

European Shortages Monitoring Platform (ESMP)

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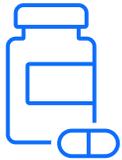
Supply and Availability of Medicines and Devices, Regulatory Science and Innovation Task Force (TRS-SAM)

1 April 2025

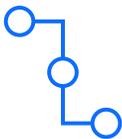
Current situation



When a potential issue that could affect multiple EU/EEA countries is identified, a large number of stakeholders must collaborate closely to ensure a **coordinated approach to collect and analyse supply and demand data** to achieve a comprehensive understanding of the situation across regions



Information on shortages across the EU are **underreported** to EMA, and often reporting is **delayed**

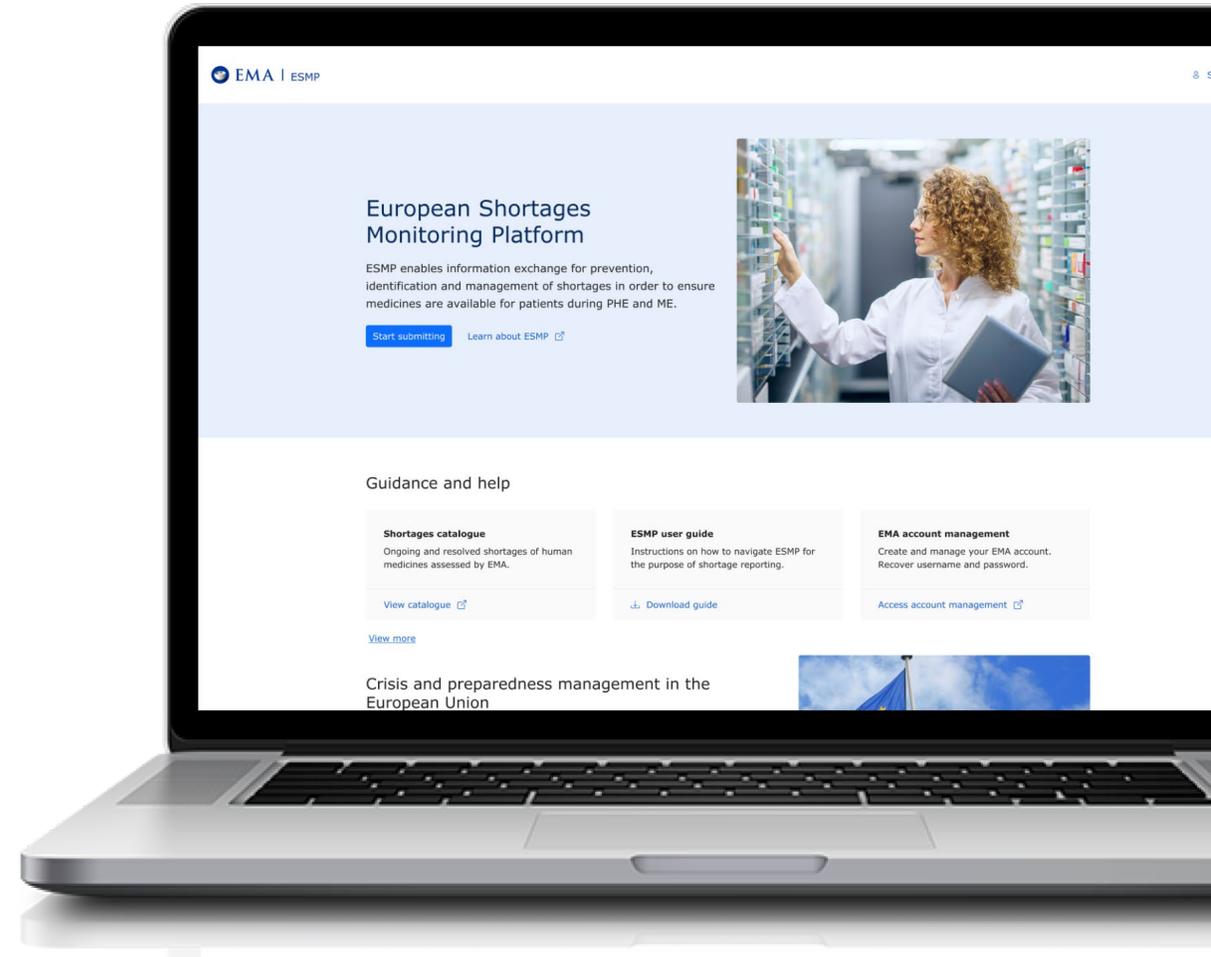


Difficult for authorities to act quickly or proactively manage shortages in collaboration with all parts of the supply chain → Need for a **streamlined and automated system**

The European Shortages Monitoring Platform (ESMP)

The ESMP is a harmonised, transparent, and collaborative IT platform for ensuring medicines are available when and where they are needed most.

