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Mandatory Stockpiling in the EU:

Rethinking today's approach to protect tomorrow's Generic Medicine supply

EXECUTIVE SUMMARY

This report analyses the long-term structural risks posed by the growing trend of mandatory national stockpiling requirements in the EU and their disproportionate impact on the off-patent pharmaceutical sector. While well-intentioned as a response to medicine shortages, current stockpiling policies are fragmenting the internal market, distorting supply chains, and undermining the long-term resilience and sustainability of generic medicine manufacturing and supply in Europe.

Evidence from the HERA AMR feasibility study[1] confirms that for sectors dominated by older, low-margin molecules, such as antibiotics, stockpiling is financially unfeasible. In practice, this translates into mounting structural risks across four critical dimensions: environmental waste and AMR exposure, economic sustainability, supply flexibility, and manufacturing investment.

Firstly, the mismatch between forecasted demand and real-world consumption leads to significant volumes of medicines, particularly antibiotics, reaching expiry. This not only results in large-scale waste but also increases environmental risks.

Secondly, mandatory contingency stockpiling shifts the financial burden of inventory holding onto manufacturers without compensation mechanisms. For many generic companies operating on tight margins, this renders the continued supply of low-cost essential medicines unsustainable. The result is product discontinuation and a reduced supplier base. These risks are compounded by disproportionate fines in case of non-compliance, which further discourage participation in already fragile markets.

Thirdly, national stockpiling obligations limit the ability of companies to dynamically allocate stock according to real-time demand. By locking inventories at the national level, stockpiling reduces distribution flexibility, creating surpluses in some Member States while others face critical shortages. This undermines resilience and weakens the EU's collective capacity to respond to supply shocks.

Moreover, claims that stockpiling reduces shortages or increases manufacturing capacity are not supported by evidence. The Technopolis study commissioned by the European Commission[2] confirms that most shortages are localised, short-lived, and manageable through existing stock

[1] European Commission: European Health and Digital Executive Agency and McKinsey Solutions, HERA AMR feasibility study on stockpiling – D6/D7 – Final report, Publications Office of the European Union, 2022, https://data.europa.eu/doi/10.2925/208305

[2] European Commission: Directorate-General for Health and Food Safety, Ecorys BV, Milieu Law and Policy Consulting, Technopolis Group, Jongh, T. d. et al., Future-proofing pharmaceutical legislation – Study on medicine shortages – Final report (revised), Publications Office of the European Union, 2021, https://data.europa.eu/doi/10.2875/211485

and cross-supplier adjustments. A study from France[3] further demonstrates that low-price environments, with limited supplier competition, are significantly more exposed to persistent shortages than settings with sustainable pricing and diversified procurement.

To address these systemic risks, this report proposes a coordinated policy shift focused on four key areas: regulatory agility, market sustainability, EU-level solidarity, and stricter oversight of national stockpiling practices.

Reducing regulatory complexity and enabling the reallocation of medicines across Member States is essential. Variation reforms must eliminate administrative burdens not linked to safety, quality, or efficacy, while digitalisation of regulatory systems and interoperability with tools such as the European Medicines Verification System (EMVS) and European Medicines Verification System (ESMP) should be accelerated.

Ensuring a competitive and predictable market environment requires sustainable pricing and reimbursement frameworks that account for inflation and increasing production costs, and which support long-term participation of multiple suppliers. Procurement processes must be revised to allow for multi-winner tenders, realistic volume forecasting, and criteria that go beyond lowest price alone.

A European Voluntary Solidarity Mechanism should be activated, based on real-time data collection through EMVS to allow for timely, needs-based stock reallocation across borders. Simplified (digital) labelling, batch release and packaging procedures are needed to enable emergency transfers without delays or repackaging costs, particularly for generic medicines.

Finally, the European Commission must take a more active role in overseeing national stockpiling measures. Stockpiling obligations should be capped, aligned with real consumption, and formally notified under Directive (EU) 2015/1535 to prevent internal market disruption and uncoordinated regulatory divergence.

In conclusion, current national stockpiling practices are not only failing to address the root causes of shortages but, more controversially, are actively introducing new vulnerabilities into the European pharmaceutical supply system. A coordinated, proportionate and technically sound EU-level approach is urgently needed to protect medicine access, manufacturing viability, and public health resilience.

[3] Dubois, Pierre & Majewska, Gosia & Reig, Valentina, 2023. "Drug Shortages: Empirical Evidence from France," TSE Working Papers 23-1417, Toulouse School of Economics (TSE).

