



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Monitoring of events and preparedness for Public Health Emergencies (PHE)

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Monitoring and mitigating **shortages of medicines** and management of public health emergencies/major events



Regulation (EU) 2022/123 applicable from **1 March 2022**

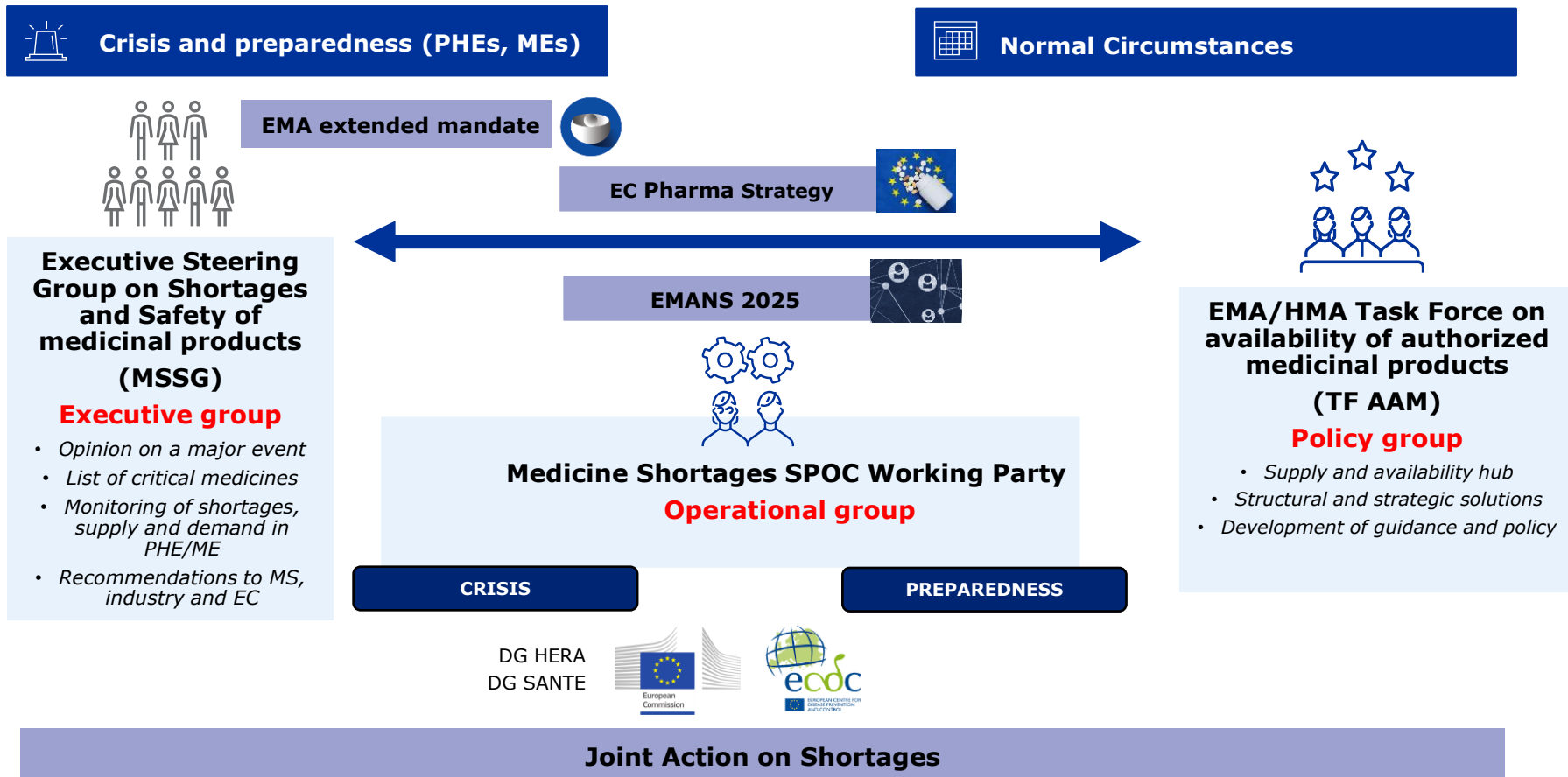
- Monitors events, including medicine shortages, which might lead to a crisis situation (public health emergencies or major events)
- Sets processes/tools for shortages reporting and coordinates responses of EU countries to shortages of critical medicines (during a crisis)
- Establishes “**Medicines Shortages Steering Group**” (MSSG) – formalises the formerly known ‘*EU Executive Steering Group on Shortages Caused by Major Event*’ Steering Group to be supported by:
 - **Working Party of Single Points** of Contacts in the **Member States** and a Network of contact points from pharmaceutical companies