- designed to improve the **prevention, monitoring, and management** of medicines **shortages** across the EU/EEA
- It will centralise and automate **data collection on medicine shortages**, giving access to real-time and comprehensive information.



The European Shortages Monitoring Platform (ESMP)



ESMP INTERFACES



Secure access:

Industry
Regulators



Open access:

General public



ESMP COMPONENTS

- Data collection
- Analysis and reporting
- Case management
- Data integration

Data collection: reporting instances



Prepared for every scenario



Normal circumstances

Routine reporting of shortages of medicinal products

Data collection: reporting instances



Prepared for every scenario



MSSG-led preparedness

Close monitoring of a subset of medicinal products triggered upon request from the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)

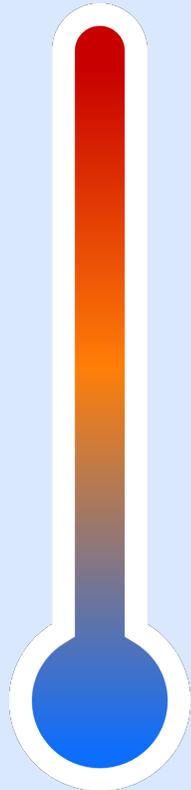
Normal circumstances

Routine reporting of shortages of medicinal products

Data collection: reporting instances



Prepared for every scenario



Crisis

Monitoring of supply, demand and availability of medicinal products in scope of a list of critical medicines for a public health emergency or major event

MSSG-led preparedness

Close monitoring of a subset of medicinal products triggered upon request from the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)

