

The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.

Statement on the immediate need to take action on medicine shortages

The European doctors are concerned about the continuously urgent problem of medicine shortages and call for concerted action at the EU level to secure medicine supplies for the autumn and winter season, as well as in the longer perspective.

The availability of medicines has been a long-standing challenge in the EU. However recently, national medical associations have reported that the problem of medicine shortages has become systemic across seasons and types of medicinal products, which is impacting patient safety and the practice of healthcare professionals.

Knowing enough about the reasons for medicine shortages, the responsible actors must act now to avoid a repeat of last winter, when European patients faced severe shortages of essential medicines, including antibiotics, paediatric formulations and medicines for diabetes. The European Union must not only mitigate but also prevent medicine shortages.

The Standing Committee of European Doctors calls on the European Commission and the Member States to take immediate action in the following areas:

1. Demand forecasting and production

Pharmaceutical companies must fulfil their obligation to supply adequate quantities of medicines to the market. This will only be possible if responsible demand forecasting systems are used and based on robust data including from public authorities. The industry should adequately plan the manufacturing timelines, considering non-medical production inputs.

The EU cannot leave it to the private actors to determine the quantity of essential medicines produced and delivered when needed the most, nor accept commercial tactics in the process of reporting possible shortages. Both the European Medicines Agency and the Health Emergency Preparedness and Response Authority must have binding tools to increase production of key medicines by the industry.

2. Communication for healthcare professionals

Healthcare professionals are key partners in mitigating the negative impact of shortages on patient safety and health. Hence, there is an utmost need to ensure that doctors have access to up-to-date information on actual shortages and available alternatives. Best practices already exist in some EU Member States, and we believe they could be easily implemented across the EU, e.g. in the context of electronic prescription tools.

3. EU list of critical medicines

Under the guidance of the joint HMA/EMA Task Force on the Availability of Authorised Medicines for Human and Veterinary Use, a new list of critical medicines will be released by the end of this year to ensure that medicines considered to be the most critical for health systems are always available. It is imperative to meaningfully involve clinicians and patients in the development of this list and to make sure that the list is of added value to prevention of shortages.

The EU landscape is already rich in many guiding lists and European doctors believe that each new one should bring clear added value. Methodology for this and future lists foreseen in the proposed legislation must be transparent.

4. Solidarity mechanism and EU stockpiling

There is not a single European country immune to medicines shortages. National attempts to resolve the issues are often proven insufficient to remedy acute problems. Before the adoption of the new EU pharmaceutical legislation, the European Commission should swiftly set up a voluntary sharing mechanism for Member States to exchange medicines in shortage.

We also call on the Member States to resort to national stockpiling only when not endangering neighbouring countries, regions or health care facilities with patients in need of the stockpiled medication. Member States may also consider, as a last resort, temporary bans on parallel trade.

5. Procurement

Well-designed procurement policies play a crucial role in ensuring stable supply of medicines. We call on the Member States to revise their national and regional tendering procedures to include criteria other than the price e.g., historic reliability of the supply, diversification of APIs supply and potentially production in Europe. The European Commission should provide support for this process.

6. Dependency on third countries

As a mid- to long-term measure the EU must become more independent from production sites outside of Europe, most importantly in case of critical medicines. In view of the above, the EU should explore measures to shift the production of essential medicines back to Europe, as well as create favourable environment for manufacturing capabilities and workforce.

In the longer perspective, European doctors believe the revision of the EU pharmaceutical legislation has a potential to improve prevention and mitigation of medicine shortages. With that in mind, we put forward a [list of amendments](#) to strengthen the proposal.