

Open Letter to COREPER: Council's homeopathic approach to Critical Medicines Act will succeed - in watering down EU health security

Brussels, 24 September 2025

[Medicines for Europe](#) is alarmed by the watering down of the Critical Medicines Act by the Council and the efforts by certain big Member States to pressure the European Parliament to also go down that dangerous path for Europe's health security. The Critical Medicines Act was requested by the Council and the Parliament to reduce medicine shortages and to strengthen strategic autonomy with clear reforms that would drive investment into manufacturing, supply chain diversification, and more EU solidarity in shortage mitigation. While far from perfect, the Commission's proposed regulation included genuine reforms to generic critical medicine markets¹, the prioritisation of funds to support manufacturing and rules to ensure that national stockpiling would not harm the supply of medicine in neighbouring countries. **We are shocked to see the concerted efforts of some Member States to water down the Act as much as possible and we question how this could be compatible with the political ambition of the European Council² to support more strategic autonomy, supply diversification, and EU solidarity.**

Some Member States are wrongly using the argument of national competence to make sure that the Critical Medicines Act will not introduce supply security criteria in generic medicine markets (most critical medicines are generic³). Despite the overwhelming data and evidence showing that these purchasing policies are built entirely on cost-containment and obtaining the lowest possible price (not low prices, the absolute lowest price) regardless of the impact on industrial consolidation and supply security. The [results](#) of these policies are staggering:

- generic medicine prices have experienced price deflation over the last few years while the price of every comparable good has experienced 30-40% price inflation.⁴
- there are fewer than 3 market suppliers for more than 80% of the critical medicines.⁵
- two thirds of generic medicine shortages are associated with highly consolidated supply.⁶
- equally worryingly, manufacturers of critical medicines are still shutting down production in Europe and moving it to China.⁷

So, what violation of national competence would the Critical Medicines Act impose on Member States?

None whatsoever, because the Act would only require Member States to fully comply with existing legal obligations such as the Public Procurement Directive or the Transparency Directive for Pricing and Reimbursement and to report to the Critical Medicines Coordination Group. And this is no market revolution because many countries are already applying these rules, albeit on a limited scale. To reduce shortages, Greece requires multi-award tenders for certain critical hospital medicines. To diversify supply, Sweden and Portugal have introduced pricing and reimbursement changes to diversify and to attract more suppliers. Nordic countries have tested (non-price) security of supply and environmental criteria for the procurement of critical antibiotic medicine. What is more, these reforms have had a negligible impact on the cost of medicine (around 8% of contracts were awarded to suppliers that did not apply with the lowest price⁸) which has been offset by the benefits of fewer

¹ [Mandatory-security-of-supply-criteria-in-procurement-and-pricing-reimbursement-under-the-Critical-Medicines-Act.pdf](#)

² [20220311-versailles-declaration-en.pdf](#)

³ Beneath the Surface: Unravelling the True Value of Generic Medicines, IQVIA, April 2024 ([link](#))

⁴ [Teva Generics Health Check 2025](#)

⁵ [Teva Generics Health Check 2025](#)

⁶ [Beneath the Surface: Unravelling the True Value of Generic Medicines, IQVIA, April 2024](#)

⁷ <https://www.fiercepharma.com/manufacturing/xellia-shutter-copenhagen-antibiotics-plant-dealing-blow-eu-reshoring-efforts>

⁸ <https://www.sykehusinnkjoep.no/4a5924/siteassets/bilder/nyheter/2024/miljokrav-legemidler-rapport/environmental-criteria-results-2024.pdf>

medicine shortages. So, what is at stake? Payers in big Member States like Germany and France do not want any constraints – even modest ones that would improve the supply of medicine for all of Europe – on their ability to squeeze manufacturers of critical medicines to get to the absolute lowest prices.⁹

Disincentivising manufacturing investments during the EU's most sensitive geopolitical momentum

On top of cost containment purchasing policies, EU critical medicine manufacturers must comply with the world's most complex and costly regulation and pay the highest energy costs. It is no wonder EU manufacturers are not lining up to invest in Europe and in more supply chain resilience. And yet, it is obvious to everyone that critical medicine manufacturers need to invest to prepare for high-risk situations like future pandemics, geopolitical tensions and war, and other major events that could spike massive demand surges for critical medicines. Despite this, the Council wants to further weaken the Critical Medicines Act provisions to prioritise financial support for these much needed health security investments, to accept state aid guidance that effectively bans any national support for critical medicine production, or to suggest that the future EU budget (multiannual financial framework) might include an effort to invest in health security. If the 'business case' for strategic autonomy from the Council is that critical medicine manufacturers should invest at a guaranteed economic loss for many years to come, they have achieved their objective.

