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

Industry Stakeholder Group (ISG)

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

Access Management

MAHs
- 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

NCAs
- User Interface
- Preparedness
- Routine shortage reporting CAPs
- User interface
- Stock and supply
- Patient estimation
- Medicine usage
- 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 collection

MAHs
- Crisis / MSSG-led preparedness

NCAs
- Crisis
- MSSG-led preparedness
- Stock and supply
- National demand

Analysis & Reporting

Data Integration

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

1
Completed □  In Progress □  Not Started

PMS : Product Management Services
RMS : References Management Services
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

Legend:
- PMS dependency
- Public delivery
- Development completed

2023

Up to Q4

Q1
- MAH Routine Shortage reporting (CAPs)
- MAH Crisis submissions (CAPs + NAPs)
- SME user acceptance testing for MAH functionalities
- Technical specifications for MAHs released
- Transition period for MAH reporting

Q2
- MAH Training on routine shortage reporting
- EMA quarterly public system demo 26/06

Q3
- MAH Training on crisis reporting
- NCA MSSG-led Preparedness and Crisis reporting go-live
- NCA Crisis submissions (CAPs + NAPs)

Q4
- NCA MSSG-led Preparedness and Crisis reporting go-live
- Public platform go-live
- NCA MSSG-led Preparedness and Crisis reporting go-live

2024

Dedicated ESMP Webpage released and updated regularly on EMA website

2025

Public Platform go-live

Legend:
- Public delivery
- MAH functionalities
- NCA functionalities

Technical specifications for MAHs released
User guide for MAHs released
Webinar on MAH Reporting 24/06
EMA quarterly public system demo 26/06
User acceptance testing: initial results

**Objective**
Ensure platform meets user requirements, functions correctly, is user-friendly, and fulfils user expectations

**Duration**
22 – 30 April 2024

**Participants**
MAH subject matter experts (SMEs)

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**Functionalities and items tested**

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

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

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**Positive feedback**

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

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**Areas for improvement**

- **Complex reporting templates** and **conditionality rules for** data submission → **ACTION TO BE TAKEN**: refined reporting templates to reduce manual insertion of data (e.g., reduced no. of columns for shortage root cause, merged fields for shortage end date and shortage expected end date)

- **Slow platform performance** → **ACTION TO BE TAKEN**: changes in mechanisms for data upload and processing, targeting largest and most comprehensive data submission flows to reduce long processing times

- **Overly comprehensive user guidance**, including instructions and technical specifications, difficulty accessing RMS lists and lack of clarity of some definitions → **ACTION TO BE TAKEN**: merged user, implementation guides and RMS lists within the same document, refinement of data element definitions with Industry representatives
ESMP Essentials: summary of webinar for MAHs

**Objective**
provide an overview of the ESMP and pharmaceutical industry reporting requirements through the platform

**Duration**
24 June, from 10:00 to 12:30 CEST

**Target audience**
Pharmaceutical industry, marketing authorisation holders of CAPs and NAPs

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**KEY TOPICS**

- **ESSENTIALS**
  - EMA *shortage management* processes at EU/EEA level
  - Overview of ESMP *vision, objectives, benefits, components*
  - ESMP *milestones and dependencies* with other EMA products and MAH requirements

- **REPORTING**
  - Reporting processes: crisis, MSSG-led preparedness, routine reporting
  - Reporting requirements: MAH requirements in crisis, MSSG-led preparedness, routine reporting
  - Data elements in scope of reporting requirements to EMA through ESMP

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

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Please note that the webinar was broadcasted live, recorded, and will be available on the dedicated event page soon.
NCAs report critical national shortages and provide data on demand for medicinal products in crisis and in preparedness situations.

MAHs perform routine shortage reporting and provide data on supply of medicinal products in crisis and in preparedness situations.

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

Users complete ESMP templates with relevant information per product.

Prevent, monitor and manage shortages.

Measures to prevent, manage and mitigate shortages in EU/EEA, such as exploring MAHs supply capacity and possibility to increase production, regulatory support, etc.

Matching of supply and demand data.


Data analytics platform.

Regulatory coordination.

SPOC WP, MSSG, and EC.
From XEVMPD to PMS, used in ESMP

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

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

**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)

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 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.

