

European Shortages Monitoring Platform (ESMP)

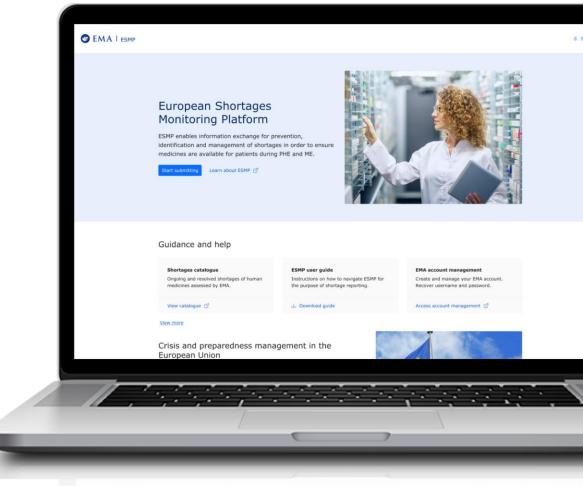
Prepared by EMA in May 2025

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The European Shortages Monitoring Platform

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 realtime and comprehensive information.





Reporting instances to EMA

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 centrally authorised medicinal products (CAPs)





Reporting instances through ESMP: Industry

	Routine shortage reporting	MSSG-led preparedness reporting	Crisis reporting
Available in:	Normal circumstances	Preparedness for a PHE/ME	Crisis (PHE/ME)
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 holder's product	MSSG announcement of preparedness action	EC recognition of a PHE/ME
Products in scope:	All centrally authorised products (CAPs) for human use	List of medicines* to be monitored for MSSG-led crisis preparedness (CAPs and NAPs) for human use	List of critical medicines* for a PHE/ME (CAPs and NAPs) for human use
Frequency of reporting:	As required , updated when new relevant information is available and shortage resolution	Defined by the MSSG	Defined by the MSSG

*For more information on the different lists of critical medicines, refer to the <u>EMA webpage on critical medicines</u>.

4 European Shortages Monitoring Platform (ESMP) Essentials



Preliminary requirements: Industry action needed

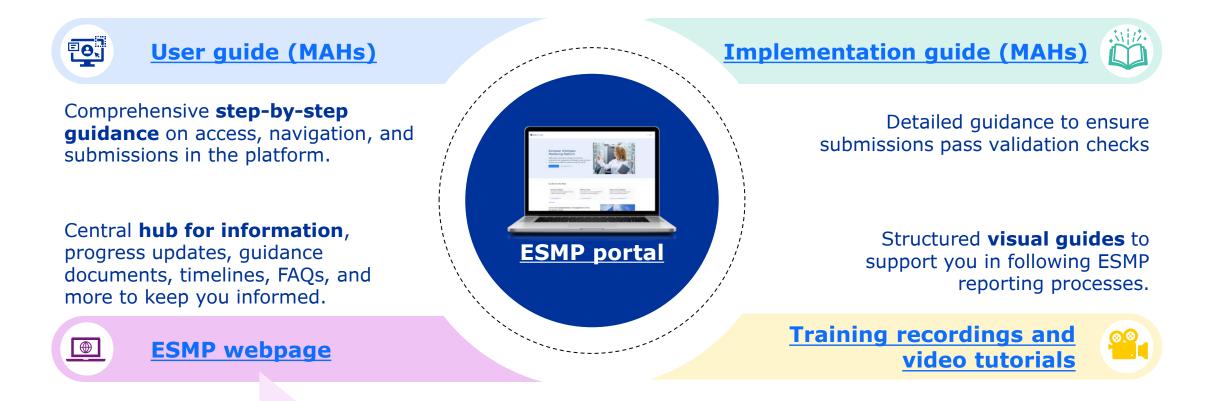
i-SPOC registration	Designate and register an industry Single Point of Contact (i-SPOC) to facilitate communication on medicines shortages*
PMS data entry	Ensure that product information at pack size level and manufacturing site information are accurately recorded in the EMA's Product Management Service (PMS)**
IRIS data entry	Ensure information on marketing status for CAPs is accurate and up-to- date in the EMA's <u>IRIS platform</u>
EMA access setup	Create an active <u>EMA account</u> and request the appropriate ESMP access roles to gain the necessary permissions for platform operations
Prepare with purpose	Assign and train an ESMP-dedicated team member(s) to know the platform inside-out and ensure smooth operations

*Mandatory for all MAHs of CAPs and NAPs of human and veterinary medicinal products in the EU/EEA as of 2 September 2022, in line with Regulation (EU) 2022/123.

**Following timelines and prioritisation set by PMS. If crisis/MSSG-led preparedness actions triggered, data for medicines in scope will need to be inserted within 2 weeks from the notification.

European Shortages Monitoring Platform (ESMP) overview

Available guidance materials



All mentioned resources (and more) are published and linked on the dedicated ESMP webpage on the EMA corporate website.





Thank you

More information: <u>ESMP webpage</u> | <u>ESMP Essentials webinar</u> | <u>ESMP RSR MAH training</u> | <u>ESMP crisis and MSSG-led preparedness reporting training</u>

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