

## 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**<sup>1</sup>.

The COVID-19 pandemic<sup>2</sup> and the Russian invasion of Ukraine<sup>3</sup>, as well as growing geopolitical tensions, including possible military scenarios,<sup>4</sup> underline the need for a bold Critical Medicines Act that:

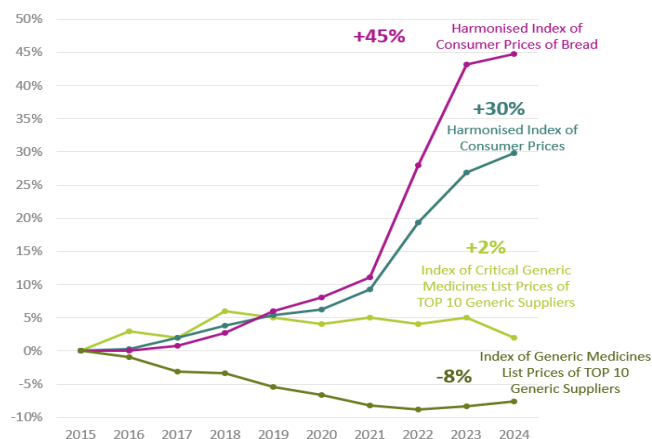
### 1. Integrates mandatory supply security and diversity into demand-side policies to address the economic root causes of medicine shortages.

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). Despite non-price criteria (MEAT) being recommended by the Public Procurement Directive (2014/24/EU), currently up to **84% of national procurement contracts follow price only criteria**<sup>5</sup> while **74% of countries use single winner tenders**<sup>6</sup>.

These practices have led to a **heavily consolidated critical generic medicines market** with worrisome trends: **46% of EU critical medicines have only 1 supplier, and 83% of the generic critical medicines have one major supplier (holding more than 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].

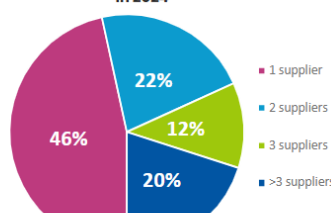
The Act should introduce ambitious market reforms to address increasing market consolidation and incentivise suppliers to be ready to mitigate shortages via:

- **mandatory** non-price award criteria in **tenders** as proposed by the Commission, to revert the existing voluntary rules (Article 18).
- implementing **multi-winner approaches where feasible**. (Article 18)
- Making it **mandatory to include pricing and reimbursement measures in national programmes supporting security of supply**, since only 40% of medicines in the general pharmaceutical market go through procurement<sup>7</sup>. While for critical medicines it is likely that this would be around 50%, not including mandatory P&R measures in national plans means that we are only acting on half of the medicines in the list (Article 19).

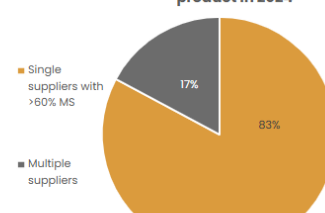


Top 10 generic suppliers provide 48% of the whole generic medicines volume

Number of suppliers per critical generic product in 2024



Market share distribution per critical generic product in 2024



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

<sup>1</sup> Beneath the Surface: Unravelling the True Value of Generic Medicines, IQVIA, April 2024 ([link](#))

<sup>2</sup> Medicines for Europe Covid-19 lessons learned position paper ([link](#)).

<sup>3</sup> 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](#).

<sup>4</sup> 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](#)).

<sup>5</sup> European Commission, [Study on best practices in the public procurement of medicines](#) (December 2022).

<sup>6</sup> Medicines for Europe Generic Market Review 2025 ([link](#))

<sup>7</sup> IQVIA, From Regulated Prices to Prices Set in Tenders ([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<sup>8</sup> 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<sup>9</sup>.

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.

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<sup>8</sup> As part of the Health, Biotech, Agriculture and Bioeconomy Section of the European Competitiveness Fund proposed by the Commission ([link](#)).

<sup>9</sup> 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).