Communication of the President of the Office of 18 July 2023 on recommendations issued by the EC, HMA and EMA on measures to avoid shortages of key antibiotics for the treatment of respiratory infections during the upcoming winter season.

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The European Commission, the Heads of Medicines Agencies [1] (HMA) and the European Medicines Agency are today issuing recommendations for actions to avoid shortages of key antibiotics used to treat respiratory infections for European patients in the next winter season. These recommendations, which have been developed through the Executive Steering Group on Shortages and Safety of Medicinal Products [2] (MSSG), complement the process to develop an EU list of critical medicines. In close cooperation with the EU Member States, the Commission will take operational follow-up actions, including, if necessary, possible joint procurements.

If the demand in the coming winter season is similar to an average level of consumption in previous years, the data collected suggest that supply to the EU of oral formulations of key first and second-line antibiotics for respiratory infections will match demand in the coming winter season. EMA and the European Health Emergency Preparedness and Response Authority (HERA) will continue to work with marketing authorisation holders [3] to strengthen measures to increase the supply of some intravenous antibiotics.

To be better prepared for the winter season, the EMA's Executive Steering Group on Shortages and Safety of Medicinal Products [2] (MSSG) agreed on the following recommendations for pro-active actions:

- Increase the production of key antibiotics: To avoid shortages in the upcoming autumn and winter season, EMA and HERA are recommending to continue to engage with marketing authorisation holders [3] to step up measures to increase production. Early action ahead of the autumn and winter season should give manufacturers enough time to ensure they have sufficient manufacturing capacity to meet the demands.

- Monitoring of supply and demand: EMA and the Commission, together with Member States will continue to monitor the demand and supplies in cooperation with companies. Given that the measures taken are designed to ensure sufficient supply, all stakeholders are reminded to order medicines as normal, with no need to stockpile medicines. Stockpiling medicines can put further strain on supplies and cause or worsen shortages.

Public awareness and prudent use: Antibiotics should be used prudently to maintain their efficacy [4] and avoid antimicrobial resistance. Medical professionals have a key role to play, and antibiotics should only be prescribed to treat bacterial infections. They are not suitable for treating viral

infections such as cold and flu, where they are not effective. Citizen awareness-raising initiatives are also advised.

In line with the European Council conclusions of June 2023, EMA and the Commission through HERA will continue to closely monitor demand and supply and interact with marketing authorisation holders [3] throughout the rest of the year to detect early any unexpected shortfalls of supplies and take any necessary measures. A dedicated HERA Board meeting with representatives of the Member States' Ministries of Health, the Commission and the industry will take place on Thursday, 20 July to discuss the matter further and agree on possible additional steps.

The recommendations are based on data collected by EMA and the European Commission's Health Emergency Preparedness and Response Authority (HERA) on estimated demand and supply of a number of key antibiotics used to treat respiratory infections (amoxicillin, amoxicillin/clavulanic acid, penicillin V, azithromycin, clarithromycin, ceftriaxone, cefotaxime and piperacillin-tazobactam). The antibiotics selected are included in the WHO Access and Watch groups [5] of antibiotics emphasising the importance of their appropriate use and availability. Data on supply forecasts and production capacity were provided by the key marketing authorisation holders [3]. These were then matched to demand estimates that were derived from historical sales data for these medicines for the winter season in the EU/EEA.

The actions on antibiotics form part of the wider framework in place in the EU to prevent and reduce shortages of medicines. They will complement the process to develop an EU list of critical medicines. The creation of this list is progressing as planned under the guidance of the joint HMA/EMA Task Force on the Availability of Authorised Medicines for Human and Veterinary Use (TF AAM). The purpose of the list is to help to ensure that medicines that are most critical for health systems across the EU/EEA are available at all times. This list will catalogue medicines with a significant impact on public health for which measures should be taken to strengthen their supply to ensure continuity of care for patients at all times. It is anticipated that a first version of the EU list of critical medicines will be released by the end of 2023.

Under its new mandate (Regulation on EMA's Reinforced Role (Regulation (EU) 2022/123)) [6], EMA has new responsibilities to monitor critical medicines shortages that might lead to a crisis situation. The Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) [7] was set up to ensure a robust response to medicine supply issues caused by major events or public-health emergencies. The members of the MSSG include representatives of EU Member States; one representative of the European Commission; one EMA representative as well as an observer from EMA's Patients' and Consumers' Working Party (PCWP) [8] and its Healthcare Professionals' Working Party (HCPWP) [9]. The group is co-chaired by EMA Executive Director Emer Cooke and Karl Broich, Head of the German Federal Institute for Medicines and the chair of the HMA.

The Commission's Health Emergency Preparedness and Response Authority (HERA)'s mission is to prevent, detect, and rapidly respond to health emergencies. HERA was established in September 2021 to replace ad hoc solutions to pandemic management and response with a permanent structure with adequate tools and resources to plan ahead the EU action in case of health emergencies. A core goal of HERA is to ensure the development, manufacturing, procurement, and equitable distribution of key medical countermeasures to address any possible gap in its availability and accessibility.

HERA is a key pillar of the European Health Union and a fundamental asset to strengthen the EU's health emergency response and preparedness.

More information available on the website: https://www.ema.europa.eu/en/news/european-health-union-eu-steps-action-prevent-shortages-antibiotics-next-winter [10]

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Medical Devices and Biocidal Products

Links
[1] https://www.ema.europa.eu/en/glossary/heads-medicines-agencies
[2] https://www.ema.europa.eu/en/glossary/medicinal-product
[3] https://www.ema.europa.eu/en/glossary/marketing-authorisation-holder
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[5] https://www.who.int/publications/i/item/2021-aware-classification
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[7] https://www.ema.europa.eu/about-us/what-we-do/crisis-preparedness-management/executive-steering-group-shortages-medicinal-products
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