

Joint letter of patient and consumer organisations:
The shortage of antibiotics should be considered a “major event”

To the EMA Executive Director

To the members of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)

Cc: European Commission

Dear Chair and members of the MSSG,

We are writing to you because we believe that the situation of antibiotic shortages should be declared a ‘major event’, as defined by the Regulation (EU) 2022/123.

Amoxicillin and amoxicillin plus clavulanic acid, especially paediatric formulations, have been in short supply in Europe since October 2022¹. Most EU Member States are affected, as well as other large countries like the USA and Canada. Supply issues are thus global, and imports are not an option to alleviate the current shortage.

The main root cause declared by producers is an insufficient production capacity to face the surge in demand provoked by an increase of various respiratory infections connected with the winter season. Various mitigating measures have been adopted by the Member States, such as recommendations for healthcare professionals and patients, regulatory flexibilities, compounding, exchanges with the main manufacturers and marketing authorisation holders, and use of alternative treatments, etc. This helped make sure that most patients could still be treated in one way or another, even if some countries experience more severe situations; in Romania, 8 patients out of 10 walk out of the pharmacy without the antibiotic they were prescribed.²

The impact of the current situation on patients, on their families and on public health cannot be overlooked. For instance, parents have been obliged to smash and dilute adult formulations of amoxicillin plus clavulanic acid as paediatric syrups were in shortage, with the risk of incorrect dosing and/or problems with adherence due to bitter taste. The substitution with a different antibiotic is also problematic as it may be less effective and/or have stronger side-effects (i.e. heavy diarrhoea). Children’s allergies to alternative formulations can also make substitutions difficult, without mentioning the parents’ anxiety when the antibiotic they were prescribed is not available. Lastly, large-scale substitutions also contribute to the development of antimicrobial resistance, while fighting AMR is a key public health priority.

The substitution of amoxicillin with different antibacterial agents also increases the risk of a cascade effect. A consistent number of other antibiotics are now in short supply in one or more Member States, and new shortage notifications continue to pop up regularly on the

¹ This is however not a completely new issue since recurring shortages of amoxicillin and amoxicillin plus clavulanic acid have been registered over the past years in some Member States like France.

² PGEU feedback to the European Medicines Agency Executive Steering Group on Shortages and Safety of Medicinal Products on Shortages of amoxicillin and antipyretics in Europe, 10/01/2023.

dedicated websites of the national medicine agencies: azithromycin, cefuroxime and sulfamethoxazole + trimethoprim are just a few examples of the molecules concerned³.

We appreciate that the EMA and the SPOC working party have been monitoring very closely the situation over that past 2 months, as well as their support provided to Member States' initiatives and their engagement with the key players in the supply chain. Nevertheless, these measures have not been sufficient to contain the crisis and to invert the trend until now.

The scope, magnitude, as well as the current and potential future greater impact of the shortage of antibiotics on patients and public health correspond to the conditions of a "major event", as defined by the Regulation (EU) 2022/123. We therefore encourage the EMA to officially raise the issue, and we invite the MSSG to adopt a positive opinion on this matter without further delay. This will not bring an immediate solution to the crisis, but it will greatly increase companies' reporting obligations, and it will provide the EMA with more detailed intelligence and stronger legal competence to coordinate actions at Union level. The adoption of a list of medicinal products considered as critical will also help identify which antibiotics require urgent action as they are already in shortage in several Member States, and which others need closer monitoring to avoid eventually being in short supply. All these are important measures foreseen in the aforementioned Regulation that can help the EU ensure more effectively the availability of essential antibiotics.

This letter is supported by the undersigned organisations:

1. AGE Platform Europe (AGE)
2. Alzheimer Europe (AE)
3. European Consumer Organisation (BEUC)
4. European Federation of Neurological Associations (EFNA)
5. European Foundation for the Care of Newborn Infants (EFCNI)
6. European Heart Network (EHN)
7. European Public Health Alliance (EPHA)
8. Health Action International (HAI)
9. International Diabetes Federation European Region (IDF Europe)
10. International Patient Organisation for Primary Immunodeficiencies (IPOPI)
11. Thalassaemia International Federation (TIF)

³ See the national shortage catalogues of the Member States: <https://www.ema.europa.eu/en/human-regulatory/post-authorisation/availability-medicines/shortages-catalogue#ema-shortages-catalogue-section>