

Introduction to shortages topic

PCWP/HCPWP meeting
1 April 2025

Monica Dias, Head of Supply and Availability of
Medicines and Devices



Ongoing activities on shortages

- Monitoring, reporting and management of potential and **critical shortages** and events to understand impact of medicines to prevent and mitigate shortages
- Examples:** discontinuation of **insulins** and critical shortages of **IV solutions** and **oncology products** marketed by TEVA and Accord
- SPMP pilot** launched in December 2024
- The **Critical Medicines Act** provides industrial policy solutions to address vulnerabilities and strengthen supply of medicines in the EU, complementing the proposed **pharma legislation**.

EU-level coordination



TF AAM – From voluntary action to EU regulation



European Shortages Monitoring Platform (ESMP)

- The ESMP was developed and released **ahead of the legal deadline** mandated in Regulation 2022/123



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

After February 2025

Maintenance, improvements and expansion

Ongoing activities on shortages

- Monitoring, reporting and management of potential and **critical shortages** and events to understand impact of medicines to prevent and mitigate shortages
- Examples:** discontinuation of **insulins** and critical shortages of **IV solutions** and **oncology products** marketed by TEVA and Accord
- SPMP pilot** launched in December 2024
- The **Critical Medicines Act** provides industrial policy solutions to address vulnerabilities and strengthen supply of medicines in the EU, complementing the proposed **pharma legislation**.

EU-level coordination



TF AAM – From voluntary action to EU regulation



European Shortages Monitoring Platform (ESMP)

- The ESMP was developed and released **ahead of the legal deadline** mandated in Regulation 2022/123



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

After February 2025

Maintenance, improvements and expansion



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Thank you

Monica.Dias@ema.Europa.eu

Follow us

