Manifesto towards an ambitious Critical Medicines Act to address shortages in the European Union

By Belgium, Cyprus, France, Greece, Hungary, Italy, Malta, Portugal, Romania and Spain

Europe relies heavily on imports of critical medicines from Asia and is increasingly facing shortages. Today, between 60 and 80 % of the active pharmaceutical ingredients (APIs) for generic medicinal products used in Europe are manufactured in India or China. This dependence, particularly in the context of health crises and military threat, but also for routine healthcare, puts the European Union at risk of supply failures with potentially severe consequences on public health.

In response, 23 European countries have called, at the end of 2023, for a Critical Medicines Act (CMA) to improve the security and resilience of medicine supply and reduce the risk of strategic dependencies for critical medicines and ingredients. The Commission then issued a Communication on 'Addressing Medicine Shortages in the EU', which led to the creation of a Critical Medicines Alliance.

Throughout 2024, this Alliance worked to identify key areas and priorities for action, proposing solutions to strengthen the supply of critical medicines in the EU. This has been followed up by the new von der Leyen Commission proposal for a “Critical Medicines Act”, a priority further asserted by Commissioner for health and animal welfare Olivér Várhelyi.

The uncertain geopolitical context, with a severe military threat and an increasing risk of new health crises makes Europe's heavy dependence, and the global concentration of critical medicines production, even more risky as the issues of security of supply and of global security become more and more intertwined.

To improve resilience and security of supply while de-risking the vulnerabilities, the Alliance produced ambitious and evidence-based recommendations, acknowledging an emergency to take action to strengthen EU production capacities of critical medicines and diversify supply chains. The signatories welcome the Commission's decision to publish a Critical Medicines Act and urge it to fully consider the ambition and the recommendations of the Alliance’s work in the upcoming legislation:

- **Elaborate a list of industrially vulnerable medicines as early as 2025 to prioritize support and strengthen EU-based manufacturing and efforts of diversification for the most critical medicines.** The conduct of a vulnerability assessment should allow us to prioritize our efforts and define the relevant scope for the proposed actions. Signatories wish to indicate their commitment to work with EMA’s Steering Group on Shortages and Safety of Medicinal Products (MSSG)[1] to facilitate delivering a first list as early as possible.
- **Enable a coordinated specific investment plan, with high EU-level cooperation and coordination, to bolster European production capacity for critical medicines, including APIs. The Alliance came to the conclusion that the existing tools only partially meet the identified need. Therefore the Commission should, through refining its current state aid and EU funding framework when appropriate, ensure future instruments fully meet this need of ambitious and targeted financial support, and should also work to incentivize private investment.**

  The market failures associated to the production of vulnerable medicines, and particularly of their APIs, need to be addressed and investments should seek to build and extend capacities, targeting in priority innovative and sustainable production technologies to ensure cost-effective and environmentally friendly production within the EU. Moreover, effective European coordination is paramount to ensure the consistency of our actions and secure firm commitments from manufacturers to enhance the security of European supply. To achieve this

[1] The MSSG recently announced the creation of a Vulnerability Assessment Methodology working group tasked with the development of a methodology to identify and evaluate vulnerabilities in the supply chains of critical medicines, in preparation for the proposed pharmaceutical legislation (Regulation, Article 130(1) point a).

goal, the EU should create a dedicated investment plan for critical medicines, consistent with the Vulnerability Assessment, that could potentially leverage both EU funding and a revision of State Aid frameworks where appropriate (through a new targeted State aid regulation or the adaptation of IPCEI and/or SGEI), and also incentivize private investment. The development of the plan would require EU-level cooperation and coordination to prevent competition distortions among Member States and promote cohesive and coordinated response.

- **Recognize the importance of supply chain diversification. As the diversification of supply chains contributes to enhance the resilience and sustainability of supply of critical medicines**, the Commission should leverage the Alliance's evidence-based methodological framework (using an explicit set of relevant evaluation criteria) to assess the prospects of potential international partnerships, ensuring that these efforts complement and reinforce efforts to strengthen European production capacities for critical medicines.

- **Define a strategy contributing to securing supplies for the EU by creating an ambitious public procurement framework and relying on joint procurement assessments.** Increasing production capacity in Europe is a necessity, but will be of limited impact if we are not able to buy differently. It is essential to define a European strategy for procurement to guarantee access to critical medicines throughout the EU. In this respect, voluntary joint European procurement mechanisms to improve availability and security of supply of Critical Medicines must be explored.

  Moreover, the erosion of the EU critical medicines manufacturing base, that led to increased concentration and vulnerabilities, is largely due to the EU's inability to value the positive externalities associated with them, in terms of security of supply or environmental quality. The Act must seek to build a legal framework for public procurement of critical medicines that integrates (i) a security of supply criteria (ii) a resilience criteria that makes it possible to value the European industrial footprint for the production of active ingredients and finished products and (iii) a criteria to account for the environmental quality of the product. Such a framework should establish clear guidelines and strive for their systematic implementation to maximize the impact of these rules. The use of multi-winner tendering could also be strengthened as it can also contribute to more sustainable markets.

- **Promote a level playing field vis-à-vis non-European competitors, regarding environmental and social standards but also unfair commercial practices.** First, there is a need to reduce the environmental and public health impact of production outsourced to countries where the environmental regulations effectively applied are less stringent than those in the EU, also leading to weakening the competitiveness of European manufacturing. It is then crucial to work towards a level playing field between API producers in and outside the EU**.** The Commission should identify precisely, through a dedicated study, the nature of the regulatory asymmetry and its impact on the competitiveness of EU manufacturers but also on environmental and public health risk, in order to take appropriate actions. Securing supply chains must be a paramount concern when implementing any action to prevent further disruptions. In addition to environmental issues, some manufacturers of active ingredients face unfair competition due to the trade practices of certain third countries; effectively eroding the competitiveness of EU-based manufacturers. The Commission needs to make more effective use of Trade Defence Instruments (TDIs), in an evidence-based manner and following a case-by-case analysis, specifically for critical medicines and its ingredients.

- **Support the development, upskilling and re-skilling of a dedicated workforce specialized in pharmaceutical production**. The Alliance identified the scarcity of skilled manufacturing workforces as a critical issue within Europe, particularly in highly competitive areas related to production of APIs and essential medicines. Addressing this challenge requires coordinated support.