European Shortages Monitoring Platform (ESMP)

Informational brief: why, who, what, when, where, how

An agency of the European Union

Why

ESMP aims to enable information exchange for better **prevention, identification and management of shortages**, and communication between the EMA, National Competent Authorities and Industry stakeholders to ensure the availability of medicines for patients during Public Health Emergencies and Major Events

Who

EUROPEAN MEDICINES AGENCY

Regulators and stakeholders in the **supply chain of medicinal products**

MEMBER STATES

- National competent authorities (NCAs)
- Single Points of Contact Working Party (SPOC WP)

INDUSTRY

- Marketing authorisation holders (MAHs)
- Single Points of Contact (i-SPOCs)

EUROPEAN REGULATORS

- European Commission
- Executive Steering Group on shortages and safety of medicinal products (MSSG)
- European Medicines Agency (EMA)

GENERAL PUBLIC

- Healthcare professionals
- Patients
- EU/EEA citizens

What

Reporting and monitoring of supply and availability of critical medicinal products across the EU/EEA

NCA SPOCs

Provide data on national demand, stock and supply levels, patient estimations, and medicines usage

MAH I-SPOCs

Provide data on medicines' availability, alternative therapies, marketing status, manufacturing details, and production plans

EMA Staff

Monitor data on medicines' supply and availability to **prevent, mitigate, and manage shortages**

General public

Consult information on critical medicines shortages across the EU/EEA

When

The minimum viable product (MVP) will be released in **three different instances**:

For MAHs: **Q4 2024** | For NCAs: **Q1 2025** | For general public: **Q1 2025**

ESMP will be used for **three different phases:**

CRISIS

Reporting on supply, demand and availability of medicinal products in scope of a tailored list of critical medicines during a public health emergency (PHE) or major event (ME)

MSSG-LED PREPAREDNESS

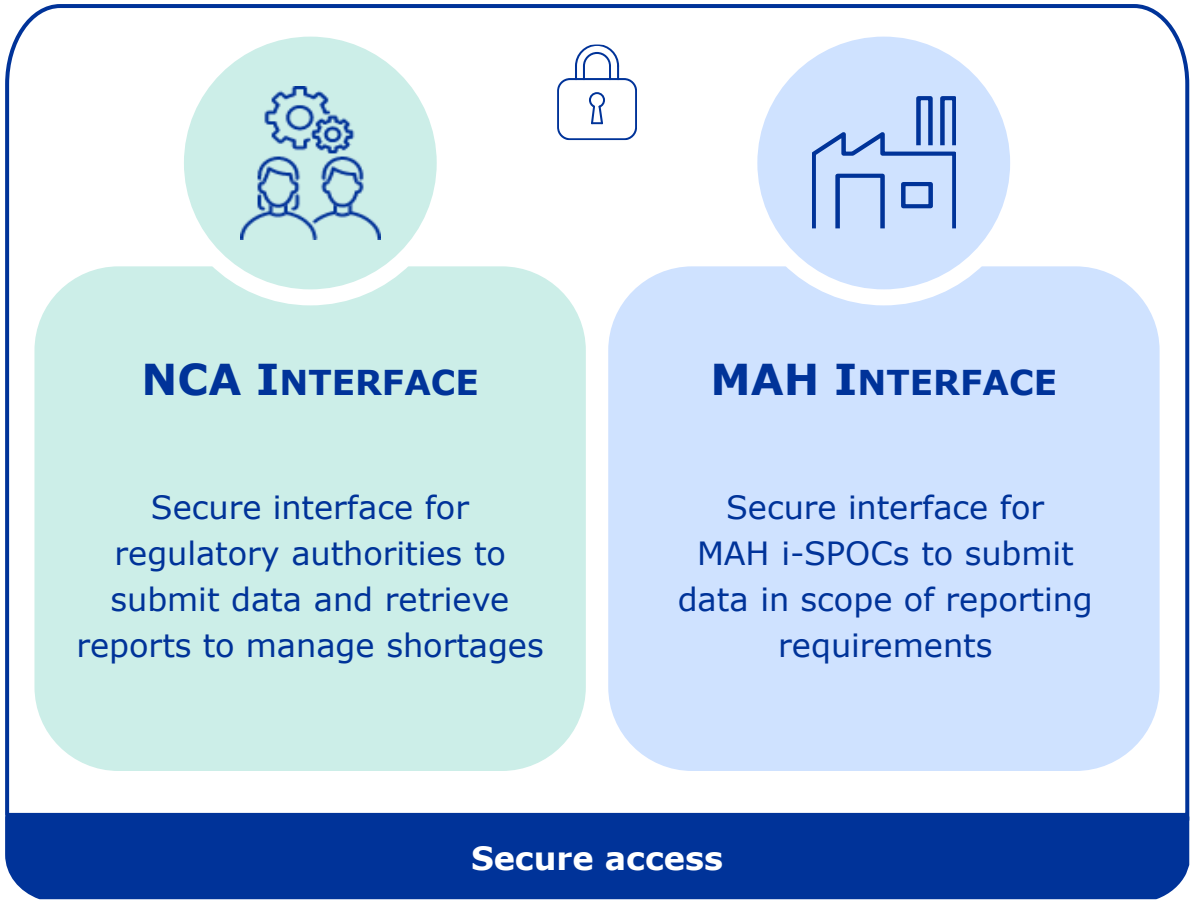
Close monitoring of a subset of medicinal products triggered upon request from the Executive Steering Group on shortages and safety of medicinal products (MSSG)