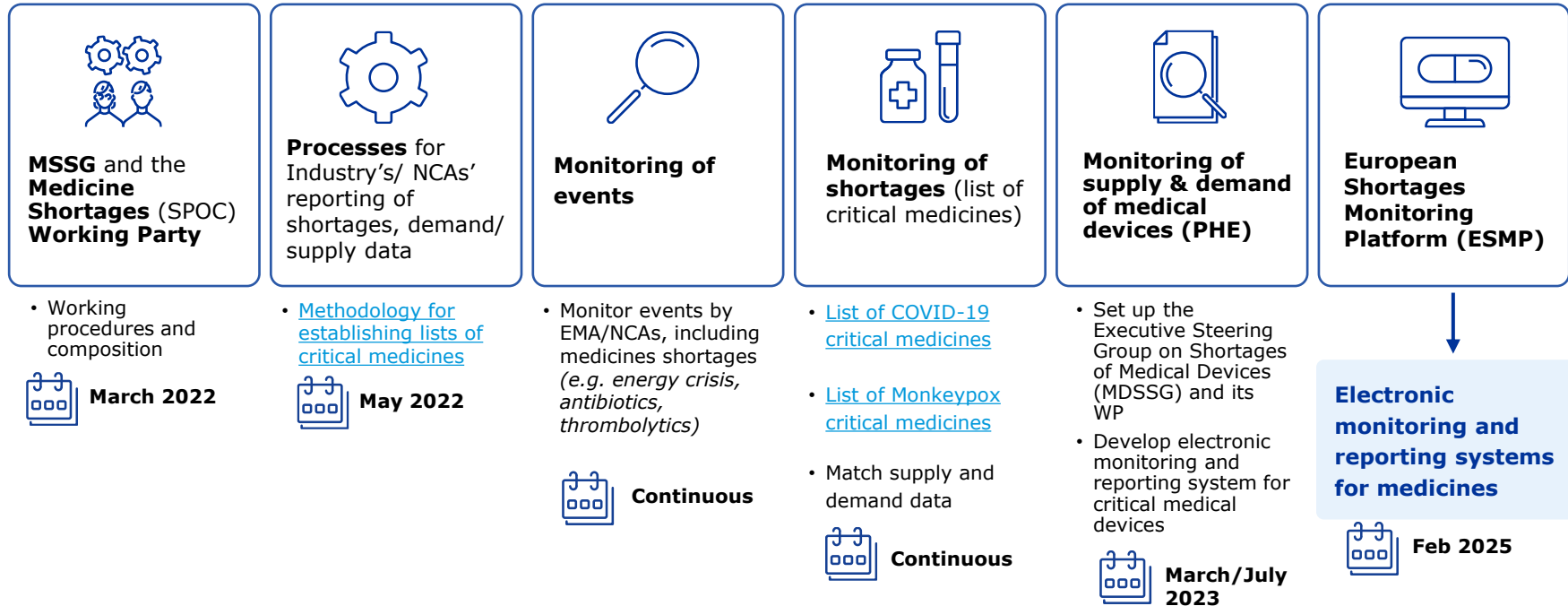
KEY BENEFIT

More coordination in preventing and mitigating medicines shortages in the EU

Availability of medicines – EU level coordination



Key milestones for medicines and devices shortages



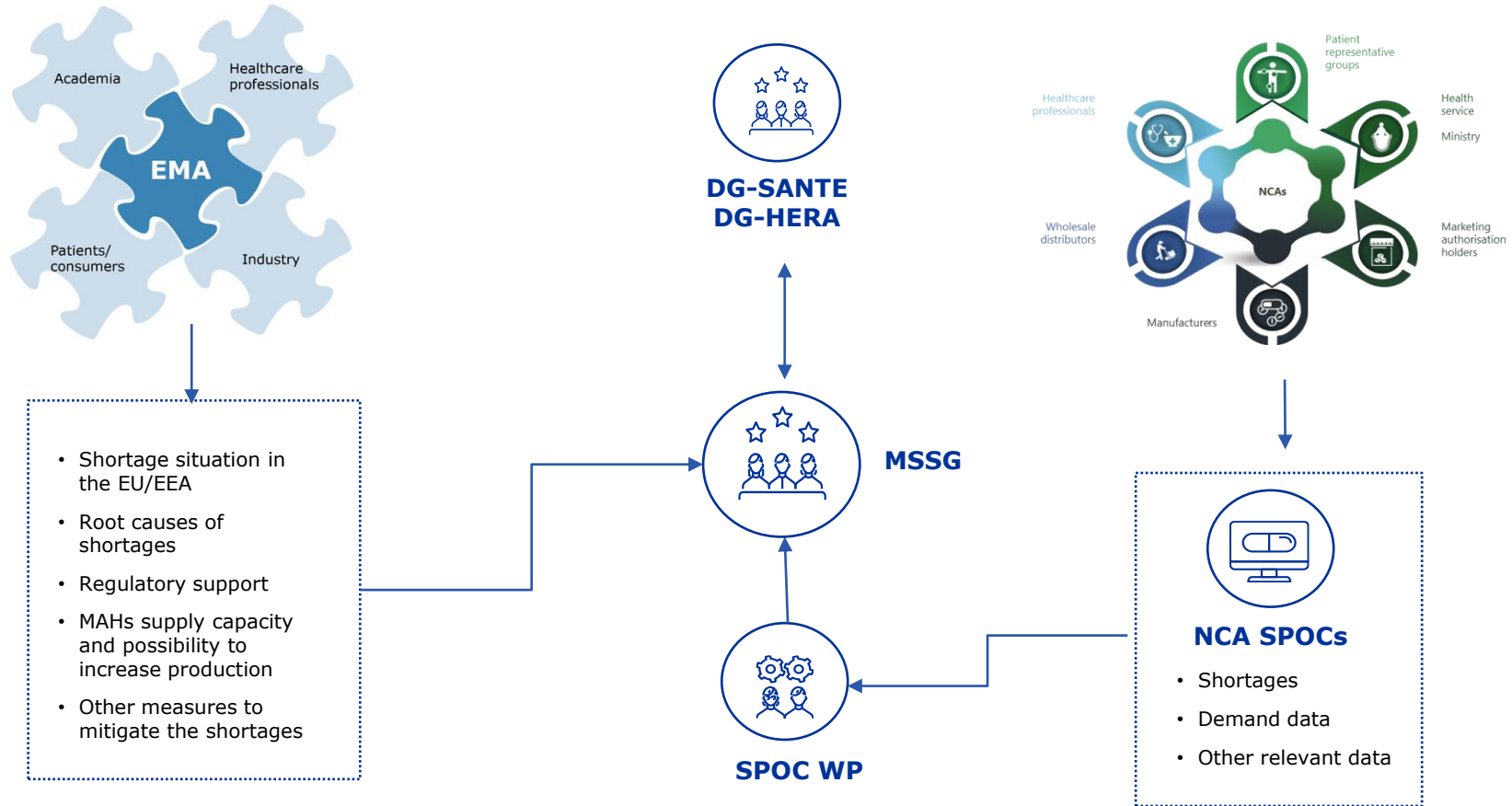
Management of critical medicines during Public Health Emergencies

Monitoring supply/demand for lists of critical medicines under Regulation (EU) 2022/123

Public Health Emergency (PHE)	No. of Marketing Authorisation Holders "in-scope"	No of monitored authorised MP/ vaccines in EU/EEA	Start of reporting obligations	Submission cadence*	Link (EMA website)
COVID-19	86	15 Centrally Authorised Products (CAPs) + all Dexamethasone Nationally Authorised Products (~ 140 NAPs)	1 October 2022	Once-every-month	List of critical medicines for COVID-19 public health emergency (PHE) under Regulation (EU) 2022/123 (europa.eu)
Mpox	2	2 Centrally Authorised Products (CAPs)	22 August 2022	Every-other-week	List of critical medicines for Monkeypox public health emergency (PHE) under Regulation (EU) 2022/123

*Subject to the **epidemiological situation**

Preparedness activities



Preparedness activities – toolkit on measures to mitigate the impact of critical shortages

European and International cooperation

- *Monitoring and exchange of information by the **SPOC WP***
- *Involvement of the **MSSG***
- *Interactions with **EU institutions** (EC services)*
- *Exchange of information with **international regulators***

Communication

- **Shortage catalogue**
- **DHPCs**
- **Public statement**
- *Recommendation on **therapeutical alternatives***
- *LTT for EMRN*
- *Liaison with **supply chain stakeholders***
- *MAH **oral explanations** to SPOC WP and MSSG*

Regulatory flexibilities

- **Labelling exemptions**
- **Extension of shelf-life**
- **Accelerating variations** for the implementation of changes to source of raw materials, manufacturing equipment, packaging, batch size, etc.
- *Liaison with EDQM – **CEP acceleration***

