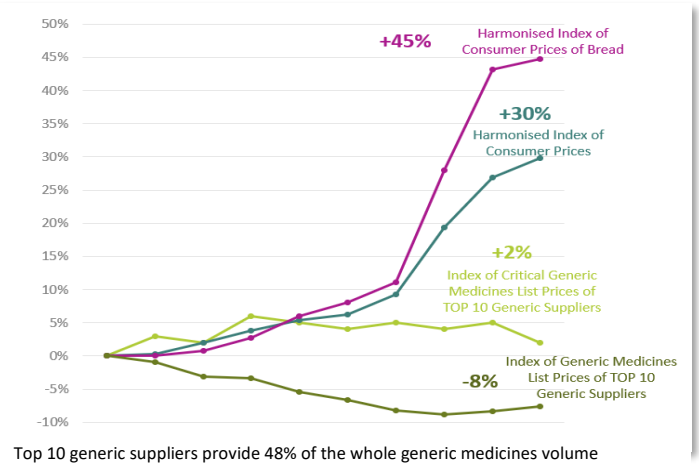
A bold Critical Medicines Act to secure critical medicines supply and address economic root causes of medicine shortages

Medicines for Europe, the European Association representing generic, biosimilar and value added medicines, is engaged in improving EU patients' equitable and timely access to medicines via open strategic autonomy and supply diversification. 7 out of 10 dispensed medicines in the EU and **9 out of 10 critical medicines are generic medicines**.

The COVID-19 pandemic[1] and the Russian invasion of Ukraine[2], as well as growing geopolitical tensions, including possible military scenarios,[3] underline the need for a bold Critical Medicines Act that:

1. **Integrates mandatory supply security and diversity into demand-side policies to address the economic root causes of medicine shortages.**

Off-patent medicine prices are fixed at national level and cannot be increased as any other commodity - in the last 9 years the price of bread rose by 45% while the list prices of the top ten generic medicine suppliers decreased by 8% (graph 1) – and up to **84% of national procurement contracts follow price only criteria** while **62% of national contracts are single winner ones**.

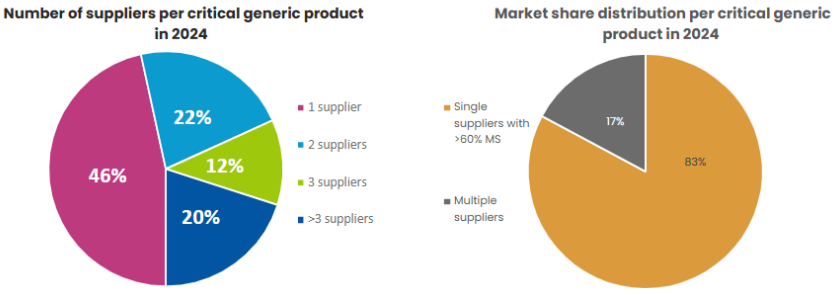


Top 10 generic suppliers provide 48% of the whole generic medicines volume

These voluntary practices have led to a **heavily consolidated critical generic medicines market** with worrisome trends: **46% of EU critical medicines have only 1 supplier, but 83% of the generic critical medicines have one supplier holding 60% of the market share**. Therefore, if one big supplier has a major issue the small suppliers might not be ready to supply the rest of the market [graphs 2 and 3].

The Act should introduce ambitious market reforms to address increasing market consolidation and incentivise suppliers to be ready to mitigate shortages via:

- **mandatory** non-price award criteria in **tenders** as proposed by the Commission, to revert the existing voluntary rules (Article 18).
- making the **division of tenders into multiple lots the rule where feasible**. (Article 18)



Source: "The state of critical generic medicines supply in Europe" Teva Study 2025

- In line with the Transparency Directive, including **pricing and reimbursement measures in national programmes supporting security of supply**, considering that in approximately 50% of cases of the EU critical medicines list, critical medicines are not subject to procurement. This includes for example paediatric antibiotics (Article 19).

[1] Medicines for Europe Covid-19 lessons learned position paper (link).

[2] The off-patent industry provided 1200 trucks with medicine to Ukraine after Russia's invasion; see also Statement on the war in Ukraine | Medicines for Europe.

[3] Europe's dangerous medicine dependency is the Archilles heel of its defence strategy' by Health ministers of 11 EU member states published on 09/03/2025 (link).

2. **Strengthens industrial competitiveness** through **substantial EU funding, flexibilities and fast track procedures in state aid**.
   The Act should expand existing critical medicines production and facilitate the "reshoring" of molecules of national security interest to the EU via:

   - **A Critical Medicines Security Fund in the EU budget** that should allocate €4 billion to medicine manufacturing in the next Multi-Annual Financial Framework[4] to support upgrades or reshoring for security of supply or environmental improvements to approximately 150 production sites in Europe.
   - **New state aid guidelines for** flexible State aid rules, including regional aid, should allow investments in innovative production processes, environmental upgrades and digitalisation.
   - **New definition of innovation for manufacturing processes:** as stated in the Draghi report, the definition of innovation in the IPCEI should be expanded to include manufacturing processes for the green and digital transitions and for the security of supply[5].

3. **Ensures European solidarity** to tackle shortages **by limiting national stockpiling** to what is **proportionate** and does **not interfere with the secure supply of medicines**.
   - The CMA should mandate ex ante notification of national stockpiling mandates to the European Commission with automatic proportionality reviews above threshold levels to ensure consistency with the Internal Market.
   - To ensure that shortages can be addressed quickly, there should be fair remuneration of stockpiling costs, regulatory flexibilities (such as digital leaflets and packaging) and no penalties for using contingency stocks to mitigate shortages in other Member States.

4. **Enables targeted collaborative procurement** where it adds a clear value, while ensuring fair and predictable terms and conditions for manufacturers. Specifically, it should:
   - include clear volume estimates, minimum binding quantities and sufficient lead times to increase demand predictability for suppliers.
   - not conflict with national procurement or established market arrangements.

5. **Supports diversification of supply chains through international strategic partnerships** via:
   - The inclusion of security of supply in free trade agreements and other international frameworks.

[4] As part of the Health, Biotech, Agriculture and Bioeconomy Section of the European Competitiveness Fund proposed by the Commission (link).
[5] Draghi report on The future of the EU Competitiveness "Important Projects of Common Interest (IPCEIs) should be expanded to all forms of innovation that could effectively push Europe to the frontier in strategically important sectors and benefit from EU financing" (page 13).