



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update on preparedness activities

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An agency of the European Union





Update on preparedness for autumn/winter (1)

Antibiotics and paediatric analgesics, antipyretics, cough syrups

On 19 September 2023 EMA presented to PCWP/HCPWP the **joint EMA/HERA exercise on antibiotics** and subsequent **MSSG recommendations**.

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





Update on preparedness for autumn/winter (2)

Antibiotics and paediatric analgesics, antipyretics, cough syrups

- ❑ EMA is exchanging information with **international regulators** to understand the availability situation in other jurisdictions.
- ❑ EMA is collecting bi-weekly reports from **Industry Associations** (incl. generic & originator manufacturers, wholesalers and distributors, API manufacturers) on any **early signals** of potential supply disruptions.
- ❑ EMA also collected feedback from **community and hospital pharmacists** (EAHP and PGEU) on the supply situation.
- ❑ **Medicine Shortages SPOC WP** reporting all shortages of the set of antibiotics to EMA.
- ❑ EMA is liaising closely with the **key antibiotic MAHs** in the context of continuous supply/demand monitoring (joint EMA/HERA exercise) and for critical shortages reported by the SPOC WP. One of the key players attended the F2F SPOC WP meeting in October 2023 and presented the supply situation to EMA and MSs.
- ❑ EMA launched a **social media campaign** on prevention of antibiotic shortages.

Conclusions

A number of pro-active actions undertaken in close cooperation with relevant stakeholders allow for better preparedness for the autumn/winter 2023-2024:



- ❑ Healthcare professionals and patients have a key role to play in the prudent use of antibiotics and avoiding stockpiling.
- ❑ HCP/PC Organisations are asked to report to EMA in case any early signals of supply disruptions of antibiotics and paediatric analgesics, antipyretics and cough syrups are identified.



Feedback on the supply situation of antibiotics and paediatric analgesics, antipyretics and cough syrups channelled to Executive Steering Group on Shortages and Safety of Medicinal Products on a regular basis. Follow-up actions undertaken whenever necessary.



Any questions?

Further information

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Back-up slides

Joint EMA/HERA exercise on antibiotics – outcome and recommendations

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

Considering the outcomes of the exercise 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**.