



Commission publishes first Union Critical Medicines list to tackle shortages

Brussels, 12 December 2023

The European Commission has published today **the first Union list of critical medicines**, together with the European Medicines Agency (EMA) and the Member States' Heads of Medicines Agencies (HMA). The publication follows the commitment made in the Commission's [Communication on addressing medicine shortages in the EU](#) to accelerate the work on this list, originally announced in the EU's pharmaceutical reform proposal. It is an important part of the EU's efforts under the European Health Union to ensure patients have the medicines they need, by fostering the security of supply of critical medicines and preventing shortages from occurring. It is also part of the EU's efforts to improve its resilience and strategic autonomy in the face of geopolitical and unexpected challenges.

A medicine is listed as critical when it is essential to ensure the provision and the continuity of quality healthcare, and to guarantee a high level of public health protection in Europe. This first Union critical medicines list contains **more than 200 active substances used in human medicines**, which are considered essential in the EU/EEA.

The inclusion on this list is not an indication that a medicine is likely to experience a shortage in the near future. Rather, it signifies the **critical importance of averting shortages for these specific medicines**, as its unavailability could cause significant harm to patients and pose substantial challenges to health systems.

The list was developed alongside with the EMA and all EU Member States. It follows a **strict methodology** to assess criticality, initially developed during the Commission's Structured dialogue on security of medicines supply launched under the Pharmaceutical Strategy, which was conducted in 2021 and drew lessons from the COVID-19 pandemic. Key stakeholder groups, including patients and healthcare professional organisations and industry associations, were consulted.

Ensuring the **uninterrupted supply of critical medicines** of the Union list is a top priority for the Commission. It will take all necessary steps to work hand in hand with the Member States and relevant stakeholders in order to prevent shortages, including implement additional measures if required.

Next steps

The Union list of critical medicines will be **reviewed annually**. As announced in the [Communication on addressing medicine shortages in the EU](#), the Critical Medicines list will be used to support and expedite the Commission's analysis of vulnerabilities in the supply chains of the critical medicines that are included on the list, following a staged approach.

On this basis, the Commission and EMA, together with the Member States (through the Executive Steering Group on Shortages and Safety of Medicinal Products), may recommend measures to address those vulnerabilities. This would be done, where relevant, in consultation with the Critical Medicines Alliance to be set up in early 2024.

For More Information

[Union list of critical medicines and Q&A](#)

[Reform of the EU pharmaceutical legislation](#)

IP/23/6377

Quotes:

The publication of this first crucial list underscores our proactive preventive measures, uniting our pledge to safeguard continuous access to vital medicines for every citizen within our Union. It stands as a testament to our dedication outlined in the Commission's Communication on addressing medicine shortages in the EU and the pharmaceutical reform proposal, solidifying our commitment to this cause. As we reach this milestone, our united commitment remains resolute, propelling ongoing initiatives to combat medicine shortages and continue prioritizing public health.

Margaritis Schinas, Vice-President for Promoting our European Way of Life - 12/12/2023

Ensuring an uninterrupted supply of critical medicines is essential for a strong European Health Union. With the publication of the first Union list of critical medicines today, we are delivering on our promise to accelerate work in this area and to take every possible measure to avert the risk of shortages for our citizens. I am very grateful to the European Medicines Agency and Member States' agencies for the cooperation on this list and for the crucial work that they are doing to prevent medicine shortages in our Union.

Stella Kyriakides, Commissioner for Health and Food Safety - 12/12/2023

Press contacts:

[Stefan DE KEERSMAECKER](#) (+32 2 298 46 80)

[Ana APSE-PAESE](#) (+32 2 298 73 48)

General public inquiries: [Europe Direct](#) by phone [00 800 67 89 10 11](#) or by [email](#)