

## FAQS

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### WHAT WILL THE ALLIANCE DELIVER?

The Alliance will provide the Commission and other EU decision-makers with advice on the most appropriate actions and instruments to tackle medicines shortages, drawing on a set of available tools:

- EU funding (including EU4Health, STEP, cohesion funding, RRF etc.), potentially coordinated with national funding to enable investment in manufacturing projects;
- partnerships with third countries to improve the security of supply;
- market incentives, such as the possibility to expand the use of capacity reservation contracts like EU Fab;
- joint procurement to enhance security of supply of critical medicines especially in the smaller markets.

The first Alliance recommendations will be detailed in a multi-year set of actions (**'Strategic Plan'**), prepared by the Steering Board and endorsed by the Forum, containing milestones and corresponding deadlines. This document aims at guiding the Commission, Member States and industry representatives in the implementations of the recommendations they choose to put in place.

The Alliance will not have a decision-making role but a consultative one. It will also form a supportive network at EU level on all topics related to this challenge.

### WHAT IS THE GOVERNANCE STRUCTURE OF THE ALLIANCE?

The **Forum** is open to all Member Organisations and convenes at least once a year to discuss high-level policy matters concerning the Alliance. For instance, the Forum is consulted before the Steering Board adopts the Strategic Plan.

The **Steering Board** comprises six representatives of the Member States (two for each representative of the trio presidency), five representatives of the industry, two representatives of patients/consumers/healthcare professionals, one representative of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG), one representative of the European Medicines Agency (EMA), and all chairs of the Working Groups. Its responsibilities include:

- formulating and endorsing the Strategic Plan;
- ensuring coherence and integration across the work of various working groups and with other existing structures;
- maintaining a roadmap outlining the implementation of the actions proposed by the Alliance, drawing on inputs from the Working Groups;
- supporting the European Commission in facilitating, communicating, and monitoring the work of the Alliance, as well as validating its outputs.

**Working Groups** will be set up by the Commission at the Steering Board's request, focusing on specific topics. These groups are open for participation to Member Organisations with relevant activities and expertise related to the designated Working Groups area of work. They provide input to the Steering Board to aid with the drafting of the Strategic Plan.

#### **HOW DO VARIOUS BODIES REACH DECISIONS?**

Decisions are reached through consensus. In case of a vote, the result will be determined by a simple majority of the respective body.

#### **WHAT IS THE WORKING LANGUAGE OF THE ALLIANCE?**

The working language of the Alliance is English.

#### **HOW DOES THE ALLIANCE USE THE UNION LIST OF CRITICAL MEDICINES PUBLISHED BY THE EMA?**

The Commission is launching a pilot exercise to analyse the vulnerabilities in the supply chains of an initial set of 10-20 substances from the EU list of critical medicines. The Alliance's efforts will initially focus on the outcomes of this analysis, expected to be published in April 2024.

Once the pilot exercise is finalised, the Commission will proceed with evaluating the remaining medicines in the Union list.

#### **HOW DOES THE ALLIANCE COLLABORATE WITH OTHER FORUMS ADDRESSING MEDICINES SHORTAGES?**

The Alliance, operating within its specific mandate for a designated period, does not replace existing forums. It maintains coordination with the following groups:

##### **Executive Steering Group on Shortages and Safety of Medicinal Products - 'the Medicines Shortages Steering Group' (MSSG)**

Given its consultative nature, the Alliance does not interfere with the mandate of the MSSG or duplicate its efforts in managing critical medicines or medicine shortages. Instead, the Alliance considers the work of the MSSG and communicates its recommendations to the MSSG.

##### **Joint Industrial Cooperation Forum (JICF)**

The Alliance considers the work of the JICF in addressing bottlenecks of medical countermeasures and leverages the expertise of its members to substantiate its work, specifically in matters related to critical medicines.

##### **National Competent Authorities on Pricing and Reimbursement and Public Healthcare Payers (NCAPR)**

The Alliance can collaborate with the NCAPR, particularly by contributing to the development of guidance on procurement practices to enhance the security of supply.

### **I missed the deadline of the initial call for expression of interest, can my organisation still join the Alliance?**

Certainly, the Alliance remains open to new members throughout all stages of its operation. However, the deadline for the initial application is important as the Commission will use it to identify participants in the Alliance's early stages.

To apply, you can follow that link: <https://forms.office.com/e/zDs4SCfcgs>

### **HOW CAN I STAY INFORMED ABOUT THE ALLIANCE'S ACTIVITIES?**

Output documents and further information (membership, working methods) are published on the Alliance's website: <https://europa.eu/!JMwrTB>

### **DOES THE EUROPEAN PARLIAMENT HAVE A ROLE IN THE ALLIANCE?**

Yes, the European Parliament is invited to participate in the Alliance's Forum.

### **WHOM SHOULD I CONTACT IF I HAVE QUESTIONS?**

For inquiries, you can reach out to the Alliance's secretariat via e-mail at [HERA-CRITICAL-MEDICINES-ALLIANCE@ec.europa.eu](mailto:HERA-CRITICAL-MEDICINES-ALLIANCE@ec.europa.eu).