



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# European initiatives to address shortages of antibiotics

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Cross-Sectoral One Health Conference on Antimicrobial Resistance  
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Presented by Emilija Matelyte  
Medicines and Medical Devices Shortages Officer, European Medicines Agency

An agency of the European Union





# Outline

- 1 EMA Extended Mandate on shortages
- 2 EMA's response to shortages of antibiotics
- 3 Joint EMA/HERA exercise on a set of antibiotics to prepare for the autumn/winter season 2023-2024
- 4 Conclusions

# Monitoring and mitigating **shortages of critical medicines** and management of major events



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

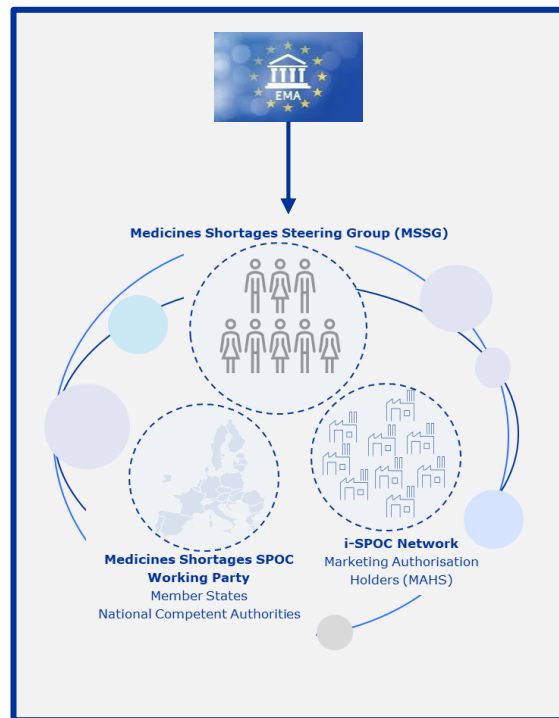
- Monitors events, including medicine shortages, which might lead to a crisis situation (public health emergencies or major events)
- Sets processes/tools for shortages reporting and coordinates responses of EU countries to shortages of critical medicines (during a crisis)
- Establishes “**Medicines 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** (SPOC WP) and a Network of contact points from pharmaceutical companies (i-SPOC)



## KEY BENEFIT

More coordination in preventing and mitigating medicines shortages in the EU

# The Extended Mandate – Medicines



## EMA:

- **Monitor events**, including medicine shortages, which may lead to a **crisis** (public health emergencies or major events)
- **Management** of shortages of CAPs
- **Collect information** from NCA SPOCs and i-SPOC for medicines in the critical list during a crisis
- **Match supply and demand** from MAHs and NCAs during a crisis
- **Coordinate responses of EU/EEA countries** to critical shortages

## MSSG:

- **Establish lists of critical medicinal products** to be monitored, provide **recommendations and coordinate measures** to prevent or mitigate shortages
- **Evaluate information** related to the public health **emergency** or the major event and provide recommendations regarding the **quality, safety and efficacy** of the medicinal products concerned
- Supported by the Medicines Shortages SPOC Working Party and MAHs (i-SPOC)

## NCAs:

- Monitor events
- Reporting requirements during crisis and under normal circumstances (critical shortages)

## MAHs:

- Reporting of shortages of CAPs
- Submit information to EMA on medicinal products on the critical medicines list during a crisis

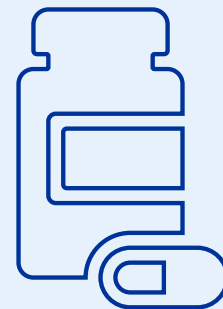
# Shortages of antibiotics – background information

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



# 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





# Measures undertaken

- **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 activities – “toolkit” on measures to mitigate the impact of critical shortages incl. antibiotics

