



Mandatory Stockpiling in the EU

Policy recommendations, solutions and alternatives

The current trend of uncoordinated national stockpiling obligations poses significant risks to the pharmaceutical supply chain, patient access to medicines, and market dynamics. By implementing the recommendations outlined in this paper, and presented below, the **EU can address the root causes of shortages, ensure a competitive and predictable market, and promote European solidarity**. With a well-designed strategy in place, the EU can better guarantee the timely availability of medicines and ultimately enhance the health and well-being of its citizens. It is time to take proactive and coordinated action to secure a brighter future for healthcare in the European Union.

Procurement, designed with the objective of maintaining security of supply with predictable demand, is equally crucial to ensure a steady medicine supply, requiring improved oversight for redistributing quantities within the EU during shortages.

Allowing patients to continue having access to a broad range of therapeutic options as well as guaranteeing that generic medicine competition remains healthy in the long term.





Reducing regulatory complexity to support the agility of the supply chain

In recent years, the proportion of resources spent on regulatory maintenance of medicinal products has substantially increased. Generic medicine companies with large portfolios are spending the same amount of resources on 3-year regulatory maintenance as they invest in R&D per year for new product development.

→ **A lack of regulatory flexibility can lead to stock-outs and delays. It increases the overall costs of bringing and maintaining the products on the market.**

ACTIONS NEEDED	
<p>Facilitate the re-allocation of stock between EU countries especially for medicines approved under national procedures (referred to as DCP or MRP medicines – around 90% of medicine registrations in Europe). Extend flexibility beyond finished product stockpiles to include upstream materials (e.g. bulk/API levels), allowing inventories to be reallocated more efficiently across markets.</p>	<p>Ensure that the variation reforms drastically reduce the burden of administrative changes that are not linked to safety, quality, and efficacy standards, but only with bureaucracy and paperwork.</p>
<p>Investment and cooperation with industry on digitalisation of regulatory data systems (EU and nationals) and interoperability with other relevant systems (i.e. Shortage reporting, European Medicines Verification System) including the integration of digital leaflets (electronic product information - ePI) for more efficient and transparent management of medication information.</p>	<p>Move towards a broader adoption of multi-country packs and labelling harmonisation to increase manufacturing and distribution resilience. Avoid expensive and time-consuming re-packaging, which not only leads to increased costs but also contributes significantly to waste.</p>

Supportive policy and regulatory measures are needed to increase the **agility of the supply chain** without **lowering EU quality and safety standards**.



Ensuring a competitive market and predictability of demand

External factors, such as the COVID-19 pandemic and the full-scale war in Ukraine, have worsened matters by driving inflation, disproportionately impacting generic medicines with its narrow profit margins and price regulation limitation.

→ **Existing strict pricing rules prioritise short-term cost-cutting over market adaptability, contributing to market consolidation in European regions.**

ACTIONS NEEDED	
<p>Ensure predictable and sustainable (regulated) market environments that would increase the number of manufacturers in the market and thereby reduce the risk of medicine shortages.</p>	<p>Adjust existing national procurement frameworks to create healthy competition and improve the design of tenders to meet objectives beyond securing the lowest price, by awarding multiple winner tenders, introducing criteria beyond price, allowing for sufficient lead times, accurate volume estimates and guarantees.</p>
<p>Implement new sustainable pricing and reimbursement models for generic medicines that ensure healthy market competition, allowing companies to adjust prices based on inflation.</p>	<p>Revise and adjust the application of national cost containment measures that discourage generic medicine manufacturers from entering or staying on the market.</p>

To address these issues effectively, **sustainable pricing and a reimbursement environment** that **attracts more manufacturers** to foster a resilient supply chain is needed.



Enabling European solidarity and voluntary stock sharing to manage shortages more efficiently

Most shortages in the EU affect only one country, making voluntary reallocation of stocks the most effective and proportionate response. The proposed European Voluntary Solidarity Mechanism offers a coordinated alternative to fragmented national stockpiling strategies, reinforcing supply resilience and solidarity across Member States.

→ **The lack of coordinated stock visibility and reallocation mechanisms across Member States creates inefficiencies, hindering timely responses to shortages and increasing reliance on fragmented national stockpiling.**

ACTIONS NEEDED

Leverage existing infrastructure (EMVS) to activate real-time, pack-level stock visibility across the EU. This would support earlier detection of imbalances and more efficient solidarity-based reallocation, without requiring new systems or high-cost investments from generic medicine manufacturers.

Continuously collect real-time data on stock levels and demand via the EMVS. This ongoing monitoring would improve forecasting accuracy and enable proactive supply adjustments, helping to prevent shortages and optimise distribution across Member States.

Streamline cross-border movement by simplifying batch release, labelling, and packaging rules during emergency reallocations. This reduces delays and prevents the need for costly repackaging, particularly burdensome for low-margin generic medicines. However, clear safeguards are needed to prevent reduced availability in lower-price countries or unintended market distortions.

Ensure system interoperability (EMVS, SPOR, ESMP) through clear legal access rights and harmonised data exchange protocols. This empowers authorities and industry to make coordinated, data-driven decisions in real time – avoiding duplication and administrative burden for manufacturers, prioritising public health coordination and overcoming data silos.

A well-functioning solidarity mechanism, based on **data-driven cooperation** and **regulatory agility**, can **reduce the need for national stockpiling** and ensure **more equitable access to medicines**.



Preventing internal market disruption through stronger oversight of national stockpiling policies

Excessive and uncoordinated national stockpiling requirements are already impacting the smooth functioning of the internal market. These practices disrupt the free movement of medicines, create artificial imbalances in availability between Member States, and reduce the overall resilience and sustainability of supply chains in Europe.

→ **Disproportionate national stockpiling obligations can fragment the internal market, and trigger cross-border shortages, thereby undermining equitable access to medicines across the EU.**

ACTIONS NEEDED	
Encourage Member States to align stockpiling policies with realistic demand forecasts and ensure such measures do not compromise the flexibility of supply chains or the availability of medicines in other EU regions.	The European Commission should engage in ongoing dialogue with Member States to encourage a proportionate approach to stockpiling, including setting clear caps on stockpiling requirements and penalties , particularly where uncompensated obligations could impact broader market stability.
The Commission may use existing policy tools to support transparency and assess the market impact of stockpiling frameworks, ensuring that they align with EU principles on proportionality .	Reinforce the importance of complying with Article 5 of Directive (EU) 2015/1535 , ensuring that any new national technical regulations are properly notified for review to avoid unintended barriers to trade.

Clear and consistent **EU-level coordination** is essential to **prevent supply chain fragmentation** and ensure **equitable access to medicines** across Member States, while upholding the integrity of the internal market.