1. EU STOCKPILING OVERVIEW

➔ I. Introduction

Timely availability of generic, biosimilar and value-added medicines is crucial to ensure optimal patient access and a well-functioning healthcare system. Medicines for Europe strongly upholds the objective to support patients with access to the medicines they need, and our members are committed to providing a safe and continuous supply of medicines as their key public health objective. To mitigate possible risks of supply chain disruptions, pharmaceutical companies implement various internal inventory policies and 'demand-supply' dynamic modeling (contingency stocks of critical materials needed to provide for demand surges) that cover API, bulk and finished products as part of their strategy to guarantee the security of supply.

The off-patent medicines sector, which provides over 70% of prescription medicines across Europe, including most antibiotics, intensive care, IV fluids infusions and injectables, and chronic disease medicines, is at the core of public health resilience. Yet, recent years have shown that **disproportionate, costly and fragmented national stockpiling obligations have introduced significant systemic risks impacting the provision of critical care and patient access, market fragmentation, reduced supply chain agility, and pressure on the economic sustainability of essential medicines.**

An EU stockpiling strategy will only succeed if it addresses, not reinforces, these vulnerabilities. The following pillars are essential to support supply resilience and ensure continuous patient access to essential medicines.

1. Alignment and proportionality are essential

Uncoordinated national stockpiling rules have already created duplicative and often contradictory requirements, which **impede the ability of manufacturers to efficiently reallocate supply where it is most needed during shortages.** In some cases, these obstacles are compounded by the **threat of penalties** for not maintaining mandated stock levels, which can **discourage manufacturers from responding flexibly to emerging supply**

2. Sustainability of supply must be preserved

Off-patent medicines are produced under highly regulated price-control mechanisms and frequently awarded through tender-based procurement. **Imposing rigid, unremunerated, or high-volume stockpiling obligations on suppliers** that operate on **tight margins and long production lead times** may trigger **market exits** and **reduce the number of suppliers**, especially for older or lower-volume products that are critical for care continuity. A **clear and**

needs across borders. Stockpiling should not lead to **artificial barriers within the internal market**, nor should it compromise **solidarity between Member States.**

enforceable cap on stockpiling obligations should be introduced, to ensure such **measures remain proportionate and do not undermine supply sustainability**.

3. Data-driven planning and rapid response based on better use of existing data should be prioritised

The European Medicines Verification System (EMVS), routinely used to prevent falsified medicines, offers a unique opportunity to **track medicine availability across Member States** in real time. This tool can support **data-driven planning and rapid response** to shortages, particularly when combined with regulatory flexibilities in labelling and pack sizes to facilitate cross-border distribution. **Advanced forecasting techniques can be leveraged to enable dynamic stockpiling** against a management fee which aims to reduce excess inventory, minimise holding costs, and improve responsiveness to changes in real-time demands by the Member States and its healthcare providers.

4. Industry should be recognised as a central actor in preparedness

Stockpiling obligations that are misaligned with **production realities, shelf lives, and actual demand forecasts** risk generating waste and delays rather than resilience and preparedness. Instead, **joint planning based on real-world data, coordinated procurement models that incorporate supply security criteria**, and **voluntary solidarity mechanisms** offer more viable alternatives for safeguarding medicine availability.

We encourage the Commission, as it develops the new EU stockpiling strategy, to differentiate between types of critical care products, recognise supply chain constraints, and avoid imposing counterproductive burdens. **The goal must now be to strengthen (not strain) the capacity of the European pharmaceutical system to deliver affordable, reliable access to essential medicines.** We stand ready to contribute with data, technical expertise, and practical solutions to ensure this initiative delivers on its promise of a more resilient Europe.

➔ II. Strategic reserves, contingency stock, and supplier obligations

In the ongoing debate around stockpiling policies for health emergency preparedness, there is frequent confusion between fundamentally different models. This confusion can lead to a disproportionate burden on the generic medicines industry, particularly when public responsibilities are shifted onto suppliers without clear frameworks or appropriate compensation mechanisms.

A **strategic reserve** is a government-owned stockpile of essential products, maintained to ensure supply during major crises. The key characteristic of a strategic reserve is that the **state assumes full ownership and financial responsibility**, ensuring that availability of essential medicines is guaranteed under exceptional circumstances. These are typically centralised and aligned with the national preparedness plans.

