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A call for a robust Critical Medicines Act – Safeguarding Europe's Health Security and Industrial Sovereignty

Europe faces a pivotal moment in its ability to provide essential medicines to its citizens. The Critical Medicines Act (CMA) was designed as a transformative policy to address recurring shortages and reduce dependency on non-EU suppliers. However, current legislative discussions are threatening to severely dilute its impact.

The stability of our healthcare systems—and the well-being of millions—depends on reliable access to critical medicines. Yet today, over three-quarters of essential active pharmaceutical ingredients (APIs) are manufactured outside the European Union, exposing us to potential external supply shocks and undermining our ability to respond to crises.

This vulnerability is not merely a logistical concern; it is a direct threat to patient care, public health, and the resilience of our entire healthcare community. It is imperative that Europe maintains and strengthens its manufacturing capabilities to ensure essential medicines are available when and where they are needed.

The economic argument for revitalising EU-based pharmaceutical manufacturing is compelling. The cost of APIs represents on average less than 10% of the final price of a medicine. By increasing production in Europe, we can dramatically improve supply security and resilience with minimal impact on health budgets. Moreover, EU manufacturers uphold the highest standards of quality and safety, operating multipurpose facilities that produce both generic and innovative drug substances. Maintaining a robust and resilient generics sector - including its critical inputs such as APIs - is not just a matter of industrial viability, it is essential for ensuring the continuous availability of life-saving medicines.

The EU's Strategic autonomy and industrial sovereignty are at stake. Europe cannot afford to lose its manufacturing know-how or become entirely reliant on non-EU suppliers for critical medicines. It is therefore essential to maintain current capabilities and restore those that have been lost but can still be recovered. Maintaining our dependency would be irreversible, threatening our health sovereignty and accelerating de-industrialisation. A strong Critical Medicines Act will secure thousands of high-value jobs, stimulate investment in advanced manufacturing and innovation and ensure the survival of a strategic sector that is vital to Europe's future and to the well being of European citizens. By contrast, a watered-down Act risks the erosion of our industrial base and the irreversible loss of strategic capabilities.

Current legislative debates threaten to undermine these objectives. The push for "flexibility" in procurement risks eliminating meaningful European preference in public tenders for critical medicines and their active substances. The absence of a dedicated EU Critical Medicines Fund and clear State Aid mechanisms leaves strategic investments unsupported. Meanwhile, EU manufacturers face higher costs and stricter standards, while non-EU competitors benefit from subsidies and lighter regulations, placing European industry at a clear competitive disadvantage.

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To address these challenges, the CMA must introduce enforceable award criteria for public procurement promoting sustainable EU-based manufacturing, prioritising supply resilience, diversified sources, and compliance with our high EU standards. At least 30% of critical medicines should be manufactured within the EU, and no more than 50% should come from any single country.

Concrete support measures are essential:

- a dedicated EU Critical Medicines Fund,
- streamlined permitting for construction or expansion of manufacturing plants dedicated to critical APIs,
- more efficient and accelerated regulatory processes,
- efficient State Aids for strategic projects, including modernisation, innovation in sustainable manufacturing and new investments for reshoring production of critical APIs.

The playing field must be levelled by imposing minimum social and environmental standards on all suppliers to the EU market and intensifying the use of trade defence instruments against unfair practices by non-EU suppliers.

Effective governance is equally crucial. The establishment of a Critical Medicines Coordination Group within six months of the Act's entry into force, with strong industry representation, will be vital. This group must be tasked with monitoring supply risks, coordinating joint procurement, and overseeing funding allocation. The risks of inaction are stark: if the EU fails to maintain a viable pharmaceutical manufacturing base, this vital industry will leave our shores and not return, and Europe will completely lose its health sovereignty.

The CMA must deliver enforceable, impactful measures—otherwise, the EU will remain vulnerable to external shocks and chronic shortages.

We urge the European Parliament and Council to seize this pivotal moment and vote for a robust, enforceable Critical Medicines Act. This legislation must restore Europe's strategic autonomy, support its industrial base, and ensure reliable access to essential medicines for all EU citizens. The recommendations of the Critical Medicines Alliance must be fully integrated, sending a clear signal that Europe is committed to sustaining and investing in its medicines supply chain. This is not only an industrial imperative—it is a moral obligation to all EU patients and the healthcare community.

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