

Communication of the President of the Office of 23 January 2023 on the publication of a joint statement of the Medicines Shortages Steering Group (MSSG) on shortages of antibiotic medicines.

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PREZES

Urzędu Rejestracji Produktów Leczniczych,
Wyrobów Medycznych i Produktów Biobójczych

Grzegorz Cessak

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EMA, the European Commission and the Heads of Medicines Agencies (HMA), through the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG), are closely monitoring and responding to current shortages of antibiotics affecting the EU.

Shortages of medicines have been an ongoing public health concern and the situation in the EU has been exacerbated by geopolitical events or trends such as the war in Ukraine, the energy crisis and high inflation rates.

A recent surge in respiratory infections has led to an increase in demand for antibiotics such as amoxicillin (alone and in combination with clavulanic acid), especially as paediatric formulations. In addition, manufacturing delays and production capacity issues have led to supply problems affecting the majority of Member States. The supply issues also affect countries outside the EU, and EMA has exchanged key information with other international regulators. Various measures have been implemented at Member State level to ensure that patients can receive appropriate treatment.

MSSG and its working party, the SPOC working party, have been closely monitoring the situation since November 2022 and have been engaging with key players in the supply chain of amoxicillin to agree possible mitigating measures such as increasing manufacturing capacity. Through EMA's engagement with its stakeholders, MSSG has received up-to-date information from community pharmacists on the situation in pharmacies across the EU. National Competent Authorities, as encouraged by the MSSG, are making use of the regulatory flexibilities available, such as allowing the exceptional supply of certain medicines or presentations that may not be authorised in a particular Member State or granting full or partial exemptions to certain labelling and packaging requirements to ensure that patients can receive appropriate treatment. In addition, MSSG supports temporary national measures such as unit dose dispensing and compounding.

The European Commission, HMA and EMA are cooperating closely, to investigate whether additional measures could be undertaken to mitigate the impact of these shortages.

MSSG will continue to cooperate with stakeholders, and the SPOC working party will continue to engage with companies to provide regulatory support to increase supplies.

MSSG and the SPOC working party will continue to closely monitor the situation together with the

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European Commission and EU Member States. Based on current information from companies and stakeholders, it is expected that the situation will improve in the coming months. Patients and healthcare professionals are reminded that alternatives are available in case of shortages.

It is important that antibiotics are used prudently to maintain their efficacy and avoid antimicrobial resistance. Antibiotics, including amoxicillin, 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.

MSSG stresses the importance of transparency in relation to shortages and highlights the need for all stakeholders to communicate in an objective and responsible way to avoid any undue public concern.

More information on the MSSG and SPOC

Under its new mandate, EMA (Regulation on EMA's Reinforced Role (Regulation (EU) 2022/123)) 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) has been 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) and its Healthcare Professionals' Working Party (HCPWP). More information can be found here: <https://www.ema.europa.eu/en/about-us/what-we-do/crisis-preparedness-management/executive-steering-group-shortages-safety-medicinal-products> [1]

The SPOC working party is responsible for monitoring and reporting events that could affect the supply of medicines in the EU. It provides recommendations to EMA's Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) on all matters related to the monitoring and management of medicines shortages and other availability issues affecting human and veterinary medicines. More information can be found here:

<https://www.ema.europa.eu/en/committees/working-parties-other-groups/medicines-shortages-single-point-contact-spoc-working-party> [2]

For more information about EMA responsibilities for monitoring and mitigating medicine and medical device shortages under Regulation (EU) 2022/123, see here:

<https://www.ema.europa.eu/en/about-us/what-we-do/crisis-preparedness-management-0> [3]

More information available on the website: <https://www.ema.europa.eu/en/news/joint-statement-executive-steering-group-shortages-safety-medicinal-products-mssg-shortages> [4]

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Medical Devices and Biocidal Products

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Links

[1] <https://www.ema.europa.eu/en/about-us/what-we-do/crisis-preparedness-management/executive-steering-group-shortages-safety-medicinal-products>

[2] <https://www.ema.europa.eu/en/committees/working-parties-other-groups/medicines-shortages-single-point-contact-spoc-working-party>

[3] <https://www.ema.europa.eu/en/about-us/what-we-do/crisis-preparedness-management-0>

[4] <https://www.ema.europa.eu/en/news/joint-statement-executive-steering-group-shortages-safety-medicinal-products-mssg-shortages>

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