



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Joint EMA/HERA exercise on the monitoring of a subset of antibiotics in preparation for the autumn/winter 2023-2024

Industry Standing Group (ISG) meeting, 26 June 2023





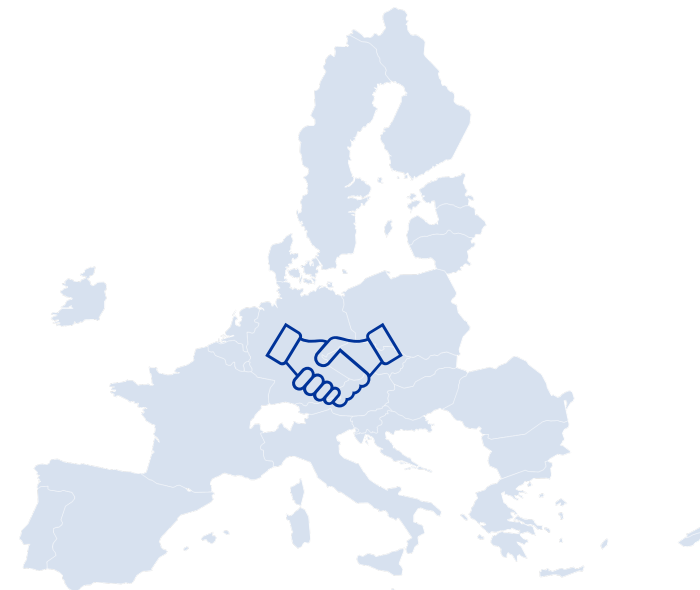
Background information

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 by EMA

- **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

Monitoring supply and demand of a set of antibiotics

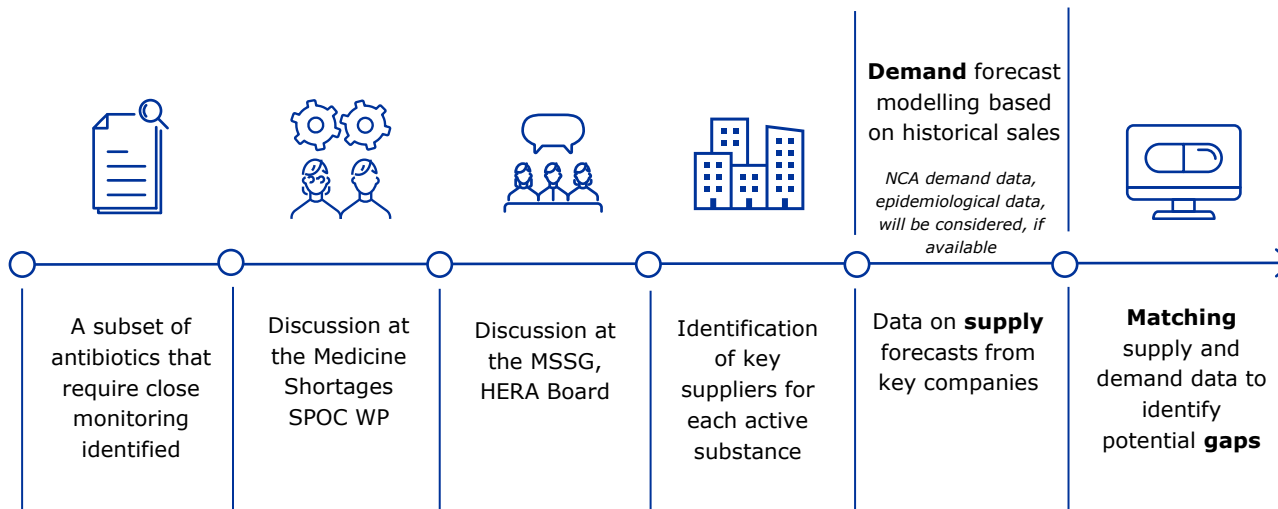
MSSG meeting on 26 January 2023 and **HERA Board** meeting on 30 January 2023 → agreement on the need to prepare for the next autumn/winter:

- **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



If needed, **HERA** together with **EMA** and **other EC services** will undertake suitable measures, taking the recommendation of the **MSSG** into account



Any questions?

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