Selfishness is the new solidarity

The first lesson of the Covid-19 pandemic was that medical supplies need to be shipped to patients and not hoarded in warehouses. We applauded the Commission's forceful leadership to make sure that solidarity would prevail throughout the pandemic (and played our own part in working with the Commission and Member States to ensure all would be supplied according to patient need). This lesson was immediately ignored after the pandemic when France (2-4 months) and Germany (6 months) introduced massive critical and generic medicine stockpiling obligations on manufacturers. For critical antibiotics, 1 month of stockpile in France and Germany is equal to the consumption of the 25 other Member States combined¹⁰ and yet these French and German stocks cannot legally be sent to these countries in a shortage. Smaller Member States have repeatedly asked the Commission to restore EU solidarity, to ensure that national stock requirements should be proportionate, and not harm supply in the rest of the EU. Despite the overwhelming evidence that solidarity must be respected so that all European patients can have access to critical medicines, the Council is working to ensure that there will be no oversight whatsoever. **The Union's future health security cannot be watered down. We plead with the Council rethink its position on the Critical Medicines Act.**



France's one-month stockpile volume is larger than the combined monthly supply of Poland, Netherlands, Portugal, Czech Republic, Bulgaria, Sweden, Denmark, Austria, Finland, Hungary, and Croatia.



Germany's one-month stockpile volume equals the combined monthly supply of Poland, Netherlands, Sweden, Denmark, Finland, and Hungary.

What are our requests for the Critical Medicines Act?

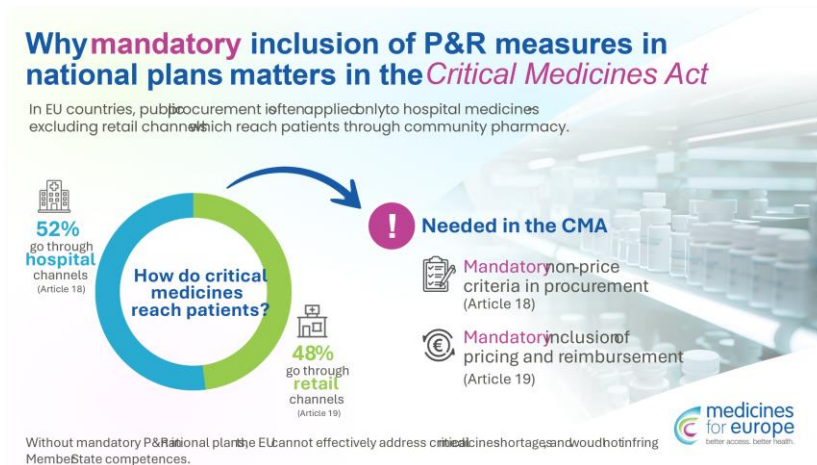
1. The Act must ensure that demand side measures support viable investments in manufacturing and supply chain resilience with:
 - **mandatory security of supply / non-price criteria to reverse market consolidation**, in public procurement - which covers approximately 52% of critical medicines - as well as on pricing and

⁹ For example, in Germany the average daily dose cost for generic medicines is 0,06 EUR, which means that the price for a month of treatment is less than 2 EUR https://www.progenerika.de/wp-content/uploads/2025/07/Generika-in-Zahlen_Jahr-2024-1.pdf

¹⁰ <https://www.medicinesforeurope.com/wp-content/uploads/2025/07/Medicines-for-Europe-Stockpiling-Report-2025.pdf>

reimbursement measures in national programmes – which covers the 48% remaining medicines on the list.

- moving away from single winner (74% of countries use single winner tenders⁹) and lowest price tenders (84% of procurement procedures follow lowest price criteria⁸) that are direct drivers of industrial and supply consolidation. The Act must correct this market failure, which will not infringe Member States competences, as they will be able to adapt these requirements to their own procurement systems and will still have full control over their medicine reimbursement decisions.



2. Strengthen European industrial competitiveness of critical generic producers through substantial EU funding and new state aid flexibilities by:

- allocating **€4 billion in a Critical Medicine Security Fund** to medicine manufacturing in the **next Multi-Annual Financial Framework** to support upgrades for security of supply or environmental improvements for 150 production sites in Europe, mainly to expand existing capacity for all critical medicines but also for targeted support for medicines of national/collective security interest to the EU.
- tailoring state aid rules to the specificities of the off-patent medicine sector, as most medicines on the critical list are off-patent⁴. The rules should allow investments in innovative production processes, capacity increases, environmental upgrades, and digitalisation. Therefore, the **Commission should either adopt new guidelines or exempt these investments through the General Block Exemption Regulation** currently under revision.

We urge the EU institutions to deliver on a meaningful Critical Medicines Act, that reduces medicines shortages, strengthens manufacturing and supply, and ensures EU solidarity for medicines availability.

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