By contrast, a **contingency stock** (also known as a safety stock) is inventory **maintained voluntarily by manufacturers as part of normal business practice for risk management** (e.g. demand variability, delays, short-term logistical issues). It is privately funded, commercially motivated, and not intended to serve public policy objectives.

A separate concept that is often conflated with strategic reserves is **mandated supplier stockpiling**, where authorities require companies to hold stock for public preparedness, but **without transferring ownership or systematically compensating the holder**. This creates a de facto public reserve through private means, often without recognising the operational and financial impact.

Remunerated stockpiling is a hybrid model where the government compensates suppliers (fully or partially) for holding certain stocks, usually for a limited list of strategic medicines. While it acknowledges public benefit, it still relies on private management. Unfortunately, this model is rarely implemented in practice, as can be seen in the comparative table of countries below.

Table 1: Types of stockpiling models and compensation mechanisms

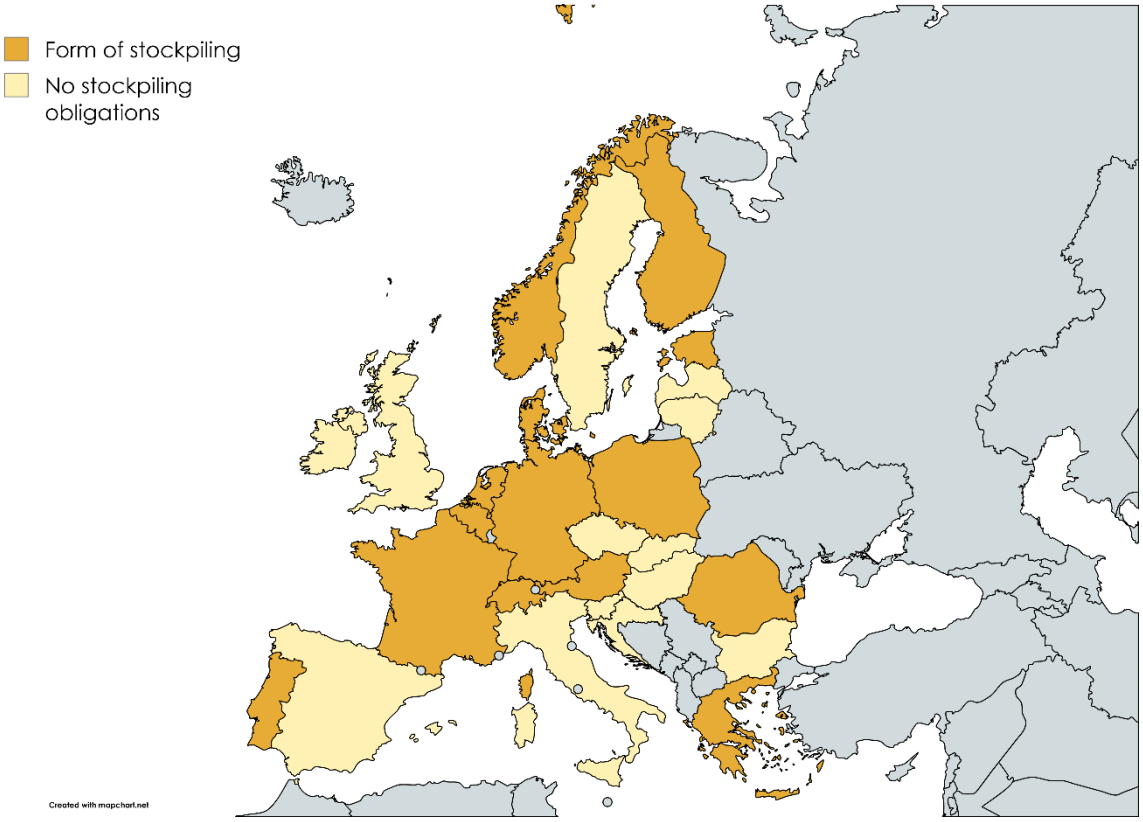
	Austria	Czech Republic	Denmark	Finland	France	Germany	The Netherlands	Norway	Poland	Portugal	Romania
Remunerated (partially)	✓	x		✓	x	x	x	✓	x	x	x
Limited to a strategic list of medicines	✓	x	✓	✓	✓	x	x	✓	✓	✓	x
Strategic reserve owned by the government	x	x	x	x	x	x	x	✓	x	x	x

Failing to distinguish between these models risks conflating public preparedness with private responsibility. For the generic medicines industry this confusion can result in policy decisions that are both inefficient and unsustainable. Clear terminology and differentiated approaches are essential to ensure that the burden of public health readiness does not fall disproportionately on manufacturers, but is shared in a structured, transparent, and equitable manner.