MAHs to start submitting packs sizes for ULCM

Review CAP and NAP data through PMS API and product UI

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

Management of pack sizes directly in PMS

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

**Registration link**

**Today**

**Q3 2024**

**Q4 2024**

**Q1 2025**

**Future**
Actions for NCAs

**National Competent Authorities**

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

### Stakeholder:

#### Marketing Authorisation Holders
- **MAH Webinar:** Reporting processes and data elements - ESMP Essentials
- **ISG meeting**
- **Publication of MAH implementation guide**
- **Publication of MAH reporting templates**
- **Publication of FAQs for MAH on webpage**
- **MAH UAT: routine shortage reporting**
- **ISG meeting**
- **PLM newsletter article: ESMP-PMS**
- **MAH training: routine shortage reporting**
- **Publication of MAH user guide**
- **Video tutorials for MAH**
- **SME newsletter article: MAH go-live**
- **ISG meeting**
- **MAH training: crisis simulation**
- **Publication of MAH user guide**
- **Video tutorials for MAH**
- **DIA Europe presentation: ESMP go-live**

#### National Competent Authorities
- **Survey on support needed for matching NAPs with NCA databases**
- **Publication of NCA implementation guide**
- **Publication of NCA reporting templates**
- **Publication of FAQs for NCA on webpage**
- **TOPRA Conference presentation: ESMP go-live**
- **UAT with NCA SMEs & ESMP-MSSG**
- **IT Directors email**
- **ISG meeting**
- **Publication of NCA user guide**
- **NCA training: crisis reporting**
- **Video tutorials for NCA**
- **CHMP announcement: MVP go-live**
- **CMDh announcement: MVP go-live**

#### General public
- **Public system demo**
- **ESMP webinar update: informational brief**
- **ESMP webpage update: MAH implementation guide, MAH reporting templates, FAQs, Industry webinar**
- **Public system demo**
- **ESMP webpage update: NCA implementation guide, NCA reporting templates**
- **Public system demo**
- **ESMP webpage update: MAH go-live**
- **Public system demo**
- **ESMP webpage update: NCA go-live**
- **ESMP video-introduction**
- **Human medicines highlights article: MAH go-live**
- **Human medicines highlights article: NCA go-live**

### Key dates:
- **Q2:** Jun 2024
- **Q3:** Jul 2024
- **Q4:** Aug 2024
- **2024:** Sep, Oct, Nov, Dec
- **2025:** Jan, Feb, Mar

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

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Please note: the presented timings may be subject to change. Specific dates will be confirmed closer to each deadline.
Main recent and upcoming events

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

**Legend:**
- MAH
- NCA
- General public
Annexes
## Overview of medicines’ lists

### Union list of critical medicines
- **Available in:** Normal circumstances
- **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)
- **Purpose:**
  - Help tracking of EU manufacturing capacity
  - Ensure security of supply and availability of critical medicines at EU level

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

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

*notifications of shortages for CAPs to follow the routine shortage reporting process*
# Reporting instances to ESMP

<table>
<thead>
<tr>
<th>Available in:</th>
<th>Routine shortage reporting</th>
<th>MSSG-led preparedness</th>
<th>Crisis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Normal circumstances</td>
<td>Preparedness (PHE, ME)</td>
<td>Crisis (PHE, ME)</td>
</tr>
</tbody>
</table>

| Purpose: | Early reporting of shortages to allow for efficient shortage prevention, management and mitigation | Specifically driven by the MSSG to address events that might lead to a PHE/ME | Focused on immediate actions to handle and mitigate the impact of ongoing or imminent crises, such as a PHE or ME |

| Submission trigger: | Potential or actual shortage of a marketing authorisation holders’ product | MSSG announcement of preparedness exercise | EC recognition of a PHE/ME |

| Products in scope: | All centrally authorised products (CAPs) | List of medicines to be monitored for MSSG-led crisis preparedness (CAPs and NAPs) | List of critical medicines for a public health emergency/major event (CAPs and NAPs) |

| Frequency of reporting: | As required, updated when new relevant information is available | Defined by the MSSG | Defined by the MSSG |
Any questions?

Further information

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