH implementation guide, MAH reporting templates, FAQs, Industry webinar</td>
<td><strong>ESMP webpage update:</strong> MAH go-live</td>
<td><strong>Public system demo</strong></td>
<td><strong>ESMP webpage update:</strong> NCA go-live</td>
<td><strong>ESMP webpage update:</strong> NCA go-live</td>
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<tr>
<td></td>
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<td></td>
<td><strong>ESMP webpage update:</strong> NCA implementation guide, NCA reporting templates</td>
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<tr>
<td><strong>Legend:</strong></td>
<td><em>MAH</em></td>
<td><em>NCA</em></td>
<td><em>Public</em></td>
<td><em>MAH go-live</em></td>
<td><em>NCA go-live</em></td>
<td><em>General</em></td>
<td><em>ESMP go-live</em></td>
</tr>
</tbody>
</table>

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ESMP communication plan: focus on MAHs

Legend:  
- Training materials/activities  
- Communication activities  
- MAH UAT: routine shortage reporting  
- ESMP webpage update  
- ESMP go-live  
- 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  
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Main upcoming events

- Regular updates on the **ESMP webpage** on EMA website
- 26 June: EMA Quarterly **System Demo**: ESMP from 9:25 to 10:05 CEST
- 28 June: **Industry Standing Group** presentation
- July: Technical specifications to be published in MAH **Implementation guide**
- July: ESMP **Communication plan** to be published

**Legend:**
- MAH
- NCA
- General public

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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
Audience Q&A Session

Start presenting to display the audience questions on this slide.
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

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- **Your input will guide us in tailoring next sessions** to better meet your needs and preferences.

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