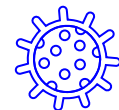




Addressing medicine shortages in the EU today, tomorrow and beyond

OCTOBER 2023



The **continued availability of safe, effective and affordable medicines** for Europeans is a top priority for the Commission. It is the foundation of a strong **European Health Union**, established as one of the key lessons of the COVID-19 pandemic.

What we want to achieve

Building on existing EU tools, including the extended mandate of the **European Medicines Agency (EMA)**, the creation of the **Health Emergency Preparedness and Response Authority (HERA)** and the **pharmaceutical reform**, the Commission is taking additional action to:



- ▶ manage critical shortages of medicines;
- ▶ improve the security of supply in the EU for the coming winter and beyond;
- ▶ reinforce the industrial policy pillar of the European Health Union.



How we plan to do this

IMMEDIATE AND SHORT-TERM ACTIONS TO MITIGATE CRITICAL SHORTAGES



- ▶ A **European Voluntary Solidarity Mechanism for medicines**: to be launched on 24 October 2023 for Member States facing critical shortages.
- ▶ A **Union list of critical medicines**: to be published by the end of 2023.
- ▶ Make use of **regulatory flexibilities** where needed.
- ▶ **EU guidance on procurement**: to be issued by early 2024 to strengthen security of supply.
- ▶ Accelerating and anticipating the **pharmaceutical reform** in cooperation with the Member States.



STRUCTURAL MEASURES FOR THE MID-TERM AND LONG-TERM

A **Critical Medicines Alliance** to be operational in early 2024. The Alliance will:

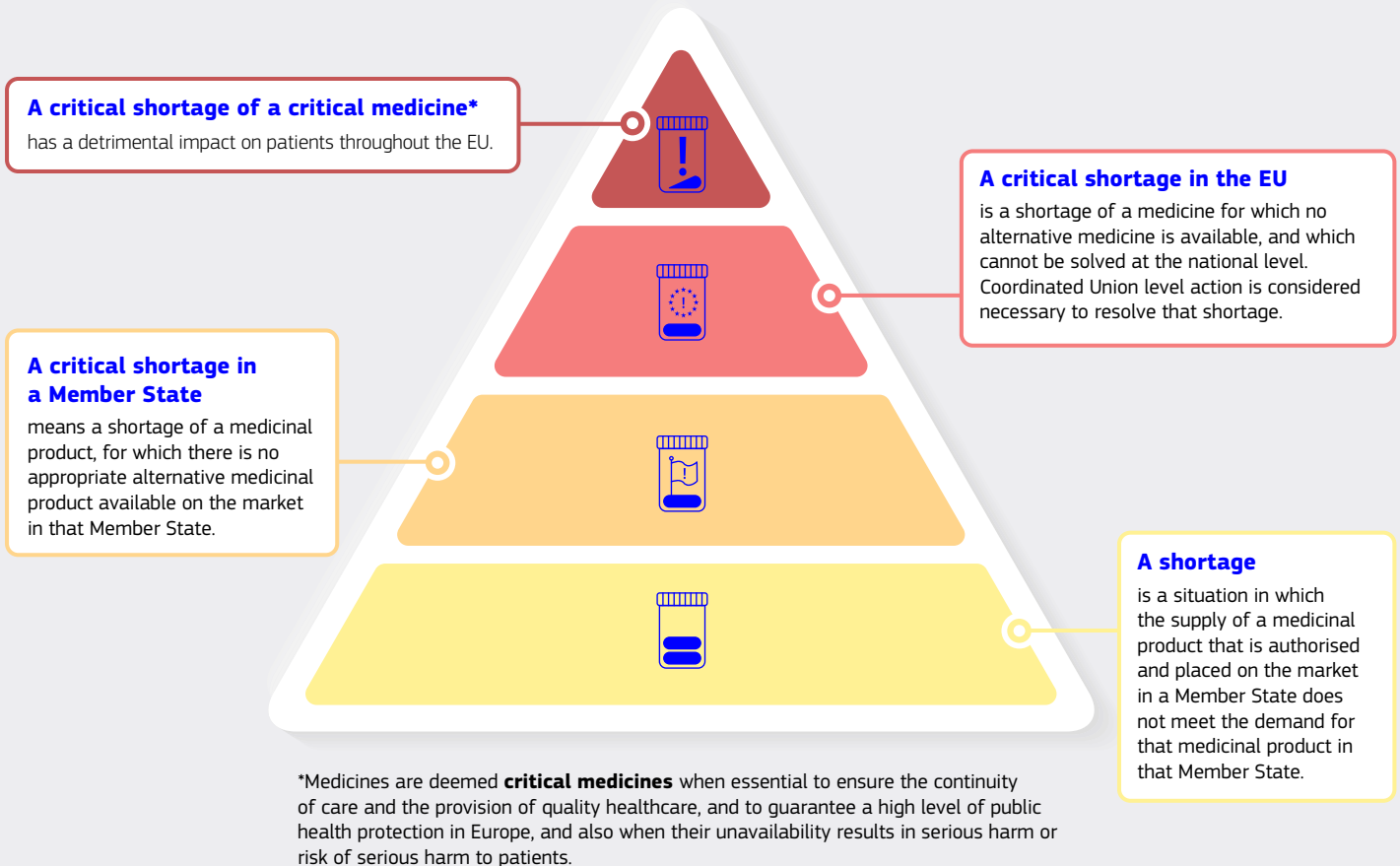


- ▶ Coordinate public procurement practices at EU level.
- ▶ Explore how to **diversify global supply chains through strategic partnerships**.
- ▶ Boost Europe's capacity to produce and innovate in the manufacturing of critical medicines and ingredients in coordinated way.
- ▶ Develop a common strategic approach to medicines **stockpiling** in the EU.
- ▶ Help leverage and align **EU and national funding**.

INTERNATIONAL PARTNERSHIPS FOR SUPPLY



- ▶ A **network of international partners** to address supply chain resilience.
- ▶ **Strategic partnerships with third countries** for the production of critical medicines.



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