



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

4.3. Update on preparedness activities

PCWP/HCPWP joint meeting, 19 September 2023

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An agency of the European Union





Introduction

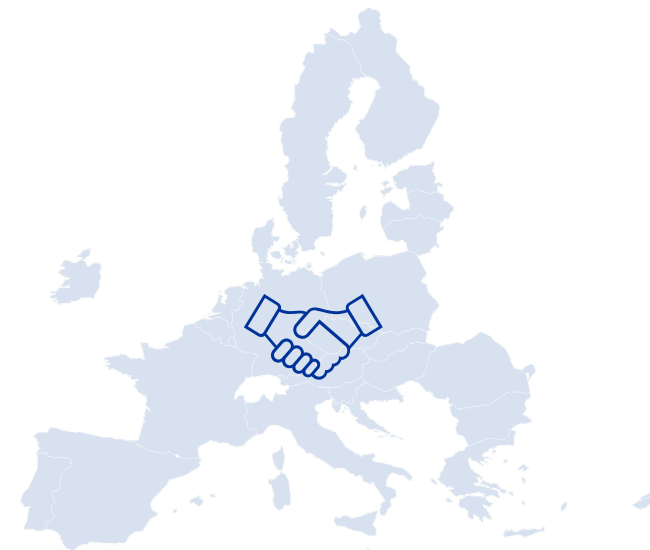
In January 2023 the Executive Steering Group on Shortages and Safety of Medicinal Products (**MSSG**) and the **HERA Board** agreed on the need to prepare for the next autumn/winter so that the situation that occurred in autumn/winter 2022-2023 would not be repeated.

❑ Joint European-level (EMA/HERA) exercise

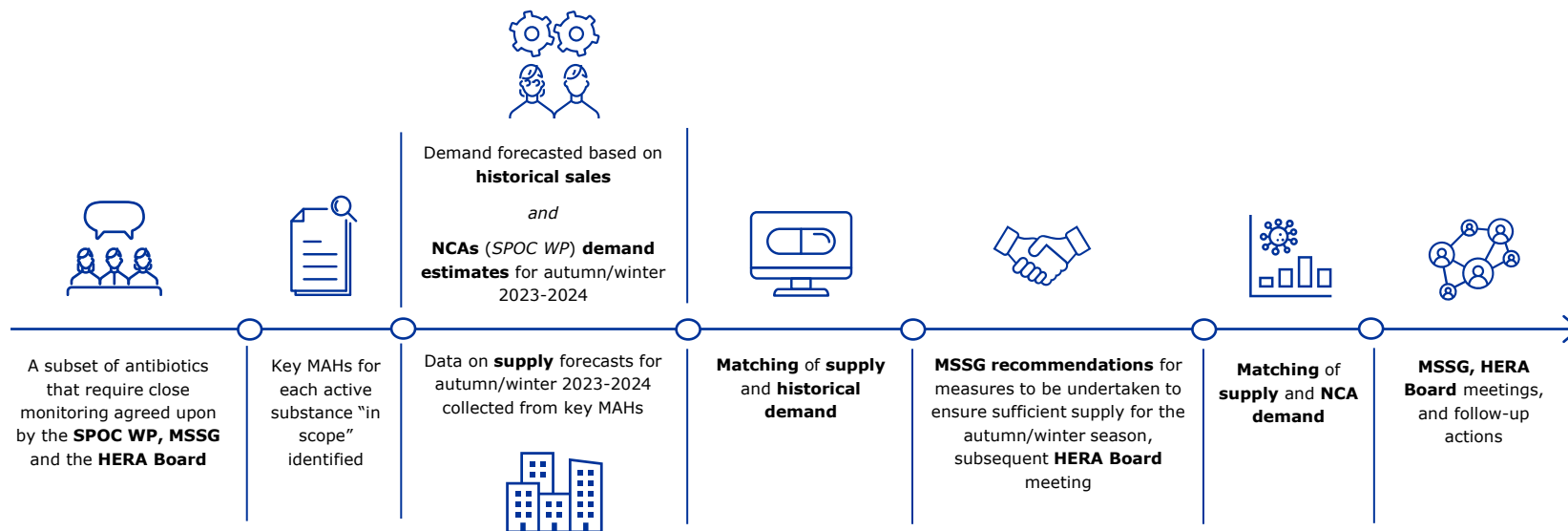
- ❑ Identify any **gaps between the supply and demand** for the next autumn/winter for a **subset of antibiotics** (*whether shortfalls could be expected*), to understand if EU-level actions need to be undertaken to ensure sufficient supply for European patients.

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 (*all pharmaceutical forms used to treat respiratory infections*):

- 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**.



Request to HCPs and PCs

Given that the measures recommended by the MSSG are designed to ensure sufficient supply:

- ❑ **HCPs** are reminded of the **prudent use of antibiotics** and asked to order antibiotic and paediatric analgesic, antipyretic medicines and cough syrups as usual
- ❑ **PCs** are asked to only purchase the necessary amounts of antibiotics, analgesics/antipyretics and cough syrups for children and only when treatment is required

Stockpiling medicines can put further **strain on supplies** and **cause or worsen shortages, limiting the availability of medicines to patients who need them**



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 → healthcare professionals and patients have a key role to play in the prudent use of antibiotics and avoiding stockpiling.



Any questions?

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