



Commission steps up actions to address critical shortages of medicines and strengthen security of supply in the EU

Brussels, 24 October 2023

The Commission has adopted today a set of actions to better prevent and mitigate critical medicine shortages in the EU, this winter, next winter and beyond. Recent critical shortages, including of certain antibiotics last winter, show that continued coordinated action is needed to address supply challenges and to make Europe's medicine supply chains more resilient in the long run. The key goals of today's [Communication](#) are to prevent and mitigate **critical shortages** at EU level. It puts a particular focus on the most **critical medicines**, for which security of supply in the EU must be ensured at all times.

This Communication builds on the work under the European Health Union, notably the reinforced mandate of the European Medicines Agency and the recently published [pharmaceutical reform](#). It follows a strong call by Member States at the [2023 June European Council](#), confirmed in [Granada](#) in October 2023, and from the European Parliament.

Mitigating critical shortages this winter and beyond

To better prepare for this winter, a lot of measures have already been taken. For instance, the European Health Emergency Preparedness and Response Authority ([HERA](#)) and the European Medicines Agency ([EMA](#)) have identified [key antibiotics](#) (including specific paediatric formulations) for which they anticipate the risk of critical shortages ahead of the winter. Measures have been put in place to assure the availability of these antibiotics.

However, more needs to be done. This is why we are stepping up our actions with:

- The launch of a **European Voluntary Solidarity Mechanism for medicines** (October 2023): the mechanism flags a Member State's needs for a given medicine to other Member States, that can respond by redistributing medicines from their available stock.
- A **Union list of critical medicines** (available by the end of 2023): Once established, this list will be the first step to analyse the supply chain of selected medicines by April 2024. This analysis will then show where additional measures are needed.
- **Regulatory flexibilities**: Member States can use regulatory exemptions to allow medicines to reach patients in a timely manner, including extending shelf-life or the quick authorisation of alternatives. There will be a dedicated Joint Action in 2024 to promote effective use of these flexibilities.
- **EU guidance on procurement** of medicines to strengthen security of supply issued by the Commission by early 2024.
- EU joint procurement for next winter for antibiotics and treatments for respiratory viruses.

Member States, the EMA and the Commission have already initiated actions that go in the direction of the proposed pharmaceutical reform to prevent and mitigate critical shortages risks. The Commission will continue working together with Member States to accelerate elements of the **pharmaceutical reform** to enhance security of supply, where possible.

Structural measures to support long-term security of supply

To diversify supply as well as stimulate and modernise production of critical medicines with all stakeholders, the Commission intends to set up a **Critical Medicines Alliance** to be operational in early 2024. The Critical Medicine Alliance will add an industrial policy pillar to our European Health Union. This will allow national authorities, industry, civil society representatives, the Commission and EU agencies to coordinate action at EU level against the shortages of medicines and to address supply chain vulnerabilities.

The work of the Alliance will focus on a targeted number of critical medicines with the highest risk of shortages and impact on healthcare systems. It will draw from a varied toolbox of policy measures to mitigate risks of shortages and increase supply, including:

- Coordinating public procurement practices at EU level;
- Exploring how to **diversify global supply chains through strategic partnerships**;
- Boosting Europe's capacity to produce and innovate in the manufacturing of critical medicines and ingredients in coordinated way;
- Developing a common strategic approach to medicines stockpiling in the EU;
- Helping leverage and align **EU and national funding**.

This could pave the way for a possible "Critical Medicines Act" in the future. To that end, the Commission will launch a dedicated, preparatory study by the end of 2023, paving the way for an impact assessment.

In the first half of 2024, the Commission will also develop a **common strategic approach to medicines stockpiling** to prevent and mitigate shortages in cooperation with Member States.

International partnerships for supply

International cooperation and the genuine integration of the global pharmaceutical industry is key to ensure the availability of medicines in the EU and across the world.

The Commission will establish a **network of international partners** to address supply chain resilience. **Strategic partnerships with third countries** for the production of critical medicines will also be set up, reflecting both local demands and needs at the EU and global level.

Background

The continued availability of safe, effective and affordable medicines for Europeans is a top priority for the Commission. It is the foundation of the strong European Health Union established as one of the key lessons of the COVID pandemic.

Our **pharmaceutical reform** announced in April 2023, includes a set of measures to improve security of supply and tackle shortages of medicines in the long-term and beyond crisis situations.

Today's Communication complements the pharmaceutical reform by further boosting the anticipation and operationalisation of some of the measures proposed in the reform, while acknowledging that additional policy tools, including industrial policy, can support the important objective of ensuring security of supply of critical medicines in the EU.

For more information

[Communication on tackling medicine shortages in the EU](#)

[Factsheet](#)

[Q&A](#)

[European Health Union](#)

[HERA](#)

[Availability of medicines | European Medicines Agency \(europa.eu\)](#)

[Medicines Shortage Steering Group](#)

[Reform of the EU pharmaceutical legislation \(europa.eu\)](#)

[A pharmaceutical strategy for Europe \(europa.eu\)](#)

[Structured dialogue on security of medicines supply \(europa.eu\)](#)

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Quotes:

The COVID-19 pandemic and the Russian military aggression against Ukraine exposed Europe's supply chains dependencies and the risk that economic dependency could be weaponised. Ensuring the availability of medicines within the EU is fundamental to building a strong European Health Union. Today's Communication is a direct response to the European Council's call in June 2023 to ensure the availability of critical medicines and diminish the EU's reliance on external sources, a call reaffirmed in the Granada Declaration.

Margaritis Schinas, Vice-President for Promoting our European Way of Life - 24/10/2023

In a strong European Health Union, it is unthinkable that patients are left without the medicines they need. Improving the management of critical shortages of medicines and ensuring a steady security of supply for the EU has been our priority since day one. We need a single market for medicines in the EU and a new approach to better tackle shortages of critical medicines. Today we are putting forward collective actions to work closer with the industry and help Member States improve the security of supply for the coming winter and in the long-term.

Stella Kyriakides, Commissioner for Health and Food Safety - 24/10/2023

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