European and International cooperation	Communication	Regulatory flexibilities	Increased supply	Controlled distribution
<ul style="list-style-type: none"><li>• <i>Monitoring and exchange of information by the <b>SPOC WP</b></i></li><li>• <i>Involvement of the <b>MSSG</b></i></li><li>• <i>Interactions with <b>EU institutions</b> (EC services)</i></li><li>• <i>Exchange of information with <b>international regulators</b></i></li></ul>	<ul style="list-style-type: none"><li>• <b>Shortage catalogue</b></li><li>• <b>DHPCs</b></li><li>• <b>Public statement</b></li><li>• <i>Recommendation on <b>therapeutic alternatives</b></i></li><li>• <i>LTT for EMRN</i></li><li>• <i>Liaison with <b>supply chain stakeholders</b></i></li><li>• <i>MAH <b>oral explanations</b> to SPOC WP and MSSG</i></li></ul>	<ul style="list-style-type: none"><li>• <b>Labelling exemptions</b></li><li>• <b>Extension of shelf-life</b></li><li>• <b>Accelerating variations</b> for the implementation of changes to source of raw materials, manufacturing site(s), manufacturing equipment, packaging, batch size, etc.</li><li>• <i>Liaison with EDQM – <b>CEP acceleration</b></i></li></ul>	<ul style="list-style-type: none"><li>• <b>Increase production capacity</b></li><li>• <b>Re-allocation</b> of product intended for other markets</li><li>• <b>Importation</b> of non-authorised products</li><li>• <b>Magistral formulations</b></li><li>• <b>Diversification</b> of the supply chain</li><li>• <i>Joint procurement (HERA)</i></li><li>• <i>Match making (HERA)</i></li><li>• <i>Central purchasing (HERA)</i></li></ul>	<ul style="list-style-type: none"><li>• <b>Rationing measures</b> <i>(ensure equitable access within the MS)</i></li><li>• <b>Limiting online sale</b> of medicines at risk</li><li>• <b>Restrictions</b> on sales in community <b>pharmacies</b></li></ul>



# Monitoring supply and demand of a set of antibiotics

In January 2023 the Executive Steering Group on Shortages and Safety of Medicinal Products (**MSSG**) and the **HERA Board** agreed on the need to prepare for the next autumn/winter so that the situation that occurred in autumn/winter 2022-2023 would not be repeated.

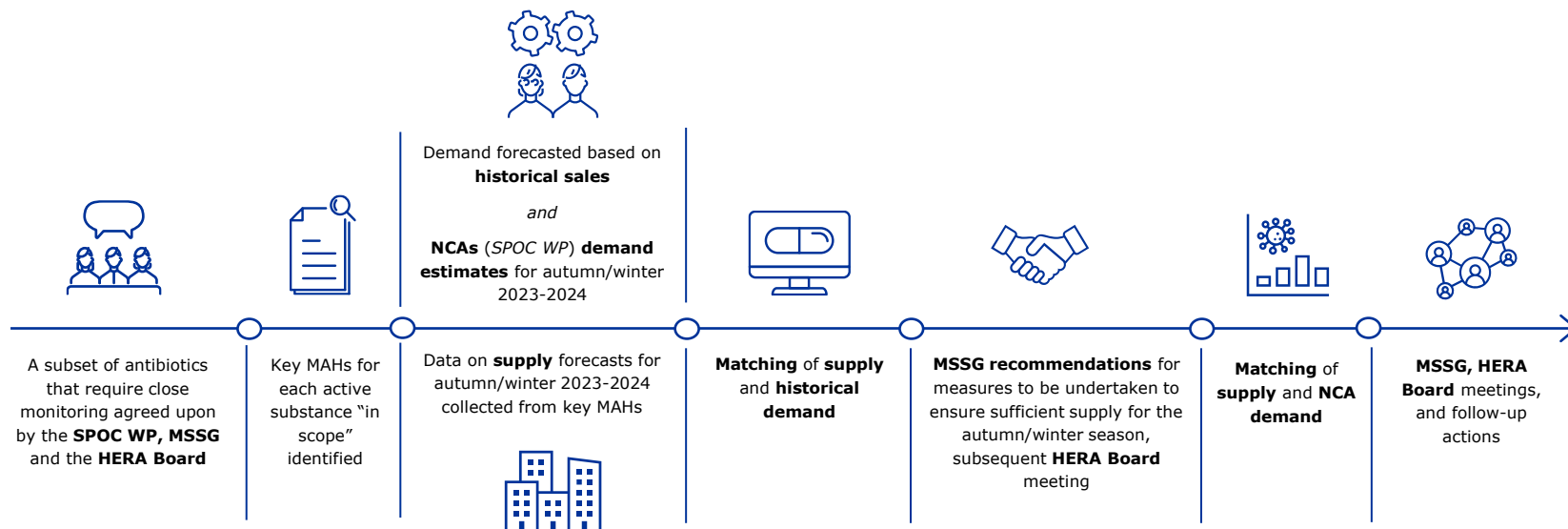
- **Joint European-level (EMA/HERA) exercise**
- Identify any **gaps between the supply and demand** for the next autumn/winter for a **subset of antibiotics** (*whether shortfalls could be expected*), to understand if EU-level actions need to be undertaken to ensure sufficient supply for European patients.