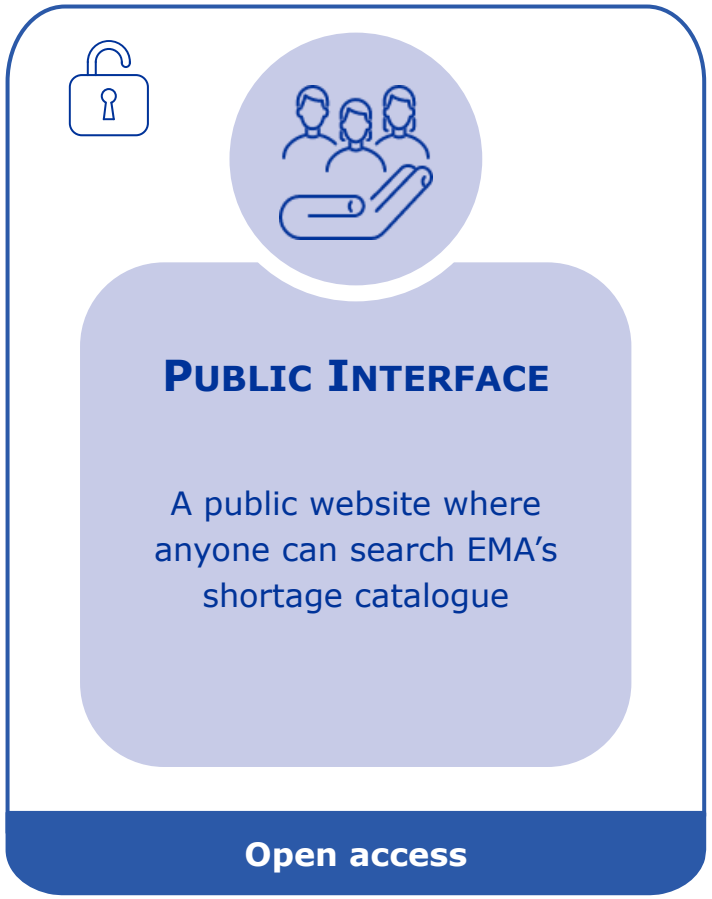
NORMAL CIRCUMSTANCES

Routine reporting of shortages of medicinal products

Where

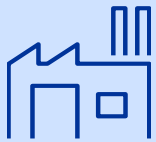
Single EMA IT platform offering 3 user interfaces for different stakeholders





How

Data submission possible through **manual reporting** and **machine-to-machine** communication



- **Tabular submission of data** through templates via the ESMP user interface for NCAs and MAHs
- **Machine-to-machine submission of data** through interoperability with NCA and MAH systems