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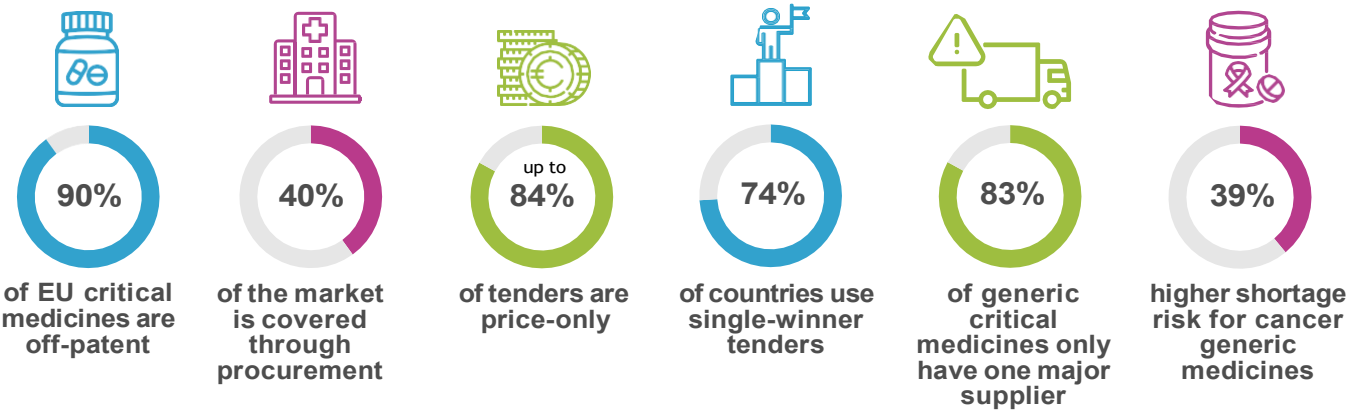
Critical Medicines Act Factsheet

Demand-side policies

A reform of demand-side policies is needed to safeguard the security of supply of critical medicines

How current demand-side policies undermine security of supply for off-patent medicines

Off-patent medicines account for 70% of dispensed medicines in the EU and 90% of EU critical medicines[1]. **The structural root cause of medicine shortages lies in the pricing and procurement of medicines**, as evidenced in Commission studies such as the *Study on medicines shortages*[2], the *Study on best practices in the public procurement of medicines*[3] and the recent *Recommendations adopted by the Critical Medicines Alliance*[4].



Demand-side policies play a crucial role in shaping the economic environment for medicines. Both procurement and pricing and reimbursement rules are key tools to generate savings for healthcare systems, while providing access to essential treatment for patients, with generic and biosimilar medicines being key drivers for this.
Across the EU, **procurement**, which is mostly used for hospital products **accounts for around 40% of the market**[5]. According to the European Commission, in the critical medicines list **52% of products go through hospital channels**[6], while the rest go through retail ones.

In spite of MEAT (Most Economically Advantageous Tender) criteria being encouraged in the Public Procurement Directive 2014/24/EU, **up to 84% of tenders rely only on the lowest price criterion**[3]. This triggers a downward spiral in off-patent medicine prices, which ultimately leads to growing industry consolidation and threatens the security of supply of critical medicines for European patients.

At the same time, national **Pricing & Reimbursement (P&R) policies play a key role for the remaining 60% of medicines** being made available to patients through pharmacies (retail), such as certain antibiotics for children. The majority of EU Member States strictly regulate the prices of medicines through various mechanisms such as internal and external reference pricing, and couple P&R rules with control of excess spending mechanisms, such as clawbacks, mandatory rebates and prize freezes, aiming to drive down the price of medicines[7].

These policies have led to the current situation where **8 out of 10 critical medicines are at risk of supply disruption.**

Today's shortages - the price of unsustainable policies

As illustrated by a recent study conducted by TEVA[8], a Medicines for Europe member, existing practices as described above cause significant vulnerabilities in the EU's supply of critical medicines, as **46% of EU critical medicines have only one supplier in the market. This figure escalates to 83% when considering suppliers holding over 60% of the market share.**

When an EU market depends heavily on a dominant supplier with only a few small players, any disruption threatens to cripple supply, because these minor suppliers lack the agility and scale to ramp up output quickly. The absence of MEAT (Most Economically Advantageous Tender) criteria in procurement intensifies this vulnerability: **eight out of ten critical generic medicines are considered at high risk of supply disruption,** and patients could lose access to vital treatments, including oncology drugs. In fact, **cancer medicines face a 39% higher probability of shortage** compared to other generics, reflecting how economic fragility and production concentration disproportionately affect these essential therapies[4].

MEDICINES FOR EUROPE **RECOMMENDATIONS:**

ARTICLE 18 OF COMMISSION PROPOSAL: PUBLIC PROCUREMENT OF CRITICAL MEDICINES

1. **Ensure mandatory non-price award criteria for the public procurement of critical medicines in line with the Commission's proposal.** Thes should also include on a mandatory basis **environmental, corporate sustainability and sustainable manufacturing criteria** (Article 18(1) & (4)), to streamline procurement processes across EU Member States.
2. Introduce **mandatory multi-slot tenders where possible** for critical medicines (Article 18(1)).
3. **Delete the reference to stockpiling obligations** in Article 18(1) as it directly undermines the overarching supply security objective of this provision.
4. **Ensure that non-price award criteria are interpreted and specified by the European Commission**, in the form of an implementing act (Article 18(1)). This is important to ensure harmonised application of non-price award criteria by contracting authorities.
5. Introduce the ability to **adjust pricing in tenders which are extended or multiannual tenders** (Article 18(1)), to allow critical medicine suppliers to absorb substantial increases in production, while ensuring supply continuity.

ARTICLE 19 OF COMMISSION PROPOSAL: NATIONAL SECURITY OF SUPPLY PROGRAMMES

1. Introduce an **obligation** for Member States to include **P&R measures applicable to critical medicines in their national programmes supporting security of supply** (Article 19(1)) given the importance of such measures.
2. Empower national security of supply programmes to **review price freezes and cost containment measures applicable to critical medicines** to enhance transparency in Article 19(1).
3. National pricing rules should include an **inflation adjustment mechanism** and a separate **assessment of supply consolidation by the national medicines agency**, which should be able to require a change to the pricing law to reverse consolidation or to encourage more diversity of manufacturers to supply the national market. These should be monitored by national programmes and reported back to the Critical Medicines Group. This should be specified in Article 19.

(1) Beneath the Surface: Unravelling the True Value of Generic Medicines, IQVIA, April 2024
(2) European Commission Study on Medicines Shortages, 2021
(3) European Commission, Study on best practices in the public procurement of medicines (December 2022)
(4) Strategic Report of the Critical Medicines Alliance, February 2025
(5) IQVIA, White Paper: From Regulated Prices to Prices Set in Tenders Tendering landscape in Europe
(6) Critical Medicines Act Staff Working Document, September 2025
(7) https://www.medicinesforeurope.com/wp-content/uploads/2025/06/Generics-Market-Review-2025.pdf
(8) Teva, Teva Generics Health Check, European Critical Medicines Supply Diversity Under Pressure (February 2025)