➔ III. Current stockpiling obligations

The map and table below provide an overview and categorise the stockpiling obligations imposed on supply chain operators in Europe, highlighting the diverging national stockpiling requirements currently in place.

Map and table 2: National stockpiling obligations in the EU and the UK



Austria

4-month stockpile required for 48 APIs and 721 medicines, based on average monthly deliveries. Exemptions apply in case of 25% demand increase, export bans, force majeure, MA withdrawal, or authority restrictions. Annual quantity reporting required. Public covers extra storage costs. Entered into force on 21 April 2025.

Denmark

Companies must hold 6 weeks' stock for 581 critical medicines. Obligation applies only to companies placing these medicines on the Danish market. Parallel importers/distributors are exempt. Stock can be kept in another EU/EEA country with exemption. It was implemented by January 2025.

Portugal

New law (Deliberation No. 233/2025) requires 2-month stock for all medicines, kept in national territory. MAHs must keep updated supply guarantee plans and notify INFARMED of shortages at least 2 months in advance. Additional obligations for medium/high impact shortages include justification, alternatives, communication plans, and mitigation measures.

Finland

Authorities manage and partially compensate mandatory stockpiles for 1,350 products (the compensation is calculated based on the capital tied up in the acquisition of the goods to be stored, using the reference rate under the Interest Act plus two percentage points). Stock must be in Finland. Quantity corresponds to 3, 6, or 10 months of previous year's sales."

France

Current rule requires a 2 to 4-month stock for medicines of major therapeutic interest. Penalties can reach 50% of turnover, capped at €5 million.

Germany

6-month stock obligation for medicines under discount agreements (mostly retail generics). Introduced by law in July 2023. Prior to this, a 3-month stock requirement was widely applied as a standard practice in discount contracts.

Sweden

Not yet implemented. The proposed model includes a 3-month stock for priority medicines based on sales data. The compensation formula includes inventory interest and holding cost. Mainly targets originator medicines. 7,606 products identified under current criteria. The national list includes 893 essential substances.

Norway

Strategic reserve owned by the state for primary care. Additional hospital stocks funded by the Norwegian procurement agency. Extra stock is sometimes reimbursed via procurement contracts.

Romania

Mandatory 3-month average stock for all prescription medicines: 1 month with the manufacturer, 1 with wholesalers, and 1 in the rest of the supply chain. In place since 2016.

Poland

3-month stock required for all reimbursed medicines. Stock should be distributed across the supply chain, but suppliers lack access to real stock data. High penalties apply. System is under review.

Czech Republic

No general obligation. In case of reported supply disruption, MAHs must deliver 1–2 months' supply (based on average past consumption) of reimbursed medicines. No further obligation once delivered. Emergency reserve system also in place: distributors hold a 1-month stock of selected products, releasable in shortages with a special 4% wholesale margin.

Slovakia

No legal stockpile obligation. An emergency supply channel exists for all reimbursed products under the 2017 Drug Law amendment. If the MAH fails to deliver within 48 hours of an HCP prescription, they must apply for reimbursement exclusion (A3). Penalties range from €100,000 to €1 million.

Greece

3 months stock obligation and the requirement to supply the market with quantities 25% greater than the current prescription.

Italy

No stockpiling obligation. MAHs must ensure sufficient stock to cover the 4-month notification period for shortages unless justified.

The Netherlands

2.5-month safety stock for all prescription medicines. Split into 6 weeks at supplier level and 4 weeks at wholesaler level.

Estonia

30-day stock of ~200 commonly used OTC and Rx products sold in pharmacies. Stock is held by wholesalers selected via tenders delegated by the Estonian Stockpiling Agency. Medicines are not purchased by the state; the Agency reimburses storage costs. Wholesalers must manage expiry. Costs covered by the state budget.

UK

No legal stockpiling obligation currently in place. From 2009–2019, around 400 essential medicines were held under the DHSC's Essential Medicines Buffer Stock (EMBS) scheme. It ended by 2022. Since Brexit and COVID-19, contingency measures include Serious Shortage Protocols (SSPs), export restrictions, and voluntary supplier stockholding (e.g. 6-week buffer requested in 2019). No mandatory national reserve or duration-based stock levels apply.

