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Mandatory security of supply criteria in procurement and pricing & reimbursement under the Critical Medicines Act

The Critical Medicines Act addresses a clear, verifiable market failure: price-driven procurement and reimbursement have produced price deflation, supplier consolidation and repeated shortages in medicines that are critical for health systems.

The Critical Medicines Act creates a narrowly **targeted EU baseline to correct cross-border distortions** that national measures alone cannot fix. This is not a takeover of national health policy by the EU; it uses existing EU legal instruments (MEAT/non-price criteria and reimbursement transparency) to require consistent national application so the whole Single Market internalises supply security.

Why EU-level, mandatory minimum criteria are proportionate and necessary

a) **A cross-border problem requires a cross-border solution**
Supply chains and manufacturing plants operate at EU/global scale; unilateral national measures cannot prevent exports, hoarding or cross-border supply collapse. A common baseline avoids a fragmented patchwork in the EU.

b) **Correcting market failure, while respecting national competence**
The proposal mandates *how* Member States must consider security-of-supply in procurement and pricing/reimbursement decisions for a *defined* list of critical medicines, it does not prescribe clinical choice or full pricing harmonisation across the EU.

c) **Ensuring fairness and preventing free-riding**
If only some Member States adopt measures for supply resilience, other Member States reap the benefits without cost; harmonised minimum requirements remove that perverse incentive and level the playing field.

Evidence in numbers of a system under stress

Dangerous market consolidation is driving shortages:

- Generic medicines bring tremendous value to public health as they cover 70% of dispensed medicines and just 19% of the EU pharmaceutical market value.[1]
- In addition, 9 out of 10 critical medicines are generic medicines.[2]
- However, it is clear that generic medicine markets are consolidating. Withdrawals in Europe have increased by 12%, while launches decreased by 3% in 2024.[3]
- 46% of critical medicines have 1 supplier and 83% have 1 major supplier in EU markets.[4]
- 2/3 of generic medicine shortages are associated with a low supplier count.[5]

Continuous price pressure has made production unsustainable:

- The price of all comparable goods has experienced price inflation in Europe of 30-40%. For example, the price of bread rose by 45%. In contrast, prices of the leading generic medicines went down by 8% despite dramatic inflationary pressures on manufacturing in Europe.[6]
- The average daily dose price for generic medicines in Germany declined by two thirds from 0,18 cents to 0,06 cents.[7]

Flawed procurement and pricing & reimbursement policies are the root cause of price deflation and industrial consolidation

- Most generic medicines in Europe are purchased through tenders or through a pricing and reimbursement (insurance) policy. Approximately 40% of medicines are procured, the rest (60%) go through mainly through reimbursement.[8]
- **52% of critical medicines are procured though through hospital channels while 48% go through retail reimbursement**.[9]
- Up **to 84% of procurement procedures follow lowest price criteria**.[10] This is valid for antineoplastic agents (cancer medicines), the overall figure for all medicines is 62%. **74% of countries use single winner tenders.** [11]
- Single winner, lowest price tenders are direct drivers of industrial and supply consolidation as only one manufacturer can supply the market. This explains why Member States must introduce security of supply criteria, in addition to price, in procurement rules.
- Pricing and reimbursement rules in almost all member states are based on capped pricing rules know as 'reference pricing'. Typically, this is based on the lowest price of a generic medicine in the national market or based on price comparisons with other markets. In addition, countries apply price freezes, across the board price reductions for whole categories of generic medicines and other cost containment measures. This explains why most generic medicines have experienced price deflation since the 2009 financial crisis. For example, Germany has maintained a price freeze for well over 10 years. In principle, these cost containment measures must be notified to the Commission to ensure compliance with the Transparency Directive. However, this has not been enforced by the Commission and there have been almost no notifications by member states.
- The Critical Medicines Act focuses on the most critical medicines for the functioning of our healthcare systems. These medicines have also experienced the highest real price deflation because they are older medicines that have been on the market for many years – therefore their capped prices have prevented any price increases in line with inflation. This also explains why there is so much consolidation of supply.
- It is not a contradiction or disproportionate to require Member States to include compliance with their legal obligations under the Transparency Directive regarding critical medicines, in the reports to the Commission foreseen by the Critical Medicines Act. Nor is it unreasonable to expect Member States to comply with these obligations to support the diversification of supply and to reduce the risk of shortages for these very critical medicines.

Principles for an effective and sustainable act

✓ **A focused scope:** Limit obligations strictly to the official EU Critical Medicines List and products with a demonstrated risk of shortage.

✓ **Risk-based mechanics:** Promote flexibility through multi-winner tenders, allow virtual stock-keeping, and graduate obligations based on a company's market share, with exemptions for generic suppliers to maintain market diversity.

✓ **Leverage existing EU instruments:** Mandate the consistent use of MEAT criteria to ensure security of supply is valued alongside price, enforcing existing legal options rather than creating new ones.

✓ **Transparency and review:** Require public reporting on supplier counts to monitor market concentration and mandate a Commission review within 24–36 months to ensure measures remain proportionate and effective.

✓ **Safeguards for sustainability:** Ensure that investments in supply security are recognized through cost-impact assessments and targeted support, guaranteeing that manufacturers of low-cost essential medicines remain viable.

[1] Beneath the Surface: Unravelling the True Value of Generic Medicines, IQVIA, April 2024 (link)
[2] Beneath the Surface: Unravelling the True Value of Generic Medicines, IQVIA, April 2024 (link)
[3] Teva Generics Health Check 2025
[4] Teva Generics Health Check 2025
[5] Beneath the Surface: Unravelling the True Value of Generic Medicines, IQVIA, April 2024
[6] Teva Generics Health Check 2025
[7] ProGenerika report Generika in zahlen 2024
[8] IQVIA, From Regulated Prices to Prices Set in Tenders
[9] Critical Medicines Act Staff Working Document
[10] European Commission: European Health and Digital Executive Agency, Gesundheit Österreich Beratungs GmbH, Tetra Tech, Vogler, S., Salcher-Konrad, M. et al., *Study on best practices in the public procurement of medicines – Final report*, Publications Office of the European Union, 2022, https://data.europa.eu/doi/10.2925/044781
[11] Medicines for Europe Generic Market Review 2025 (it's 20 out of 27 countries)