Increased supply

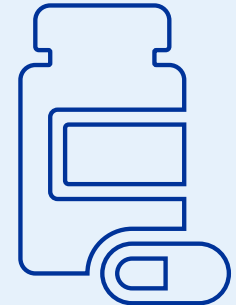
- **Increase production capacity**
- **Re-allocation** of product intended for other markets
- **Importation** of non-*authorised* products
- **Magistral formulations**
- **Diversification** of the supply chain
- *Joint procurement (HERA)*
- *Match making (HERA)*
- *Central purchasing (HERA)*

Controlled distribution

- **Rationing measures** (*ensure equitable access within the MS*)
- **Limiting online sale** of medicines at risk
- **Restrictions** on sales in community **pharmacies**

Shortages of antibiotics – background information

- The shortages are being closely monitored by EMA's Medicines Shortages Single Point of Contact Working Party (SPOC WP) since November 2022, which is responsible for **monitoring and reporting events that could affect the supply of medicines in the EU**
 - amoxicillin and amoxicillin/clavulanic acid
- A dedicated **subgroup** investigated causes of the shortages and extent of the situation in EU/EEA
 - Majority of EU MSs and EEA countries affected by shortages of paediatric formulations
 - Increase in demand, manufacturing delays, production capacity issues



Shortages of thrombolytics – background information

- Shortages of alteplase and tenecteplase being closely monitored by EMA's Medicines Shortages Single Point of Contact Working Party (SPOC WP) since April 2022
 - Single supplier
 - Increased demand worldwide; capacity not increased quickly enough
 - Shortages affect all markets supplied

- Close communication with MAH continues
 - Biweekly EMA-MAH meetings
 - Submission of weekly stock reports to EMA and NCAs
 - Presentations by MAH to MSSG and SPOC WP



Shortages of antibiotics and thrombolytics – interactions at EU and international level

- **Discussions** with DG **SANTE** and DG **HERA** to determine ability to mitigate impact of these shortages
- Interaction with **international regulators**:
 - Situation affects countries outside EU
 - Shortage catalogue entries also published in other jurisdictions
 - Discussions held with other regulators to investigate further
 - mitigation options and availability of alternatives



Shortages of antibiotics & thrombolytics: measures undertaken

- **Engagement with MAH/manufacturers to agree possible mitigating measures**, incl. communication, increase manufacturing and supply, regulatory flexibilities, controlled distribution
- Central role of MSSG in **sharing best practices** (incl. **Toolkit** on mitigating measures)
- **Interaction** with other **stakeholders** in supply chain (wholesaler industry associations, HCP/PCs organisations) at EU and national level
- **Oral explanations** at SPOC WP and MSSG to highlight criticality of situation and for MSs to discuss directly with MAHs
- **Interaction with MAHs in 3rd countries** to secure extra products from those markets for the EU
- **Communication** to reassure the public & promote rational use of medicines in shortage e.g. [Joint EMA/EC/HMA public statement on shortages of antibiotic medicines](#)
- [EMA's shortages catalogue](#) updated with information to healthcare professionals and patients (e.g. amoxicillin/clavulanic acid, tenecteplase)

Take home messages

- EMA is currently monitoring supply and demand for medicines in the critical list for COVID-19 and MPOX.
- EMA continues to manage shortages of centrally authorised medicinal products and critical shortages of nationally authorised medicinal products outside of major events / public health emergencies (e.g. amoxicillin, thrombolytics).
- IT development work on ESMP is underway to ensure delivery by early 2025
- For critical medical devices, preparatory work ongoing to set up necessary structures and establish interactions with relevant medical device stakeholders
- Close collaboration with ECDC for epidemiological data and with DG HERA and DG SANTE for data collection and analysis of supply and demand information (incl. on IT tools)

Thank you

Further information

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Back up slides

Overview of lists of critical medicines and medical countermeasures in the EU

Crisis preparedness

- Article 6(1) Regulation (EU) 2022/123 - list with main therapeutic groups of medicines for emergency care, surgery and intensive care
- C(2021) 6712 final, Art.2/ COM(2021) 576 final, Task 1 HERA List of critical medical countermeasures (MCMs)



Crisis Response

- Article 6(2) Regulation (EU) 2022/123 – List of critical medicines for a Public Health Emergency (PHE)
- Article 6(3) Regulation (EU) 2022/123 – List of critical medicines for a Major Event (ME)
- Article 7(1), Regulation EU 2022/2372 - HERA List of MCMs – PHE



Structural security of supply

- Outcome of the Structured Dialogue on the Security of Supply of Medicines – EU list of critical medicines