To illustrate, Germany's six-month stock for a population of 80 million represents the equivalent of nearly two years' worth of supply in the Netherlands (population 18 million). If such stock leaks into parallel trade circuits, it could severely destabilise smaller or less protected markets, reducing local inventories and undermining equitable access across the EU. Whilst designed individually in each country, the effect of these stockpiling obligations is never felt in a silo. Together, the introduction of these measures creates a 'domino effect' whereby countries which do not have stockpiling obligations in place may choose to follow the example, governed by the fear of losing their own stock to the countries where strong stockpiling obligations are in place.

These national stockpiling practices do not operate in isolation. They interact with broader market mechanisms such as public tendering. In many cases, tenders last for a fixed period (e.g. 24 months), during which suppliers are required to maintain an additional stock (e.g. two months of supply). If this stock cannot be used or sold after the tender ends, it effectively becomes waste. In this scenario, this unused inventory can represent a loss equivalent to approximately 8.3% of the total contracted volume (2 months over 24). This illustrates how such stockpiling requirements, though designed to enhance security of supply, can unintentionally increase both environmental waste and financial costs, particularly in systems without rollover mechanisms.

In addition, the current approaches to stockpiling focus almost exclusively on finished-dose inventories. Introducing greater flexibility, by also allowing stock to be held at earlier stages of production, such as bulk level, would support a more universal and efficient use of available inventories. This should not translate into additional obligations but rather offer manufacturers the option to manage buffers where it is most effective within their supply chain. Such flexibility can improve responsiveness to demand fluctuations while reducing unnecessary waste.

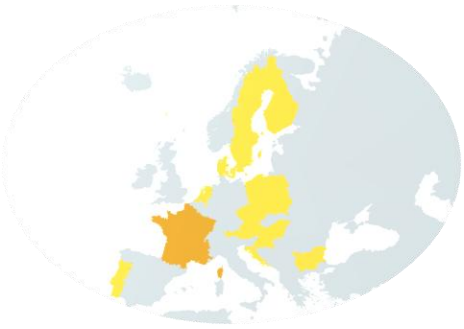
Stockpiling cannot compensate for structural market failures. Without viable market conditions, no amount of stock will prevent future shortages. Today's tendering models and

unsustainably low prices are forcing suppliers to exit the market. Without fair and viable conditions, stock requirements only add burden, while the root causes of shortages remain unaddressed.

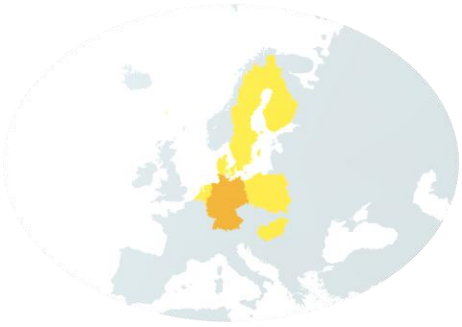
➔ IV. Case study: Volume of critical generic antibiotic medicines in the EU market

Significant disparities in stockpiling volumes across Europe are placing disproportionate pressure on manufacturing capacity. In several large markets, one month of stockpiled critical generic antibiotics is equivalent to the combined monthly needs of multiple smaller Member States. **France (29%)** and **Germany (17%)**, together account for **46%** of the total volume of critical generic antibiotic medicines in the analysed European market.[4]

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.



Without alignment, as shown in this case study, the disproportionate national demands risk overwhelming manufacturing capacity, undermining the stability of supply chains and equitable access to essential generic antibiotics across European nations.

➔ V. Countries' stockpiling insights

Table 3 outlines a comparative view of national stockpiling approaches across the EU, highlighting both best practices that support supply resilience and systemic challenges that threaten sustainability.

[4] Based on internal analysis by Teva using data from IQVIA MIDAS® MAT. Quarterly sales data released Q2 2024. count of products with sales of >0 standard unit.

