



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1.3. Monitoring of events and preparedness for Public Health Emergencies/Major Events

PCWP/HCPWP joint meeting, 28 June 2023

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An agency of the European Union





Outline

- 1 EMA's extended mandate
- 2 Case study – shortages of antibiotics
- 3 EC proposal for a revision of the Pharmaceutical Legislation to enhance security of supply
- 4 Conclusions

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



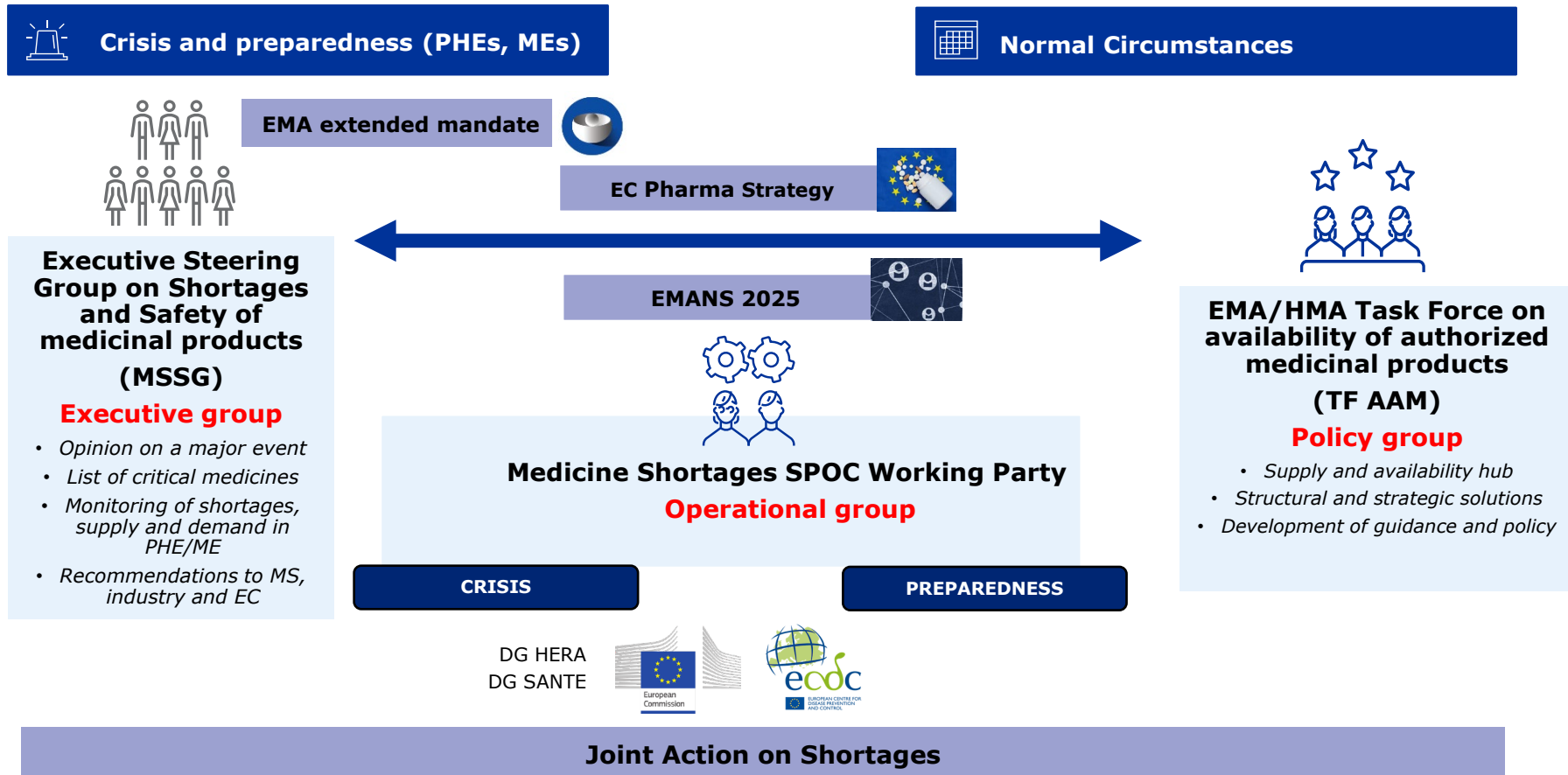
Regulation (EU) 2022/123 applicable from **1 March 2022**

