

EPF's call for action to ensure patients' continued access to safe, high-quality medicines across the EU

The European Patients' Forum (EPF) is deeply concerned about the growing problem of shortages in the EU in recent years, undermining patients' fundamental right to equal access to safe, quality healthcare.

From everyday medicines and antibiotics to highly specialised products, many patients across Member States have experienced difficulties in accessing the medicines and treatments they need. For example, in Belgium, patients with cystic fibrosis regularly suffer shortages of enzyme replacement therapy, which is critical in their treatment, while a widely used anti-nausea medicine, often used in oncological care, is nowhere to be found. The situation is similar in Greece, where penicillin injections, used to treat certain types of bacterial infection, are often in short supply. Likewise, some patient organisations have reported persistent shortages of several medicines to treat organ transplant patients, with no or limited information to patients on the situation and varying levels of communication from authorities on the issue.

Shortages and availability issues are major public health problems that can seriously harm patients' health and safety, quality of care, professionals' ability to deliver care, and health system functioning. If a medicine is not available when the patient needs it, it can have life-threatening consequences. Their impact on patients ranges from having no treatment at all, to having to use an alternative treatment that may or may not be equally suitable and may create safety issues (e.g., increased risks of medication errors, adverse interactions, etc.). They can also lead to delays in care/therapy in 59% of cases and, in 35% of cases, to the cancellation of care (abandonment or cessation), as highlighted by a recent survey of EU hospital pharmacists¹.

EPF calls for **urgent solutions to current shortages** and for a **comprehensive, multistakeholder approach to understanding the root causes of shortages and finding appropriate long-term solutions**.

Of note, from the perspective of patients, the impacts of shortages not only relate to medicines, but also to medical devices and human resources for health, including in many areas of crucial importance in health emergencies, such as pathology and nursing.

The focus on shortages in recent EU initiatives, including the review of the EU pharmaceutical legislation or the European Commission's communication on shortages², is a first step in the right direction. We also welcome EMA's specific recommendations³ to prevent shortages of antibiotics for this winter and the Agency's efforts to develop guidance for various stakeholders to prevent and

¹ EAHP 2023 Shortage Survey Report, accessible [here](#).

² European Commission, "Addressing medicines shortages in the EU", accessible [here](#).

³ European Medicines Agency, "European Health Union: EU steps up action to prevent shortages of antibiotics for next winter", accessible [here](#).

mitigate shortages, including patient and healthcare professionals' organisations⁴. We call for these policy measures to be guided by patients' and public health needs, and therefore involve patients and their representatives at every stage. In particular:

- **EPF calls on the Commission and Member States to reach out to all stakeholders to find solutions and harmonise communication practices across Europe, thereby ensuring a high degree of transparency.** Member States' authorities should engage in regular dialogue with patient organisations in their countries to establish regular information exchanges, implement accessible, user-friendly tools and databases, and develop communication campaigns to ensure the safe use of alternatives and make the best use of available supplies. In addition, Member States should exchange best practices on digital solutions that can support better prevention and management of shortages, such as systems that inform doctors in real time if a medicine they are prescribing is in shortage.
- **EPF calls on pharmaceutical companies to live up to their commitments to patients.** Among other things, they must fulfil their notification obligations, be transparent about commercially-driven decisions and pre-empt any negative impacts on patients, prepare for potential production problems, and communicate regularly with the authorities and other relevant actors to get an accurate picture of forecasts and demand to help ensure sufficient supply at all times.
- **EPF calls for an effective solidarity mechanism between Member States to alleviate shortages in the short term, which must be accompanied by transparency on available stocks.** Such a mechanism can only work if Member States have reliable and detailed information on medicines' stocks and can assess the availability of any medicine at any time on their respective markets.
- **EPF calls for measures to continue to guarantee patients' right to receive patient leaflets in their language in the event of shortages and supply chain issues.** While specific regulatory flexibilities can help alleviate short-term supply issues, access to high-quality information is an essential aspect of health equity, which should not be undermined in the event of a shortage. Patient leaflets contain important information to ensure the safe use of medicines and should remain easily accessible in all circumstances, thereby enabling patients to play an active role in their health and care.
- **EPF calls for patients to be involved in subsequent versions of the Union list of critical medicines, given that patients were not involved in the first version drawn up by the Commission, the EMA and the Member States.** Patient involvement is essential to ensure that the criteria for defining what constitutes a "critical" medicinal product meet patients' needs and guarantee fair access to critical medicinal products in the EU.
- **EPF calls on the EU co-legislators to streamline patient involvement in measures to address shortages and security of supply in the revised EU pharmaceutical legislation, thereby encouraging a similar approach at national level.** Meaningful patient involvement in the development of policy solutions is needed to ensure that policy responses meet patients'

⁴ European Medicines Agency, "Good practice guidance for patient and healthcare professional organisations on the prevention of shortages of medicines for human use", accessible [here](#).

needs. In particular, specific mechanisms for patients to report shortages and supply disruption issues at national level – including experiences with alternatives – need to be put in place to improve data collection and understanding of the societal impacts of shortages.

- **EPF calls for measures to strengthen the resilience of the supply chain and avoid disruption in times of crisis.** We call for an open discussion on ways to support the diversification of the supply of active pharmaceutical ingredients to increase the resilience and flexibility of the supply chain, thereby ensuring continuity and security of supply. In this process, public health and patient safety should be the driving factors.
- **EPF calls for the development of transparent public procurement strategies that consider long-term impacts on patients and the availability of medicines in the award criteria.** Any specific clauses or criteria relating to the guarantee of supply can only be assessed with patients' participation. The question of whether manufacturers respect this guarantee of supply, i.e., whether the medicine is accessible and available in practice, is something that only patients, their carers, and healthcare professionals see and experience directly.
- **EPF calls for joint procurement mechanisms coordinated at EU level, particularly for medicines that pose major access problems.** These include "cheap" generics whose production is not considered economically viable, particularly at national level, or highly innovative medicines that would reach the poorest EU countries with long delays.

EPF is ready to support efforts to put in place a comprehensive, patient-centred system to prevent shortages and mitigate the impact on patient communities. In the meantime, we will continue to monitor the situation and voice the concerns of the patient community, while conveying best practices for patients and patient organisations in the event of shortages and providing community support services.

ABOUT EPF

The European Patients' Forum (EPF) is an umbrella organisation of patient organisations across Europe and across disease areas. Our 79 members include disease-specific patient groups active at the EU level and national coalitions of patients representing 21 countries and an estimated 150 million patients across Europe. www.eupatient.eu