Table 3: Best practices and systemic challenges in stockpiling policies

What works well	Sharing of best practices
	Limited, reimbursed lists help maintain supply while easing burden on suppliers [AT, FI, PT]
	Flexible mechanisms like foreign batch substitution or alternative product acceptance support continuity [CZ]
	Time-limited or volume-limited obligations reduce waste and improve feasibility [DK, IT]
	Existence of government-owned or managed stockpiles adds resilience [NO, SE]
	Strategic financial incentives (price increases, fee exemptions) support critical medicine availability [PT]
	Coordinated national and regional support to hospital systems facilitates hospital stockpiling [SE]
	Early shortage notification linked to verifiable stock ensures preparedness [IT]
	Governments open to reform and improvement signal better long-term sustainability [FI]

What needs fixing	Systemic challenges
	Overly broad scope of obligations strains supply and discourages MAH participation [CZ, PL, DE, FR, NL]
	High stockpile volumes disproportionate to national size risk distorting regional supply [DE, FR]
	Significant medicine waste due to rigid volume/duration requirements, especially with short shelf-life products [FI, PL]
	High fines and regulatory burdens pose risks of market exits or non-compliance [FR, PL, RO, CZ]
	Exclusion of parallel importers creates an uneven playing field and disincentivises manufacturers [DK]
	No financial support for companies despite mandatory requirements leads to compliance gaps [RO, FR, PL]
	Mandatory stockpiling paired with pricing pressures (e.g. price cuts) weakens commercial viability [AT]
	Preferential systems combined with stockpiling reduce system efficiency [NL]
	Long stockpile durations not aligned with procurement cycles (e.g. hospitals' utilisation) reduce flexibility and create waste[FI]

2. RISKS OF STOCKPILING

➔ I. Assessing impact of stockpiling

Present **risks**

The current stockpiling framework, though well-intentioned, is already having serious unintended consequences on availability, sustainability, and equity across the EU pharmaceutical market. **Medicines for Europe conducted a targeted survey among its member companies in the generic medicines sector**. The objective was to gather **tangible, up-to-date data on the operational and regulatory impact of stockpiling requirements** across EU and national levels. **Ten of our largest member companies**, representing a significant share of the European generic medicines market, actively contributed to this exercise by providing detailed input based on their manufacturing and supply experiences. **Below, we share some key findings and insights**[5] that reflect the practical challenges, risks and opportunities identified through this industry-led assessment.

Table 4: Overview of the major areas of impact of stockpiling

AREAS OF IMPACT	
Pharmaceutical industry (costs, operations, manufacturing capacity, etc.)	**Environment** (waste of products, sustainability concerns, destruction of medicines, etc.)
Member State markets (restrictions on moving products across Member States, supply chain disruptions, etc.)	**Patient access to essential medicines** (collateral effects, shortages affecting other countries, etc.).

[5] Data sourced from Medicines for Europe's 2025-member survey on EU stockpiling.

a) **Impact on the pharmaceutical industry**

National stockpiling policies are creating significant economic and operational burdens for generic medicine manufacturers, **9 out of 10 companies** identify *increased costs and operational complexity* as one of the **most critical risks** to long-term supply availability. **9 out of 10 companies** emphasise the urgent need for **financial support (including price adjustments)** as a key requirement for a viable EU-wide stockpiling framework.

> ***"Without financial support, stockpiling forces manufacturers into unsustainable trade-offs: higher costs or reduced supply."***

b) **Environmental impact**

The current approach to stockpiling is generating considerable waste and undermining sustainability goals, **7 out of 10 companies report that they have had to destroy stockpiled medicines due to regulatory constraints, as it is not possible to roll out contingency stocks, due to overstocking or the contradicting requirements from procurers for over a year long expiration dates.** Companies **estimate a 12% average increase in scrap** and **15% in gross inventories** linked to current requirements in key markets such as **Germany and France**. **CO_2 emissions, water usage, and overall environmental impact** are estimated to have risen by **around 6%** as a direct result of these measures.

> ***"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."***

c) **Impact on Member State markets**

Current national approaches are creating fragmentation and reducing flexibility across the internal market, **9 out of 10 companies** cite **restrictions on intra-EU stock reallocation** as a high risk to supply security. **70% of companies have observed longer stockout periods and reduced availability of medicines in smaller or less profitable markets, as resources are redirected to meet stricter obligations in larger countries.** Imbalances are evident, **7 out of 10 companies** have observed **oversupply in some countries and shortages in others** due to uncoordinated stockpiling.

> ***Stockpiling is intended to prevent shortages, but it is currently helping to create them, just not in the same country.***

d) **Impact on patient access to essential medicines**

The unintended consequence of rigid stockpiling policies is that **essential medicines are becoming harder to access in certain regions**, **70% of companies** have seen **stockouts of essential medicines,** directly linked to the diversion of capacity and stockholding to fulfill stockpile quotas. **50% of respondents said they have had to discontinue products from their portfolios, reducing therapeutic diversity in the name of regulatory compliance,** citing unworkable requirements, especially in hospital tenders.

