Critical Medicines Act Factsheet

Stockpiling

medicines for europe
better access. better health.

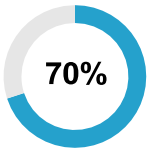
Proportionate and sustainable stockpiling to safeguard patient access

Why the EU needs coordinated, proportional and sustainable stockpiling rules for critical medicines

National stockpiling mandates were introduced to improve security of supply. But across the EU, they are **fragmented**, **disproportionate** and **financially unsustainable**, especially for **generic** and **off-patent manufacturers** responsible for **70% of dispensed medicines** and **90% of EU critical medicines**. A recent report revealed that **7 out of 10** of **Europe's largest generic medicine suppliers** have had to **destroy** unsold stock due to **existing stockpiling obligations**.[1]

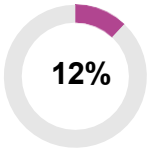
The hidden cost of stockpiling obligations: waste, shortages and market disruption

Destruction of medicines



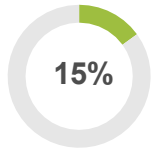
70% of Europe's largest generic suppliers have reported destroying medicines[1]

Environmental waste



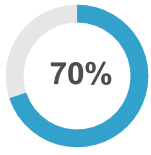
12% average increase in waste due to expiry[1]

Inventory pressure



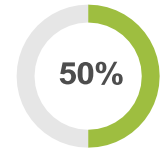
15% rise in gross inventories linked to stockpiling[1]

Supply inequity



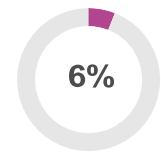
70% report longer shortages in smaller EU markets[1]

Market exit risk



50% have discontinued products due to unworkable stockpiling[1]

CO_2 and water use



6% environmental impact increase reported[1]

Current national stockpiling obligations **incentivise destruction, consolidation,** and **market exits,** rather than solidarity and resilience, leading to:

- ✗ Decreased access for patients in smaller countries
- ✗ Threats to supply security
- ✗ Market distortions, inefficiencies and avoidable waste

Overstocking is not equivalent to preparedness.

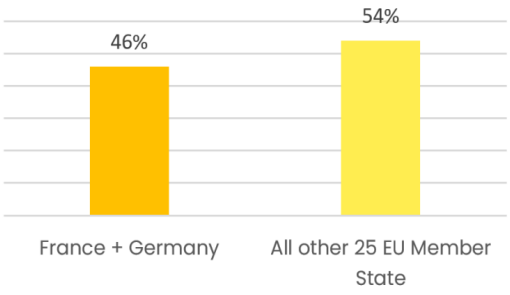
✓ Resilience comes from smart procurement, diversified suppliers, and sustainable pricing, not medicine destruction

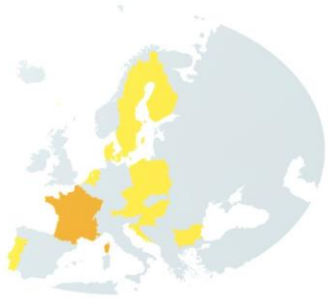
> ***"Due to national contingency stock obligations, today, for every 100 medicines produced, 10 are destroyed. Every wasted unit is a unit unavailable to a patient[1]"***

(1) Data sourced from Medicines for Europe's 2025-member survey on EU stockpiling and "Mandatory Stockpiling in the EU: Rethinking today's approach to protect tomorrow's Generic Medicine supply" report, https://www.medicinesforeurope.com/wp-content/uploads/2025/07/Medicines-for-Europe-Stockpiling-Report-2025.pdf

A picture of *inequality* and the *fragmentation* it creates

France and Germany represent almost half of total EU monthly consumption of critical antibiotics[2]





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.

Stockpiling was meant to prevent shortages, but it is currently helping to create them, just not in the same country. There is a real need for **EU-level coordination** and **solidarity** to mitigate the negative effects stockpiling can have.

The Critical Medicines Act can fix this but only if contingency stock rules are proportionate, compensated, and coordinated

Stockpiling rules must be **harmonised, sustainable** and **data-driven**, especially for older, low-margin essential medicines. The CMA provides an opportunity to fix this but only with key improvements.

MEDICINES FOR EUROPE RECOMMENDATIONS:

ARTICLE 19 OF THE COMMISSION PROPOSAL: NATIONAL SECURITY OF SUPPLY PROGRAMMES

Require stockpiling obligations to be integrated into national security programmes
- → Ensures **planning, transparency** and **cross-border coherence**
- → Enables **realistic demand forecasts** and **avoids duplications** or **excesses**

ARTICLE 20 OF THE COMMISSION PROPOSAL: CONTINGENCY STOCK REQUIREMENTS

1. **Exempt medicines under contingency stock obligations from parallel exports**
   - → Prevents stock intended for national resilience from leaving the country
2. **Exempt companies from fines when responding to shortages in other Member States through solidarity stock transfers**
   - → Encourages **cooperation, not penalisation**
3. **Require proportionate penalties only in cases of abusive non-compliance**
   - → Ensure sanctions do **not drive product withdrawals** or **discourage supply**
4. **Mandate fair remuneration for holding contingency stocks**
   - → Must include **cost of storage, inflation** and **losses due to expiry**
   - → Without this, **small players exit**, and **supply becomes dangerously concentrated**
5. **Define harmonised EU stockpiling scope and limit to 2 months' average national consumption**
   - → Must be based on **vulnerability assessments** (e.g. single-source dependency, past shortages)
   - → Requires **ex-ante notification to the Commission** with an **automatic proportionality review**
6. **Enable simplified redistribution across borders via regulatory flexibilities**
   - → **EU-wide packaging, e-leaflets** and **digital authorisations**
   - → Supports **rapid solidarity transfers** and **efficient inventory management**

(2) Based on internal analysis by Teva using data from the following source: IQVIA MIDAS® Quarterly sales data released Q2 2024, Measure: count of products with sales of >0 standard unit, Time Period: MAT Q1 2014 - Q1 2024, reflecting estimates of real-world activity. Copyright IQVIA. All rights reserved. Gx Health Check 3.0