

#### **EUROPEAN COMMISSION**

#### **PRESS RELEASE**

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# Commission launches the Critical Medicines Alliance to help prevent and address shortages of critical medicines

The European Commission's Health Emergency Preparedness and Response Authority (HERA), working with the Belgian Presidency of the Council of the EU, have today launched the **Critical Medicines Alliance** at the margins of the informal EPSCO Council meeting of health ministers, as part of the actions to build a strong European Health Union.

The Alliance brings together national authorities, industry, healthcare organisations, civil society representatives, the Commission and EU agencies to **identify the best measures to address and avoid shortages of critical medicines**.

First <u>announced</u> by the Commission in October 2023, the **Alliance will focus on industrial policy and complements the reform of the EU's pharmaceutical legislation** as <u>proposed by the Commission</u>. It is a direct response to the call of more than 23 Member States for **more strategic autonomy** in the sector.

Following an <u>open Call for expression of interest</u>, launched on 16 January 2024, the Alliance has now some **250 registered members**, including ministries of governmental agencies representing Member States, companies or organisations as industry representatives, and non-governmental organisations.

# Key strategic actions of the Alliance

Set up as an inclusive and transparent consultative mechanism of key stakeholders, the Alliance will:

- work to enhance security of supply;
- strengthen availability of medicines;
- reduce EU supply chain dependencies.

This will ultimately contribute to a more resilient and sustainable pharmaceutical industry in Europe and more secure medicine supplies for citizens.

To strengthen security of supply, the Alliance will develop **strategic recommendations** to address and avoid shortages. Key factors being analysed include an over-dependency on a limited number of external suppliers, limited diversification possibilities, and limited production capacities. This will build on the Commission's vulnerability analysis of supply chain bottlenecks of critical medicines on the Union list of critical medicines. The recommendations will form together of a multi-year 'Strategic Plan', containing milestones and corresponding deadlines for their implementation.

Contacts: names and telephone contacts of Spokesperson and Press Officer



Discussions in the Alliance will help the Commission to identify innovative 'pipeline investment projects', which could benefit from EU and national funding to strengthen manufacturing in the EU.

The Alliance will also look at how **market incentives**, such as the possibility to expand the use of capacity reservation contracts and **joint procurement** can be used to enhance security of supply of critical medicines.

The Alliance will take a holistic view of the supply chain, and its members can identify new synergies to work with each other more effectively, including **creating new partnerships**. Given the global nature of the supply chain, and the strong interest expressed by, for example, several partners from the Western Balkans, as well as EU neighbourhood countries to participate in the Alliance, these new partnerships could bring the **diversification of the supply chain** of critical medicines.

## **Next steps**

The Alliance is launched for 5 years. As of the launch today, work will begin, with **publication of its first recommendations on actions to take** to improve the supply of critical medicines foreseen by the end of the year. While the first call for expression of interest is now closed, the Alliance remains open to new members at all stages of its operation.

## **Background**

Recent critical shortages of medicines have highlighted the importance of security of supply in and across the EU. The Commission took action to combat shortages, starting with a <u>Communication presenting actions to better prevent and mitigate critical medicine shortages in the EU</u>, adopted by the Commission on 24 October 2023 and followed by a <u>first Union list of critical medicines</u> by the EMA on 12 December 2023.

The Commission has carried out an analysis of supply chain vulnerabilities for a first tranche of 11 critical medicines on the Union list by April 2024. The outcome of this work will inform the scope of the mandate of the Critical Medicines Alliance.

## For more information

Alliance website

**HERA** website

Communication on addressing medicines shortages in the EU

<u>European Medicines Agency list of critical medicines</u>

# Quote(s)



Stella **Kyriakides**, Commissioner for Health and Food Safety: "Today's launch of the Critical Medicines Alliance is our operational response to ensuring that our citizens always have access to the medicines they need. We are adding an industrial dimension to our European Health Union, which will focus on how we address vulnerabilities in the supply chain and recommend priorities areas of action, like strengthening manufacturing capacities and diversifying international supply chains. The Alliance will pool resources and expertise from governments, industry, health professionals, and civil society, coming together with a shared goal -ensuring that our patients are better protected and have more equal access to medicines they need. This is our European Heath Union in action."

Frank Vandenbroucke, Deputy Prime Minister and Minister of Social Affairs and Health of Belgium: "COVID-19 demonstrated how crucial European cooperation and solidarity is to fight a health crisis. Creating access to vaccines to all European citizens was a prime example. In the same vein, a true European Health Union should guarantee the availability of critical medicines to all Europeans. The Critical Medicines Alliance is new industrial pillar for our European Health Union, with exactly this ambition. Bringing all stakeholders together in an Alliance is crucial. Not only to tackle shortages, so every EU citizen can find necessary medicines in their own country, but also to reduce our dependence for basic medicines on countries like China and India. There's a lot of work to be done. It is time to go to work now."