

Monitoring and mitigating shortages of medicines – current activities

PCWP/HCPWP meeting
20 November 2024

Head of Supply and Availability of Medicines and
Devices – EMA



EU-level Coordination

Medicine shortages SPOC working party & Executive steering group on shortages and safety of medicinal products (MSSG)

- Continuous **monitoring, reporting and discussion** of 1) potential and critical shortages and 2) events to understand impact of medicines and **to prevent and mitigate shortages**.
- Examples: **Antibiotics situation** for winter 24/25, **natural disasters** such as hurricanes or floods.

ESMP Go-live

November 2024

Go-live for Industry Routine shortage reporting for CAPs

February 2025

Go-live for Industry and Regulators' Crisis and MSSG-led preparedness reporting



MSSG Solidarity Mechanism

The VSM is used as a **last resort** to **temporarily alleviate critical shortages in a Member State**.



Allows a MS to **request assistance** from other Member States in obtaining stocks of a medicine **during critical shortages**

6 VSM procedures concluded, all successfully

Conditions:

1. EMA already notified of the shortage (SPOC WP)
2. No or insufficient therapeutic alternatives available
3. Insufficient quantities to treat critical indications
4. No or insufficient relief from short-term measures
5. Urgency (e.g., < 1 month supply)

[MSSG Solidarity mechanism process \(europa.eu\)](https://european-council.europa.eu/media/en/press-articles/2024/06/18/Pages/20240618_MSSG_Solidarity_mechanism_process_europa.eu)

Shortage Prevention/ Mitigation Plans (SPMP)

- SPMPs as **tool to improve availability of medicines**.
- Templates published 18 June 2024.
- **SPP** identifies possible risks in the supply chain (vulnerabilities in the supply chain) and includes proposals to manage those risks (**preventive document**).
- **SMP** outlines specific steps to manage a shortage to mitigate and minimise its impact (**reactive document**).
- **SPMP pilot launch in December 2024**



Any questions?

Further information

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