> ***Penalties for non-compliance are pushing lifesaving drugs out of the market. We are not building resilience, we are witnessing dangerous market consolidation that is severely limiting medicine availability.***

➔ II. Long-term effects of stockpiling

Future **risks**

The long-term risks associated with mandatory stockpiling are already becoming apparent and are likely to intensify without corrective policy alignment. These concerns were clearly identified in the HERA feasibility study on AMR stockpiling[6], which concluded that increasing private-sector inventories is financially unfeasible. Specifically, the study warned that "for a sector like manufacturing of largely genericised antibiotics, [stockpiling] might have a negative impact on the EU's remaining supplier landscape and manufacturing networks."

a) Structural risk of medicine waste

When demand forecasts do not match real-world consumption, stockpiling fails to provide effective supply continuity. Overestimation leads to medicine waste, while underestimation results in shortages. This is particularly problematic for products with limited shelf-life, such as many

[6] European Commission: European Health and Digital Executive Agency and McKinsey Solutions, HERA AMR feasibility study on stockpiling – D6/D7 – Final report, Publications Office of the European Union, 2022, https://data.europa.eu/doi/10.2925/208305

antibiotics, where unused stock frequently reaches expiry and must be destroyed. Additionally, product-specific destruction costs (e.g. PZN-based) can be high enough to jeopardise the overall financial viability of a product.

b) Financial unsustainability and product discontinuation across the generic portfolio

Mandatory stockpiling increases the fixed costs associated with maintaining supply. For many low-margin generic products, especially older molecules, these additional obligations render continued commercialisation unsustainable in the absence of compensation mechanisms. Companies may be forced to reassess their portfolios and withdraw products that cannot bear the burden of unreimbursed inventory holding and the risks of high fines in case of non-compliance with the obligation, directly reducing market availability of essential medicines.

c) Supply-demand mismatch and loss of distribution flexibility across the EU

National or regional stockpiling strategies often do not align with actual care provider and patient needs or real-time demand fluctuations. This misalignment limits the ability of manufacturers to allocate medicines dynamically to where they are needed most, increasing the risk of both surplus in some regions and critical shortages in others. Inflexible stockpiling models therefore reduce the overall resilience and responsiveness of the pharmaceutical supply chain in future crises.

d) Reduced industry capacity to invest in supply resilience and public health priorities

The operational overload and financial demands of maintaining stockpiles, such as storage, monitoring, logistics, and shelf-life management, consume resources that could otherwise be allocated to support strategic investments in areas such as product development, regulatory innovation, or manufacturing capacity upgrades. For the generic medicine sector, which operates on volume-based models with low margins, this diversion of capacity directly undermines long-term investments and production sustainability.

3. BREAKING THE MYTHS

➔ I. *"Contingency stocks have helped reduce shortages"*

There is **no conclusive evidence** that stockpiling has reduced the number of reported shortages. On the contrary, data from the **Technopolis study commissioned by the European Commission**[7] confirms that most shortages are **localised and temporary** and can typically be offset by other suppliers without significant volume loss.

Moreover, **structural factors** such as **low supplier numbers** and rigid **national pricing policies** have a far greater impact on shortages. For example, the study *"Drug Shortages: Empirical Evidence from France"*[8] demonstrates that **lower medicine prices significantly increase both the likelihood and severity of shortages**, especially for multisource products with few suppliers. Concentrating stock in anticipation of future demand often leads to **waste or misallocation**, rather than greater resilience.

➔ II. "Contingency stock has helped increase manufacturing capacity"

Mandatory stockpiling is **not an effective strategy to increase manufacturing capacity**. Instead of supporting structural investment, it **immobilises working capital** and forces manufacturers to allocate resources to storage rather than production. Industry already maintains internal safety stock systems, but these are often **misunderstood by public authorities**, leading to duplication and inefficiency. Only 2 out of 10 companies increased manufacturing capacity as a result of stockpiling policies and reimbursement challenges linked to stockpiling mandates.[9]

The disconnect in definitions-between "stockpiling," "reserved inventory," and routine inventory control-has led to **poorly designed obligations** that overlook the economic and logistical constraints of generics production.

4. 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.

[8] Dubois, Pierre & Majewska, Gosia & Reig, Valentina, 2023. "Drug Shortages: Empirical Evidence from France," TSE Working Papers 23-1417, Toulouse School of Economics (TSE).