## **Why is it important?**

- Proactive approach to shortages
- Basis for discussion with industry and MSs



# Matching of supply and demand – overview



# A subset of antibiotics

Based on the data collected, outcomes are available for the following set of antibiotics:

- ☐ Amoxicillin
- ☐ Amoxicillin/clavulanic acid
- ☐ Penicillin V
- ☐ Azithromycin

- ☐ Clarithromycin
- ☐ Ceftriaxone
- ☐ Cefotaxime
- ☐ Piperacillin-tazobactam

# Outcome of the exercise

Subject to specific assumptions\* and if **the demand** in autumn/winter season of 2023/2024 **does not exceed that for the chosen historical demand scenario\*\***, it can be concluded that:



The supply to the EU of majority of **oral formulations** of key first and second-line antibiotics for respiratory infections will **meet the demand** in the autumn/winter season.



The supply to the EU of particular strengths of some **intravenous** antibiotics and **one oral liquid** antibiotic **will not adequately meet the demand**.

- \* 1. Historical sales data is a suitable proxy for actual demand
- 2. All manufacturers will fulfill their orders, and there will be no impact on API availability/manufacturing/distribution
- 3. No new ME/PHEs impacting the availability of antibiotics
- 4. No new or more virulent strain of a disease relevant for the active substances will occur

\*\* prediction of demand for each active substance using the best available information, with the aim to reach the right balance between existing uncertainties with regards to the actual future demand, and the public health need to prepare for the next autumn/winter

# MSSG recommendations

On 14 July 2023, EMA's MSSG agreed on the following recommendations for pro-active actions allowing to be better prepared for the autumn and winter season:

- EMA/HERA to continue to engage with MAHs to step up measures to **increase production** of the medicinal products concerned.
- EMA/HERA to **continue monitoring the supply and demand** of this set of **antibiotics** and extend the monitoring to paediatric formulations of **OTC medicines** commonly used in the autumn/winter season (*analgesics, antipyretics, cough syrups*).
- **Communicate** to the public on the preparedness activities undertaken at EU level to proactively approach shortages of antibiotics in the EU, also reminding HCPs of **prudent use of antibiotics** and highlighting the need for all involved stakeholders to **avoid stockpiling**.

# Conclusions



Discussions with industry to increase production capacity of the medicinal products concerned are ongoing.



The supply and demand continues to be monitored, in cooperation with the MAHs for antibiotics and Industry Associations.



The supply situation in the EU/EEA is being monitored through the SPOC WP, and in cooperation with community and hospital pharmacists to better understand the situation “on the ground”.



The actions undertaken ensure better preparedness for this autumn/winter season, but close cooperation with all stakeholders is essential. Feedback on the supply situation channelled to MSSG on a regular basis. Follow-up actions undertaken whenever necessary.



# Any questions?

## Further information

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emilija.matelyte@ema.europa.eu

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

**Telephone** +31 (0)88 781 6000

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