- 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

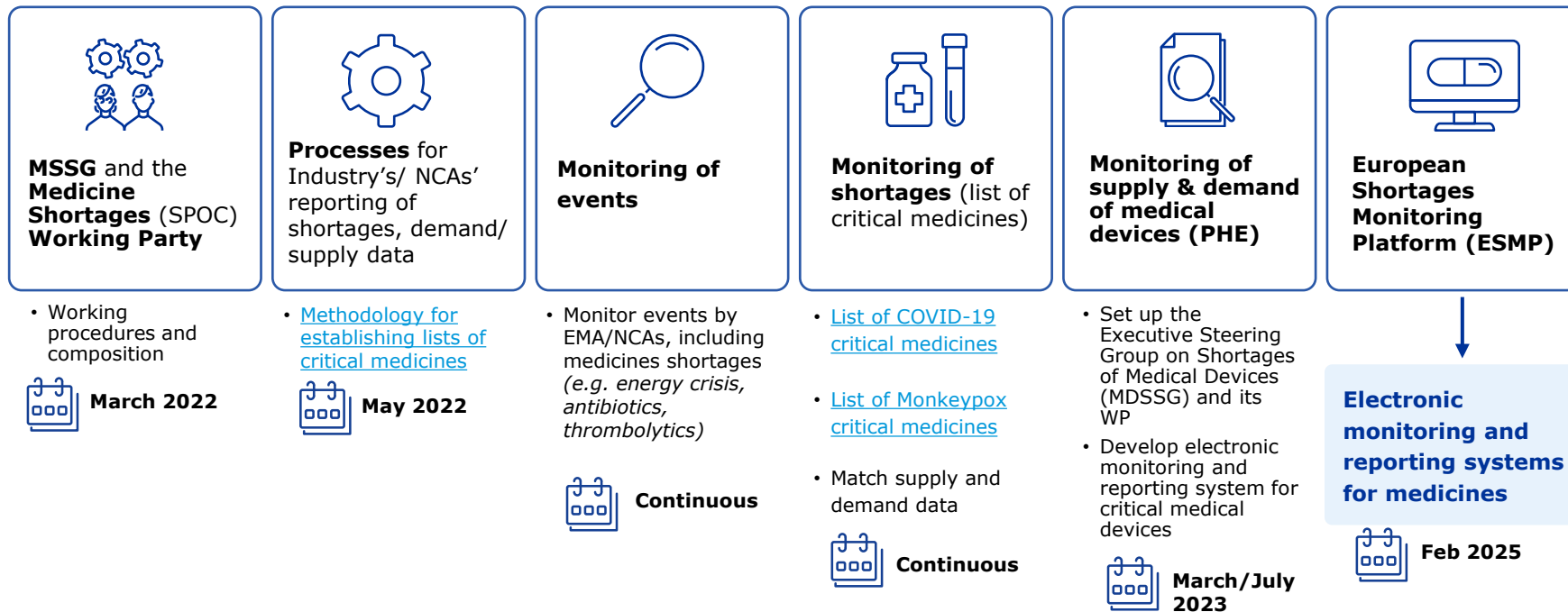


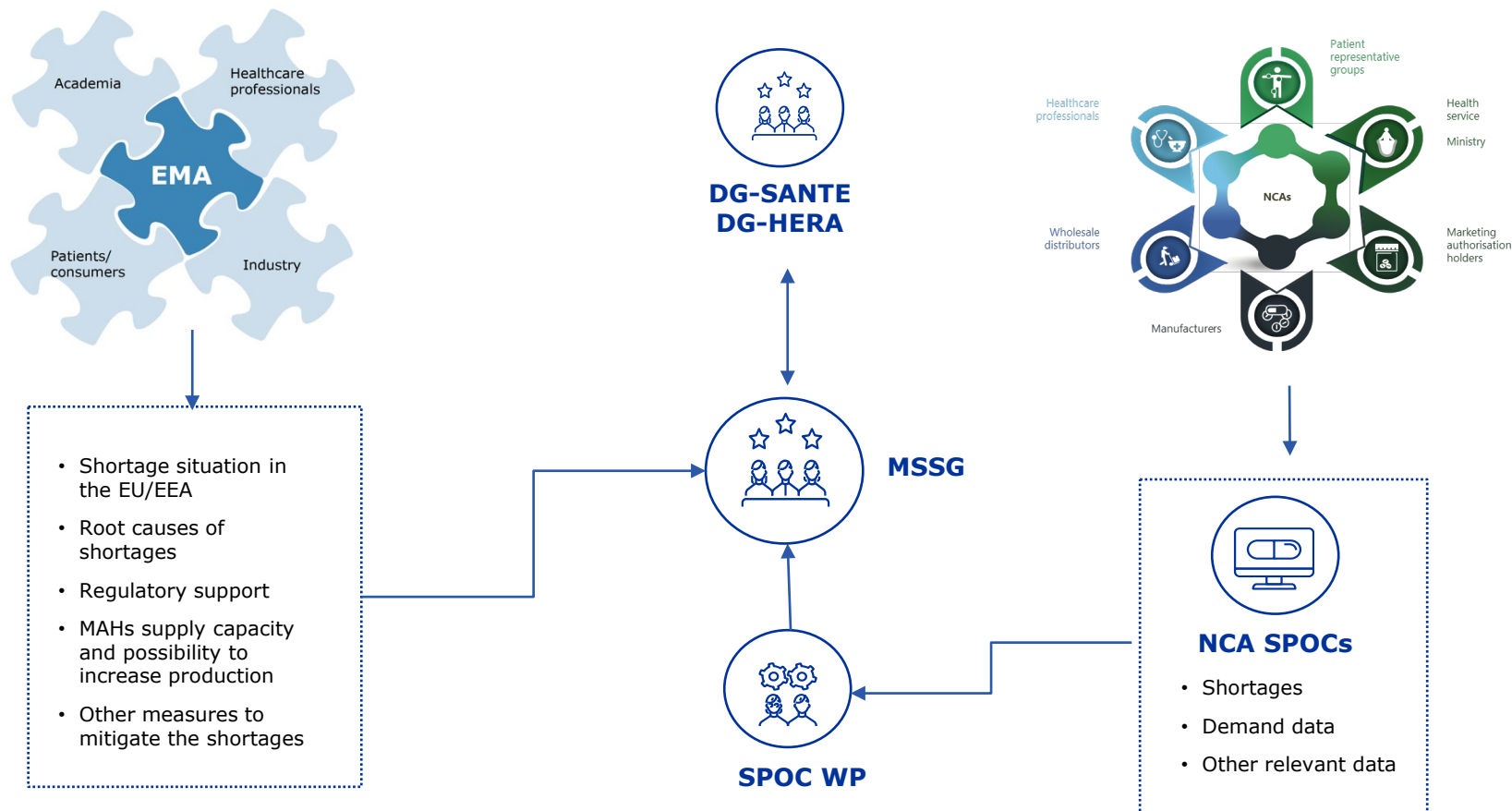
KEY BENEFIT

More coordination in preventing and mitigating medicines shortages in the EU



Key milestones for medicines and devices shortages







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 site(s), 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-authorized products
- **Magistral formulations**
- **Diversification** of the supply chain
- Joint procurement/ match making / 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**





Case study – shortages of antibiotics

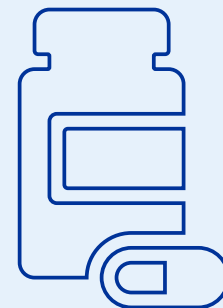
Background information

Shortages closely monitored by EMA's Medicine Shortages Single Point of Contact Working Party (SPOC WP) – responsible for **monitoring and reporting events that could affect the supply of medicines in the EU** – since November 2022

