Manifesto for a coordinated Industrial policy to address critical medicines shortages in the European Union

Europe relies heavily on imports of critical medicines from Asia and is increasingly facing shortages. Between 60 and 80 % of the active pharmaceutical ingredients (APIs) used in Europe are manufactured in India or China[1]. Around 1 in 6 active ingredients are not manufactured in Europe[2].

23 European countries have called for a Critical Medicines Act (CMA) to improve the security and resilience of medicine supply and reduce dependencies for critical medicines and ingredients. This call to action to ensure adequate availability and production of critical medicines and components was reiterated by EU leaders at the June 2023 European Council and reinforced by the October 2023 Granada Declaration. In response, the Commission issued a Communication on 'Addressing Medicine Shortages in the EU', which announced a Critical Medicines Alliance and a preparatory study for a Critical Medicines Act. Additionally, the European Economic and Social Committee issued an exploratory opinion "Securing Europe's medicine supply: envisioning a Critical Medicines Act".

We strongly welcome the launch of the Critical Medicines Alliance and the work done so far by the European Commission to establish the first European Union list of critical medicines and to assess their supply chain vulnerability. This work provides a targeted list of critical medicines with highest risk of shortages that should serve as a priority list for strengthening of manufacturing.

In the context of the Critical Medicines Alliance and a potential Critical Medicines Act, we believe it is necessary to implement a concerted European strategy and coordinate large-scale European action to effectively address the market failures and other factors that still hamper the EU's resilience efforts. There is a need to strengthen the Union's industrial capacities in the long term by complementing national investments and accelerating the implementation of the EU industrial strategy, and effectively prevent the shortages of products on the Union List of Critical Medicines. In addition to addressing the risk of shortages, strategic autonomy on critical medicines is becoming a European policy priority.

However, there currently is no targeted European strategy to boost the EU manufacturing capacity for critical medicines and APIs through sustainable and innovative production.

---

[1] Rapport Biot et al. ruptures médicaments, 09/20219
[2] PwC study

Such EU strategy will depend on two priorities. First, there must be a structural EU-wide financial incentive to manufacture critical medicines ingredients within Europe. The Critical Medicines Alliance can provide the framework for a better integration of the security and resilience of supply guaranteed by EU-based production facilitated by a concerted effort in the procurement of medicines. Second, financial incentives must be provided in the short run to build the required production capacity within Europe. Such incentives should, for example, target innovative and sustainable production technologies to ensure cost-effective and environmentally friendly production within the EU.

Outsourcing the production of critical medicines consumed in Europe to non-European countries in some cases also contributed negatively to the global environmental footprint. There is a need to reduce the environmental and public health impact of European production outsourced to countries where environmental regulations are less stringent, and introduce a level playing field between producers in and outside the EU. Ambitious policies should be set up by the European Commission, e.q. as part of the potential Critical Medicines Act, to bridge **the competitive gap caused by the asymmetry of environmental standards.** These structural reforms will take time.

Besides, strong incentives for investment in industrial capacity are needed to level-up relevant production and novel capacity and simultaneously to increase security of supply, develop more environmentally friendly production processes and enable EU coordination to reduce competitive risks for the internal market.

While some R&D projects to develop and/or ameliorate production processes can be funded under non-notified state aid regimes, the current rules limit the ability of Member States to implement projects to foster European production in most therapeutic areas (e.g., oncology and antibiotics require dedicated production units and significant financial investments), including through innovative production processes. Even if *ad hoc* project notifications are allowed, this leads to isolated national projects, while efforts should be coordinated at EU level.

Early evidence points to a market failure that currently prevents strong EU manufacturing capacity for critical medicines. A pharmaceutical company's decision to use a non-EU supplier to manufacture its active ingredients is based on financial considerations that do not take sufficiently into account security of supply, social and environmental standards, and how to maintain technological leadership with serious consequences for EU patients and additional costs for healthcare systems in the event of trade tensions or health crises.

Therefore, France, the Netherlands, Italy, Hungary, Greece, Malta, Slovakia, Cyprus and Romania, contingent upon national budgetary decisions, will, further informed by the work carried out in the Critical Medicines Alliance and the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG), assess the feasibility of launching a coordinated and inclusive investment plan at the EU level to strengthen critical pharmaceutical production capacities. This investment plan, in coordination with the European Commission, will be designed to be flexible, aiming to support diverse pharmaceutical needs across the Union.

This investment plan could potentially include, among other funding mechanisms, the proposition of an 'Important Project of Common European Interest' (IPCEI) and other dedicated state-aid regimes, such as the General Block Exemption Regulation (GBER). This initiative will be discussed at the JEF-IPCEI High-Level Meeting.

All Member States, and EEA members interested in participating to this European Critical Medicines Industrial Plan at EU level, as well as all companies, including SMEs, can progress together through the stages of the project's preparation. The Signatories invite all other Member States to join this initiative, which remains open. **They aim to develop operational financing solutions and perspective to have a potential investment plan approved by the EU Commission in 2025**.