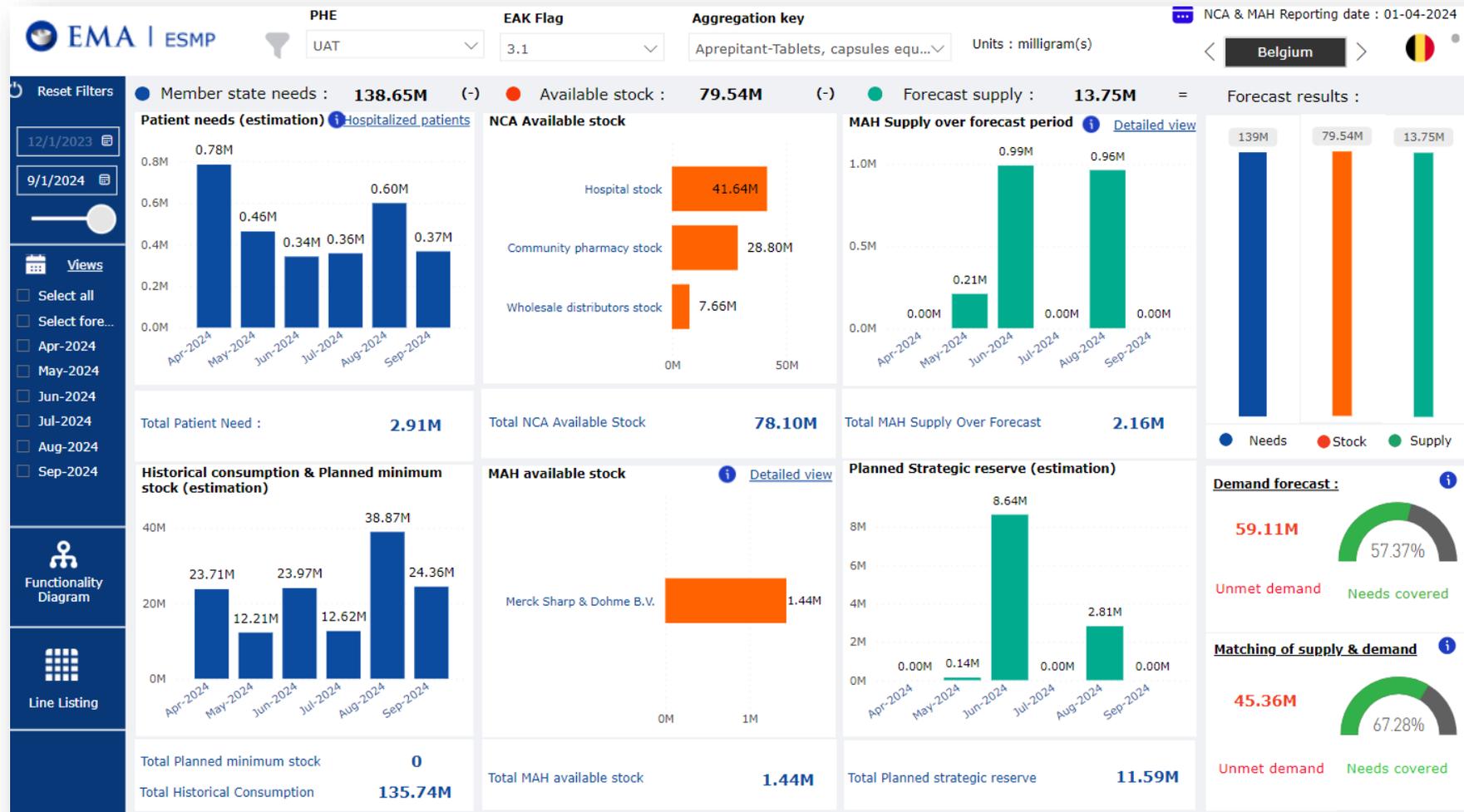
Normal circumstances

Routine reporting of shortages of medicinal products

Data collection: interface for industry crisis reporting

The screenshot displays the EMA ESMP (European Shortages Monitoring Platform) interface. At the top left, the logo 'EMA | ESMP' is visible, and at the top right, there are links for 'Guidance and help' and a user profile 'John Doe'. A dark blue sidebar on the left contains a navigation menu with the following items: 'Home', 'CRISIS SUBMISSIONS', 'Marketing status CAPs', 'Marketing status NAPs', 'Availability information', 'Manufacturing information', 'Alternative therapies', 'ROUTINE REPORTING', 'Routine shortage reporting', 'Submission history', and 'Guidance and help'. The main content area is titled 'Reporting for critical medicines' and features a prominent warning box: 'My critical medicines in scope of reporting'. This box states that some medicines are deemed critical by EMA and are subject to close monitoring, and lists two steps: '1. Update missing or incorrect marketing status of medicines in scope of reporting.' and '2. Submit all required information from the submission checklist.' To the right of this warning, there are two sections: 'Step 1: Update marketing status' and 'Step 2: Submission checklist'. 'Step 1' includes buttons for 'Submit marketing status for CAPs' and 'Submit marketing status for NAPs'. 'Step 2' includes buttons for 'Submit availability information', 'Submit manufacturing information', and 'Submit alternative therapies'. Below the warning box, there is a section for 'Routine reporting' with a button for 'Routine shortage reporting'. At the bottom of the page, there are links for 'Privacy', 'Cookies', and 'EMA Service Desk'.

Analysis and reporting



Case management

Dynamics 365 | IRIS Standard | Search | New look | ? | SM

← Show As Show Chart + Create Case Refresh Collaborate Run Report Share

ESMP - Shortages Summary View

Edit columns Edit filters Filter by keyword

<input type="checkbox"/>	Case Title	Customer	Process Type	Case Su...	Sub-Sta...	EMA As...	Case Fol...	Subn
<input type="checkbox"/>	EMA/SH/S000...		Availability		Submit...	AA		2E
<input type="checkbox"/>	EMA/SH/S000...		Availability		Submit...	PD		1E
<input type="checkbox"/>	EMA/SH/S000...		Availability		Submit...	E		1E
<input type="checkbox"/>	EMA/SH/S000...		Availability		Submit...	E		1E
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<input type="checkbox"/>	EMA/SH/S000...		Availability		Submit...	E		1E
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<input type="checkbox"/>	EMA/SH/S000...		Availability		Submit...	E		1E
<input type="checkbox"/>	EMA/SH/S000...		Availability		Submit...	E		1E

Rows: 19

Platform for general public: EMA shortages catalogue

The Agency provides information on critical **medicine shortages affecting or likely to affect** more than one EU country and recommendations to patients and healthcare professionals.

Publication of shortage catalogues regarding:



Ongoing shortages



Resolved shortages



Benefits of establishing ESMP



PREVENTION OF SHORTAGES

- **More information** on shortages
- **More opportunities** to monitor supply and demand to prevent and mitigate potential shortages



EU-WIDE APPROACH

- Working towards **harmonised reporting** standards across the EU/EEA
- Increased EU coordination for faster actions to prevent shortages

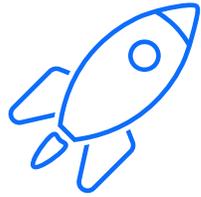


TRANSPARENCY & COLLABORATION

- **Easier collaboration** among different actors
- **More support** to users
- **Public access** to information about medicines shortages

When we know more, we can do more

Development timeline



28 November 2024

Go-live for Industry
Routine shortage
reporting for centrally
authorised products
(CAPs)



29 January 2025

Go-live for all Industry
and Regulators'
reporting



After February 2025

Scope expansion and
improvements



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Thank you

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