REGULATORY REQUIREMENTS

European Shortages Monitoring Platform (ESMP)

What?

Launch of the new ESMP to gather information about medicine supply in order to prevent and manage human medicine shortages in EU and EEA.

From when?

First full version of the platform from January 2025.

Applicable for

Human use medicinal products

Changes

New platform fed with product information data from PMS and from IRIS (for marketing status)

- Routine shortage reporting
- MSSG-led preparedness reporting
- Crisis reporting

Action required

Preliminary requirements for Industry before reporting
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-todate in the EMA's IRIS platform

FOR CAPs:
Report shortages when exist a Potential or actual shortage of a marketing authorisation holder's product

List of medicines* to be monitored for MSSG-led crisis preparedness (CAPs and NAPs)
Close monitoring of a subset of medicinal products triggered upon request from the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)

List of critical medicines* for a PHE/ME (CAPs and NAPs)
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