[9] Data sourced from Medicines for Europe's 2025-member survey on EU stockpiling.

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	
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.	**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.
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.	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.

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	
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.	**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.
Implement new sustainable pricing and reimbursement models for generic medicines that ensure healthy market competition, allowing companies to adjust prices based on inflation.	**Revise and adjust the application of national cost containment measures** that discourage generic medicine manufacturers from entering or staying on the market.

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.	**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.
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.	**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.**

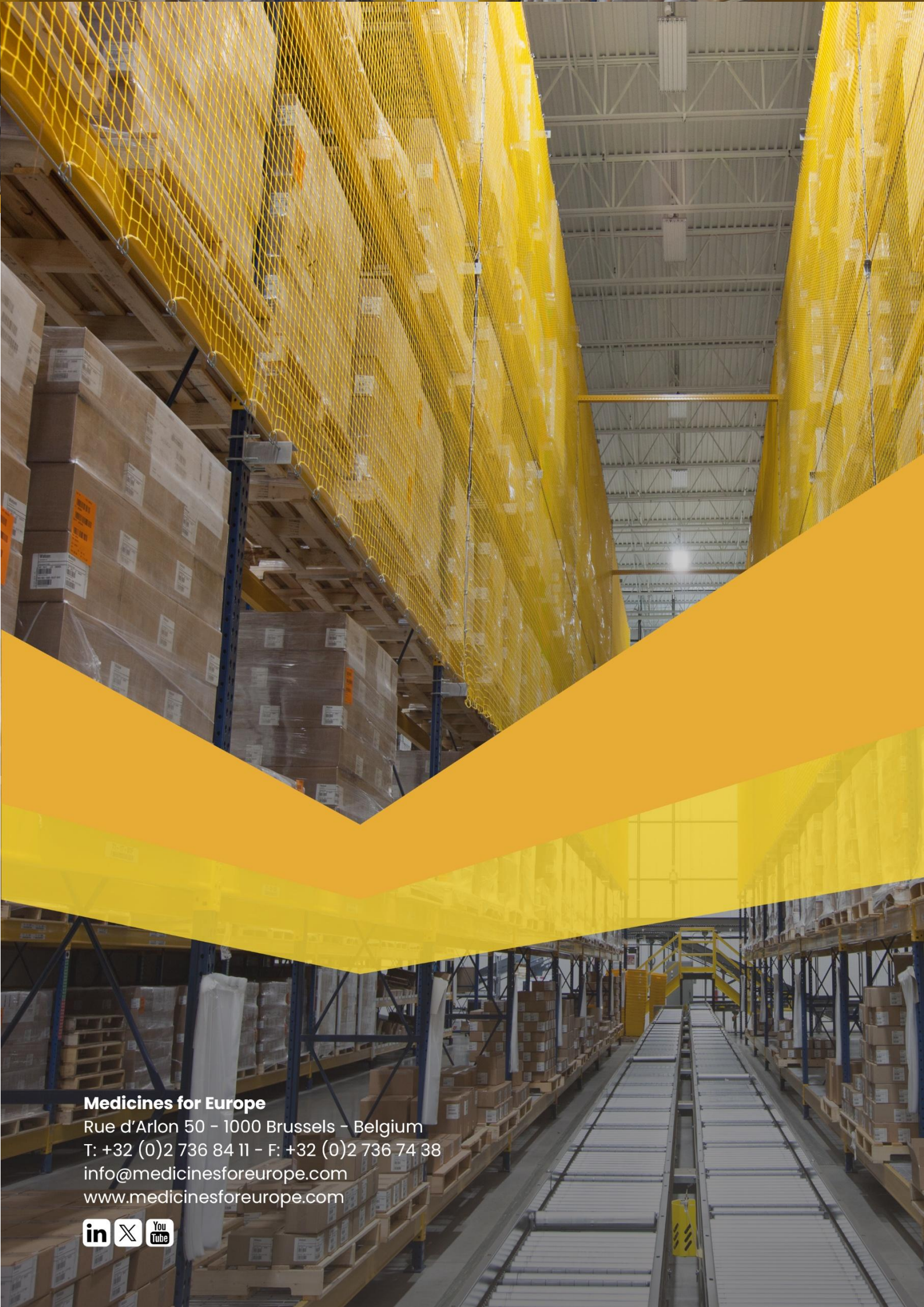
Preventing internal market disruption through stronger oversight of national stockpiling policies

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.



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