Critical Medicines Alliance

CRITICAL MEDICINES ALLIANCE

DECLARATION

OBJECTIVES

As signatories of this declaration, private and public actors involved in the supplying of critical medicines and APIs in the EU, we declare to work towards achieving the objectives of the Critical Medicines Alliance ("the Alliance"); namely, to participate to the Alliance as a consultative mechanism for the implementation of the Communication on addressing medicines shortages in the EU the "Communication")[1].

In line with the conclusions of the June 2023 European Council the objective of the CMA will be to provide an inclusive and transparent consultative mechanism to the Commission on the identification of the challenges and on the most appropriate actions and instruments to address the vulnerabilities of the supply chain of a set of priority critical medicines[2].

Additionally, (in compliance with competition rules and EU's international commitments), while maintaining a primary public health goal of strengthening the supply of critical medicines, the Alliance contributes to the industrial competitiveness of the EU, its open strategic autonomy and its economic security in these sectors, as underlined in the Granada declaration of October 2023[3].

To do so, the Alliance ensures collaboration between Member States, industry (pharma, chemistry, biotech, finance, logistics) and all relevant stakeholders, including civil society representatives. It will identify priority areas for action, draw up a multi-year strategic plan detailing said actions, and ensure its monitoring.

PRINCIPLES

The Alliance adheres to the following principles:

- Openness: the Alliance is open to participation by any company or organisation willing to sign this Declaration ("Declaration") and which complies with the eligibility criteria outlined in the Terms of Reference , throughout the lifetime of the Alliance.
- Transparency: the Alliance has a dedicated website where output documents and further information (membership, working methods) will be published. With regards to the activities of the Alliance, by reports on meetings, discussions, information exchanged, and agreements reached will be made and duly kept.

[1] https://commission.europa.eu/system/files/2023-10/Communication_medicines_shortages_EN_0.pdf
[2] identified on the basis of the mandate given to the Commission services under the Communication
[3] https://www.consilium.europa.eu/en/press/press-releases/2023/10/06/granada-declaration/

- Diversity and inclusiveness: the Alliance is open to all stakeholders of the relevant industrial value chains: public authorities, healthcare professionals, patients' and consumer representatives, the pharmaceutical industry and their customers, upstream and downstream players, financial institutions, research and technology organisations, and other interested stakeholders (for example distributors, pharmacists, NGOs).

All members and persons involved in the activities of the Alliance shall fully respect all applicable laws and regulations, in particular national and EU competition rules. The Alliance members shall abide by the competition compliance programme.

Without prejudice to necessary measures in relation to Union security interests (including security of information, supply, IP, and know-how), conflict of interest and reciprocity, the Alliance shall maintain relations and lines of communication that are as open as possible with other industry collaboration fora and associations, both in Europe and at international level.

The EU market is among the most open in the world, and the tasks of the Alliance shall in no way affect access to the EU market, whether through sales or establishment, or to EU or national funding - these remain governed by EU law (including programme conditions, State aid rules, international trade commitments, etc.) and national law where applicable.

WORKING METHODS

Any organisation with existing or planned activities of relevance to the supplying of critical medicines and Active Pharmaceutical Ingredients can join the Alliance by signing up to this Declaration, provided they meet the eligibility criteria set out in the Terms of Reference. Eligible organisations can join at any point in time. For this purpose, an invitation to participate will remain available on the European Commission's website. The activity of the Alliance is organised by a Steering Board and Working Groups covering the main issues at stake.

The Steering Board prepares the Alliance's work, ensures consistency and integration of the work of the different working groups, maintains a roadmap of the implementation of the actions proposed by the Alliance, and supports the European Commission in facilitating, communicating, and monitoring the work of the Alliance, as well as validating its outputs. Its composition is detailed in the Terms of Reference.

The working groups will be open for participation to Member Organisations with appropriate activities and expertise in relation to the working groups' area of work. Working groups are set up by, and their membership is defined by, the European Commission. If required by the topic, working group's membership may be limited to organisations established in the EU. Participants commit to support the objectives of the working groups of which they are members and to actively participate in them, providing inputs and contributing to the collective work within their remit and area of expertise.

DELIVERABLES

The objective of the CMA will be to identify priority areas for action and propose solutions to support the supply of critical medicines in the EU including incentives for relevant projects.
Based on the outcome of the vulnerability assessments carried out by the Commission or an external contractor and of the work of the working groups, the Steering Board will identify priority areas for action and propose solutions to support the supply of each relevant priority essential medicine and APIs identified as vulnerable.

Based on the above, the CMA Steering Board will draw up a multi-year set of recommendations (strategic plan) with clear deliverables and deadlines, and ensure its implementation/monitoring, to be endorsed by the CMA Forum. The CMA Forum will also evaluate every 2 years if the strategic plan remains adapted to tackle the issues of shortages of critical medicines and APIs.