- *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 were affected by shortages of paediatric formulations
- Increase in demand, manufacturing delays, production capacity issues





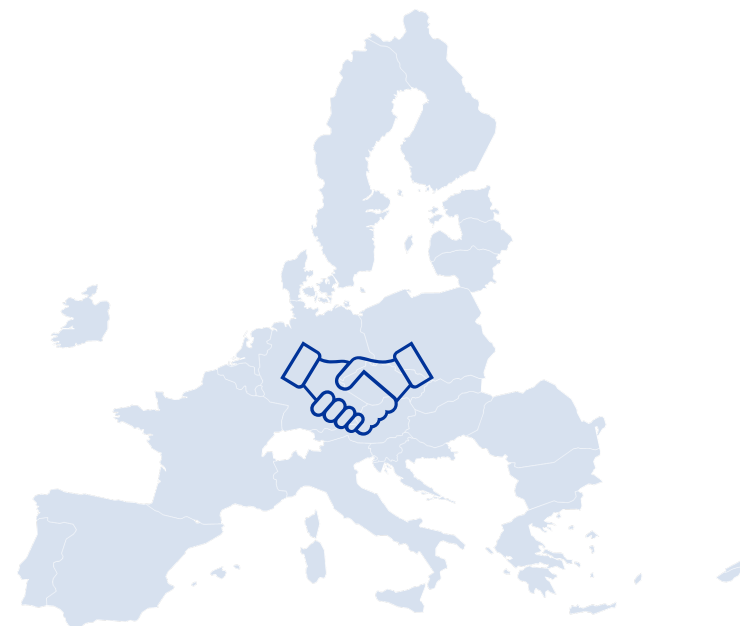
Measures undertaken

- **European and international cooperation**, incl. discussions with DG SANTE and DG HERA to determine ability to mitigate impact of these shortages, and exchange of information with international regulators
- **Engagement with MAH/manufacturers to agree possible mitigating measures**, incl. communication, increase manufacturing and supply, regulatory flexibilities
- 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
- **MAH presentations to** MSSG to highlight criticality of situation and for MSs to discuss directly with MAHs
- **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

