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Amoxicillin, alone or in combination with clavulanic acid, is an antibiotic
used to treat a wide range of bacterial infections.
This shortage started in October 2022 and has several root causes; the main reason was a surge in respiratory infections that led to an increased demand for antibiotics. This was compounded by manufacturing delays and production capacity issues (lack of personnel).
The shortage affects or may affect all Member States where the medicine s marketed.
The shortage situation has improved or has been resolved in most countries. While some intermittent shortages of amoxicillin and amoxicillin/clavulanic acid continue to occur, alternative antibiotics are available in most countries.
For up-to-date information about the status of a medicine shortage in a particular EU/EEA Member State, consult the <u>national shortage register</u> or contact the <u>national competent authority.</u>
EMA's <u>SPOC working party</u> engaged with key stakeholders in the supply chain of amoxicillin and amoxicillin/clavulanic acid to agree on possible measures to mitigate the impact of the supply shortage, such as ncreasing manufacturing capacity. The SPOC working party is responsible for monitoring and reporting events that could affect the supply of medicines in the EU. Summaries of the SPOC working party meetings can be found on <u>EMA's website</u> . Furthermore, EMA, together with the European Commission's Directorate General for Health Emergency Preparedness and Response (DG HERA), monitored the supply and demand of a subset of antibiotics, including amoxicillin and amoxicillin/clavulanic acid. As a result, the Medicine Shortages Steering Group (MSSG) issued recommendations to help ensure the availability of key antibiotics used to treat respiratory nfections. More information about this cooperation is available on the

<sup>&</sup>lt;sup>1</sup> This document was modified on 17 July 2023 to update the list of Member States affected and to reflect ongoing monitoring by EMA and DG HERA; and on 2 September 2024 to reflect the fact that the situation has improved or resolved in most countries.

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## Shortage of amoxicillin and amoxicillin/clavulanic acid Various presentations including paediatric formulations and presentations

	Following the actions taken, the situation has improved or has been resolved in many EU Member States. EMA's SPOC working party continues to monitor the shortage situation in cooperation with the relevant stakeholders and takes appropriate actions when necessary.
Information to healthcare professionals	<ul> <li>A surge in respiratory infections during the winter of 2022/2023 led to an increase in the 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 led to supply problems in the majority of the EU Member States.</li> <li>Although the situation has since improved, shortages are still ongoing in some countries. Where shortages are ongoing, alternative antibiotic can be prescribed based on national guidelines. Please check the current availability status of alternative medicinal products with your national competent authority.</li> <li>As for all antibiotics, amoxicillin should only be prescribed to treat bacterial infections and not viral infections such as cold and flu, for which they are not effective.</li> <li>It is important not to overorder amoxicillin to prevent shortages.</li> </ul>
Information to patients	<ul> <li>A surge in respiratory infections during the winter of 2022/2023 led to an increase in the demand for antibiotics such as amoxicillin (alone and in combination with clavulanic acid), especially as formulations for children. In addition, manufacturing delays and production capacity issues led to supply problems in the majority of the EU Member States.</li> <li>Although the situation has since improved, shortages are still ongoing in some countries. If amoxicillin is not available in your country, your doctor will prescribe an alternative antibiotic. For children, your pharmacist may make a preparation themselves. Ask your pharmacist for advice on how to give this preparation to your child.</li> <li>Your doctor will only prescribe amoxicillin to treat bacterial infections and not viral infections such as cold and flu, where antibiotics are not effective.</li> <li>If you have any questions you should speak to your doctor or pharmacist.</li> <li>Please consult your national shortage register for further advice, including advice on alternatives, if applicable.</li> </ul>
Status	Ongoing