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Members of the European Parliament
Rapporteur and Shadow rapporteurs
European Parliament

Mr. Neofytos CHARALAMBIDES

Minister of Health

Republic of Cyprus

Presidency of the Council of the European Union

Mr. Oliver Varhelyi

Commissioner for Health and Food Safety

European Commission

Subject: The Critical Medicines Act must deliver on EU health security

Brussels, 5 March 2026

Dear Members of the European Parliament,

Dear Minister Charalambides,

Dear Commissioner Varhelyi,

Medicines for Europe is closely following the trilogue negotiations on the Critical Medicines Act.

We urge negotiators to align on a compromise based on the objectives originally set out for this Regulation and the political ambition of the European Council¹: to support more strategic autonomy, supply diversification and EU solidarity. At an unprecedented time of geopolitical instability and continued supply chain fragility, the CMA is a unique opportunity to address long-standing market failures that contribute to shortages and external dependencies.

The Critical Medicines Act was requested by Member States and strongly supported by the European Parliament in response to persistent medicines shortages and growing vulnerabilities in Europe's pharmaceutical supply chains. The Regulation must not fall short of the shared ambition to enhance Europe's open strategic autonomy, resilience, and solidarity in the field of medicines.

There have been repeated reports, including from the European Commission² and more recently, from the European Court of Auditors³, highlighting the importance of addressing economic root causes of shortages. Moreover, recent reports from pharmacists' associations (EAHP⁴ and PGEU⁵) confirm that **economic root causes continue to play a key role in approximately 50% of cases**. These trends highlight how price-focused policies are contributing to market fragility, industrial consolidation and increases risk of shortages.

¹ [Versailles Declaration](#)

² European Commission, [Communication on Medicine Shortages](#)

³ European Court of Auditors, [Critical shortages of medicines](#)

⁴ PGEU, [Medicine Shortages Report 2025](#)

⁵ EAHP, [Medicines and Medical Devices Shortages Survey 2025](#)

The evidence is clear that current procurement and reimbursement policies are overwhelmingly driven by cost-containment objectives. With 74% of countries using single-winner tenders⁶ and up to 84% of procedures awarding contracts based on lowest price alone⁷, little attention is paid to market sustainability or security of supply. The consequences are clear: more than **80% of critical medicines have fewer than three suppliers across the whole EU**⁸, two-thirds of shortages are linked to highly consolidated supply⁹, and manufacturers of critical medicines continue to shut down European production and relocate to China¹⁰.

Medicines for Europe therefore supports a bold Critical Medicines Act that introduces **mandatory security of supply award criteria** for the 52% of critical medicines that are hospital medicines sold via procurement. For the other 48% sold via retail,¹¹ **mandatory inclusion of pricing and reimbursement measures in national plans** for security of supply should be the norm. The proposed approach respects national competences by building on existing EU legal frameworks, including the Public Procurement Directive and the Transparency Directive, and by promoting their consistent application.

We need to be clear, **without meaningful demand-side policies included in Articles 18 and 19, the Critical Medicines Act will not achieve its aims** of improving **the availability, supply and production of critical medicines** within the EU.

We remain at your disposal for any further information you may need on this critical matter.

Yours sincerely,



Adrian van den Hoven,

Director General of Medicines for Europe

⁶ Medicines for Europe [Generic Market Review 2025](#)

⁷ European Commission, [Study on best practices in the public procurement of medicines](#)

⁸ Teva, [Generics Health Check 2025](#)

⁹ IQVIA, [Beneath the Surface: Unravelling the True Value of Generic Medicines](#)

¹⁰ <https://www.ft.com/content/4b9684e4-72da-49e9-b11b-abe8a20b9507>: Europe's last maker of key antibiotics ingredients shuts biggest domestic factory

¹¹ European Commission, [Critical Medicines Act Staff Working Document](#)