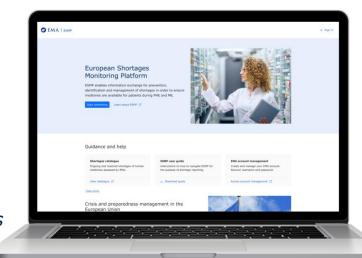
Network reporting via the **ESMP** during a crisis

The European Shortages Monitoring Platform (ESMP) supports management of medicine availability across the EU/EEA. This fact sheet outlines the reporting obligations for Network users in times of crises.



HOW IT HAPPENS PHASE WHAT HAPPENS

Activation and notification

- EC recognises a PHE/ME
- List of critical medicines is adopted
- · Reporting frequency is defined
- EMA notifies NCAs of reporting requirements
- · NCAs' SPOCs receive an email with instructions to begin reporting via ESMP
- The ESMP interface for crisis reporting is activated and visible to ESMP NCA users

Data review and input

- NCAs log into ESMP to submit information on national demand, stock and supply, patient estimations, and medicine usage at the defined reporting frequency set by MSSG
- · NCAs follow steps for reporting via dedicated templates and webforms in the ESMP

monitoring

- · EMA and NCAs monitor the levels of supply and demand through ESMP-SMART dashboards
- EC, MSSG, EMA and NCAs assess the risk levels of shortages and coordinate responses
- ESMP matches information on the supply and demand of medicines in scope of reporting and creates SMART dashboards
- EC, MSSG, EMA and NCAs discuss potential actions

End of reporting requirements

- EC declares the end of a crisis and the MSSG announces the end of reporting activities
- EMA notifies NCAs that reporting via ESMP is no longer required
- NCAs' SPOCs receive an email with instructions to end reporting via ESMP
- The ESMP interface for crisis reporting is de-activated and not visible to ESMP NCA users

ESMP webpage

NCA User guide

NCA Implementation guide

Training and events

Comprehensive repository of ESMP-related information (access, implementation, guidance)

Step-by-step guidance on access, navigation, and performing submissions in the platform

Guidance on data elements to ensure submissions pass validation checks

List of past and future ESMP events, including recordings of trainings and Q&A sessions

FAQs

Ask EMA

EMA account management portal

EMA Service Desk

Frequently asked questions by MAHs and national competent authorities

Submit general questions to EMA, not related to a specific submission/procedure

Consult instructions and submit questions on access, account, and registration requests

Submit technical questions on the use of the portal or report issues

EC: European Commission

ME: major event

EMA: European Medicines Agency

NCA: national competent

ESMP: European Shortages Monitoring Platform

PHE: public health

MSSG: Medicines Shortages Steering Group

SPOC: single point of



Classified as public by the European Medicines Agency