



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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European Medicines Agency

Recommendations of the Executive Steering Group on Shortages and Safety of Medicinal Products on the availability of a subset of antibiotics

Preparedness for the autumn/winter 2023-2024

1. Introduction

Throughout the past autumn and winter season the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) and its Medicine Shortages SPOC Working Party (SPOC WP) monitored critical shortages of antibiotics such as amoxicillin (alone and in combination with clavulanic acid). A number of measures were undertaken to mitigate the impact of these shortages to European patients such as regulatory flexibilities, communication to stakeholders, controlled distribution, European and international cooperation, and interactions with the key companies in the supply chain to increase supply to the European market.

To ensure better preparedness for the autumn/winter 2023-2024, in late January 2023 the MSSG and the HERA Board tasked EMA and HERA with the monitoring of supply and demand for a specific set of antibiotics used for respiratory infections, in cooperation with the key marketing authorisation holders (MAHs) and National Competent Authorities (NCAs) in EU/EEA.

On 14 July 2023 the MSSG discussed the results of the joint EU-level exercise on matching supply and demand, and based on the outcome agreed on recommendations for measures to be undertaken proactively by all stakeholders to ensure sufficient supply for European patients for the upcoming autumn/winter season.

2. Recommendations

2.1. Increase supply of medicinal products

- **Cooperation with the key MAHs and manufacturers** – interaction with companies by EMA/HERA to agree on measures to prevent potential shortages through increased manufacturing capacity of concerned medicinal products.



2.2. Monitoring of supply and demand

- Continued **monitoring of forecasts of supply and demand** for a subset of antibiotic medicinal products for human use in the EU/EEA by EMA and HERA in cooperation with the concerned MAHs and NCAs, where required.

2.3. Communication

- **Information to the public** on measures taken at EU level to prevent shortages of antibiotic medicines in the EU, promoting the prudent use of antibiotics and highlighting the need to avoid of stockpiling by all relevant stakeholders.

3. Adoption of recommendations by the MSSG

The recommendations were adopted by the MSSG on 14 July 2023 with a possibility to be updated whenever necessary.