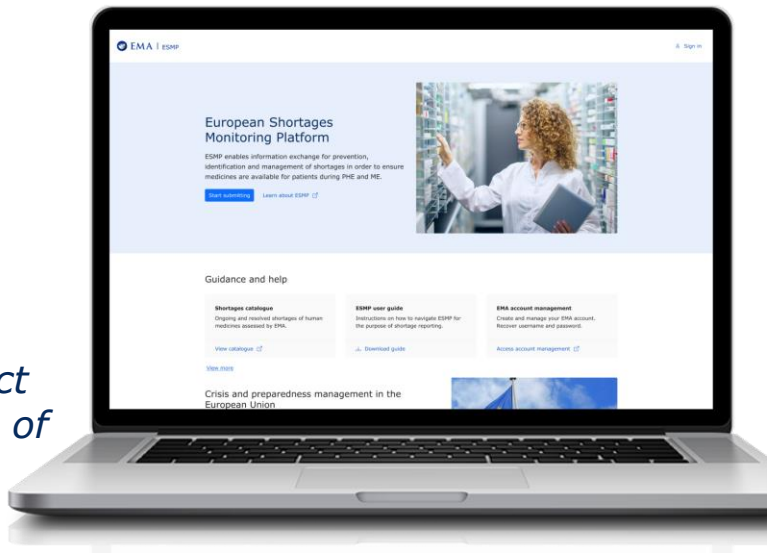
Industry reporting via the **ESMP** in **normal circumstances**



The European Shortages Monitoring Platform (ESMP) supports management of medicine availability across the EU/EEA. This fact sheet outlines the reporting obligations for MAHs to EMA in case of shortages of centrally authorised products.

PHASE	WHAT HAPPENS	HOW IT HAPPENS
1. Recognition of a shortage	• MAHs become aware of a potential or actual shortage of a centrally authorised product (CAP)	• MAHs continuously monitor the supply chain and evaluate market needs to identify potential and actual shortages
2. Data input	• MAHs log into ESMP and select the products from their portfolio for which they intend to report a shortage • MAHs submit shortage information through a reporting template and review and update the information as applicable	• MAHs follow steps for reporting via the routine shortage reporting process in the ESMP
3. Data maintenance	• MAHs frequently review and submit updated data to ensure accurate information is available to EMA until the shortage is resolved	• MAHs repeat steps for reporting via the routine shortage reporting process in the ESMP to update reported shortages and indicate when the shortages are resolved
4. Data monitoring	• EMA continuously monitors all reported shortages and reaches out to the MAH if more information or follow-up actions are required	• Where applicable, MAH i-SPOCs and MAH ESMP users receive email communications by EMA on follow-up actions

ESMP webpage	Comprehensive repository of ESMP-related information (access, implementation, guidance)
MAH User guide	Step-by-step guidance on access, navigation, and performing submissions in the platform
MAH Implementation guide	Guidance on data elements to ensure submissions pass validation checks
Training and events	List of past and future events, including recordings of trainings and Q&A sessions
FAQs	Frequently asked questions by MAHs and national competent authorities
Ask EMA	Submit general questions to EMA, not related to a specific submission/procedure
EMA account management portal	Consult instructions and submit questions on access, account, and registration requests
EMA Service Desk	Submit technical questions on the use of the portal or report issues

EMA: European Medicines Agency

ESMP: European Shortages Monitoring Platform

MSSG: Medicines Shortages Steering Group

i-SPOC: industry single point of contact

MAH: marketing authorisation holder