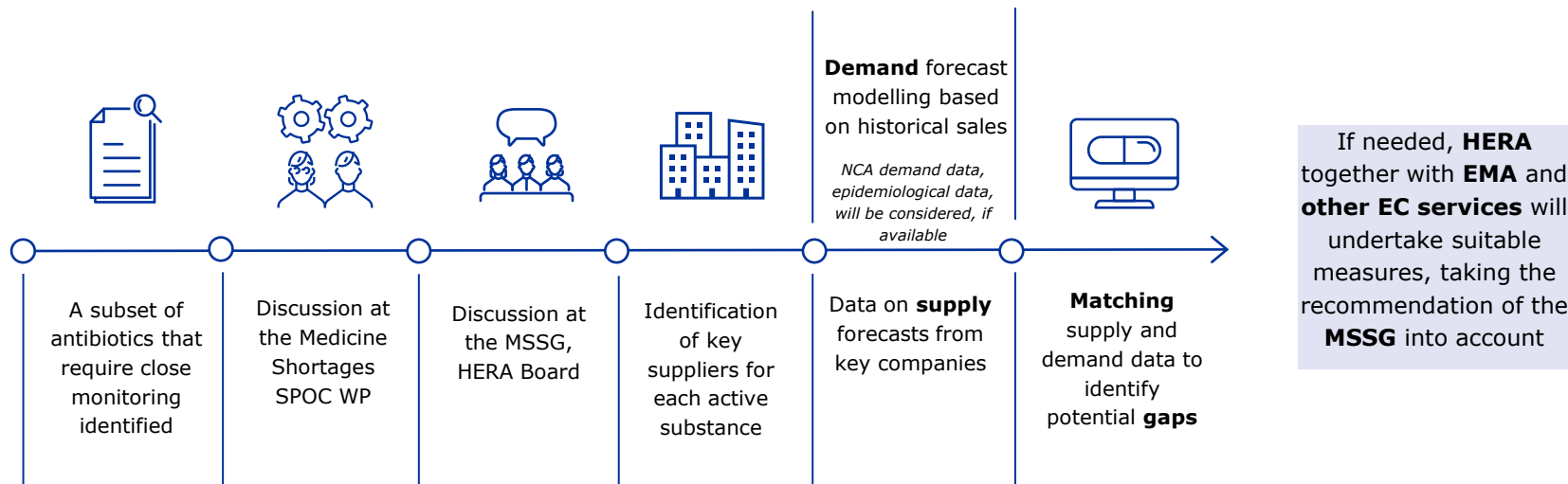
Preparedness for the next autumn/winter season

MSSG meeting on 26 January 2023 and **HERA Board** meeting on 30 January 2023 → agreement on the need to prepare for the next autumn/winter:

- **Joint European-level (EMA/HERA) exercise**
- Identify any **gaps between the supply and demand** for the next autumn/winter for a **subset of key antibiotics** (*whether shortages could be expected*), to understand if EU-level actions need to be undertaken to ensure sufficient supply for European patients.



Roadmap – monitoring of supply and demand of a set of antibiotics





EC proposal for a revision of the Pharmaceutical Legislation to enhance security of supply



Monitoring/management of withdrawals and shortages, including critical shortages

Reporting obligations → Earlier notifications (12 months/6 months)

Shortage prevention plans / Shortage mitigation plans

EMA's role in monitoring and management of shortages and critical shortages strengthen

EU recommendations on measures to prevent to mitigate the critical shortage (EU coordination through the MSSG)

Security of supply

Union list of critical medicinal products

Obligations of MAHs and other actors

MSSG recommendations on appropriate security of supply measures

scope of ESMP to be expanded



Conclusions

- EMA continues coordinating/managing shortages of centrally authorised medicinal products and **critical** shortages of nationally authorised medicinal products outside public health emergencies/major events (e.g. amoxicillin) under **preparedness activities**;
- As of 2 February 2023, EMA is also responsible for coordinating responses to **shortages of critical medical devices**, including in-vitro diagnostics, during public health emergencies.
- Under the HMA/EMA TF AAM, EMA is developing a **Union list of critical medicinal products**
- IT development work on **ESMP** is underway to ensure delivery by early **2025**
- Close collaboration with **ECDC** for epidemiological data and **with EC** for data collection and analysis of supply and demand information (incl. on IT tools)



Any questions?

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