efpia

European Federation of Pharmaceutical Industries and Associations

MEDICINE SHORTAGES
EFPIA PROPOSAL FOR ACTION

December 2024





EXECUTIVE SUMMARY

The innovative pharmaceutical industry is dedicated to ensuring patients receive the medicines they need and supports EU-coordinated efforts to strengthen supply chains and prevent shortages across Europe. However, addressing supply issues is complex and requires tailored solutions. Challenges can arise from various factors, such as manufacturing constraints, limited capacity due to lengthy investment lead times, and unexpected surges in demand from public health emergencies, improved diagnostics, evolving medical practices, forecasting errors, or other factors diverting supply from the patients. Additionally, medicines have diverse production and supply needs; for instance, biological products, vaccines, and plasma-derived therapies often require specialized in-house facilities due to their technical demands. In recent years, EFPIA members have invested in making supply chains more resilient. Our global, geographically diverse network enables us to adapt production and deliver medicines where they are needed most.

RECOMMENDATIONS

Together, all stakeholders share a responsibility and commitment to building resilient supply chains that ensure patients receive the medicines they need. Authorities and regulators play a vital role in strengthening medicine supply security through effective, targeted policies that address the specific causes of shortages. By prioritising risk-based solutions, authorities can reduce administrative burdens and enable manufacturers to focus on delivering the right medicines to patients. Any measures considered should be risk-based, proportionate, sustainable, and provide efficient, workable solutions that serve public health needs. EFPIA calls for:

I. Develop a Harmonized EU Shortage Prevention and Mitigation System

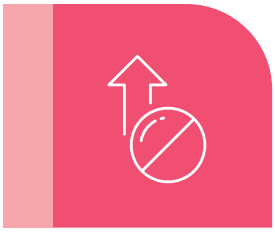
1. **Endorse a harmonized definition of shortage** (with supply and demand defined according to Article 2 of Regulation 2022/123/EU), **and reporting through an interoperable IT monitoring/notification system including the European Shortage Medicine Platform (ESMP) and the European Medicines Verification System (EMVS).** A harmonized shortage reporting system should maintain the notification period for temporary disruptions to two months.

2. Adopt a risk-based approach focused on a harmonized EU list of critical medicines **defined through a standardized methodology that evaluates therapeutic indication and availability of alternatives in a market.** For instance, **Shortage Prevention Plans (SPP) and Shortage Mitigation Plans (SMP) should be required only for critical medicines and harmonised at EU level** to optimise resources and focus the manufacturers' efforts on bringing medicines to patients. **Any measure intended to address shortage risks of critical medicines needs to recognise the specificities of each medicine and be tailored according to their characteristics.**

II. Improve Understanding and Transparency of Patient Demand and Drivers of Shortages

3. Improve transparency and understanding of demand through timely epidemiological data (from the European Centre for Disease Prevention & Control), and **regular and early dialogue with authorities to prepare the required supply.**

4. **Use of the EMVS for shortage prevention and monitoring of stocks.** The information stored in the EMVS provides real-time intelligence regarding the number of packs for all prescription products being supplied by manufacturers on the various Member States' markets, the number of packs dispensed in national pharmacies and hospitals, the number of packs exported (and/or imported), as well as on the level of stocks present in the supply chain at Member State level. Hence, if the security of supply is comprised in the distribution process, the solution to the issue is not in the manufacturing process.



III. Enhance Supply Security Through EU-owned Strategic Reserves and Regulatory Flexibilities

5. **Adopt contractual tools to increase the security of supply in the form of EU-owned strategic reserves that operate in alignment with the EU solidarity principle** **instead of** disproportionate and uncoordinated national stockpiling requirements that are detrimental to agile supply of medicines to meet real patient needs, and leverage EU solidarity mechanisms between Member States that would allow Marketing authorization Holders (MAHs) to quickly redeploy inventories, therefore avoiding uneven distribution of stocks.

6. **Enable timely and agile changes to manufacturing processes and the supply chain** to avoid unnecessary barriers and delays to change due to regulatory processes that can create or worsen shortages.

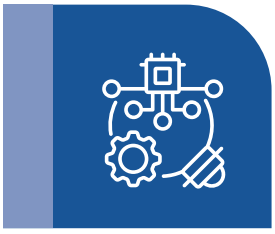
7. Leverage electronic Product Information (ePI) and other regulatory flexibilities to **facilitate the reallocation of medicine stocks** such as standardized EU/multi-country packs and labelling.

IV. Create an Environment that Strengthens EU Manufacturing & Commercial Base

8. **Reduce bureaucratic hurdles and adopt smart regulation**, while ensuring the transition to a level playing field in environmental and manufacturing standards does not disproportionately impact innovation. The duplication of data reporting at EU and national level is resource-intensive for regulators and the lack of interoperability limits the ability to react to real shortages.

9. Invest in existing manufacturing infrastructure and incentivize the future of new innovative medicines. **Incentives and investment need to be seen in a holistic approach, looking at the whole ecosystem including adjustments to be made to boost the EU competitiveness.** The recommendations should focus on ensuring the necessary framework conditions and market environment to drive investments in research, manufacturing, economic viability and commercial frameworks rather than calling for various types of subsidies and state aid instruments. The medicines under development today will be the critical medicines of tomorrow.

10. Adopt value-based procurement guidelines for innovative and generic medicines that consider broader criteria than price, including environmental endpoints and supply sustainability, for example, based on the Most Economically Advantageous Tender (MEAT) criterion, and ensure multiple winners, **while ensuring the implementation follows international competition rules.**



V. Enhance Global Supply Chain Resilience

11. Increase global supply chain resilience, **including by diversifying international supply chains, facilitating the movement of healthcare goods, regulatory cooperation and addressing upstream dependencies**, via partnership agreements with key trading partners. Further leverage existing bilateral tools such as Free Trade Agreements and Mutual Recognition Agreements on Good Manufacturing Practice, complemented by a holistic agenda on trade and health at the multilateral level (WTO).

THE MEDICINES MANUFACTURING JOURNEY

-36/18 months

-12 months

-6 months

-4 months
-4 weeks

Distribution

Forecasting & planning

Source raw, starting materials and other ingredients
Order starting materials
Plan manufacturing, distribution, transportation

Understanding which product we plan to deliver, when and where

Manufacturing

Prepare starting materials
Manufacture APIs and pharmaceutical products

Ensuring production capacity that will meet forecasted demand

Medicines become available in bulk and companies can still label and package bulk medicines to supply them where needed

Bulk medicines are allocated according to countries' needs

Packaging & labelling

- Medicines are prepared to be delivered to patients in accordance with country specific requirements (labels, packaging, reimbursement information and leaflets)
- Serial numbers are uploaded in the EMVS, corresponding to the number of packs being released for distribution in each Member State

Ensuring sufficient supplies to meet countries' demand.

Medicine released for distribution

Medicine is distributed to pharmacies, wholesalers, distributors, local health authorities
Hospitals and pharmacists scan the datamatrix on medicines' packs and the information is automatically registered in the EMVS

Distributing medicines and preventing counterfeit medicines entering the supply chain

Medicine available to patients

Pharmacies, wholesalers and distributors notify shortages to manufacturers and authorities

INTRODUCTION

The innovative pharmaceutical industry is committed to supplying medicines to the patients who need them and supports EU-coordinated efforts to improve the resilience of supply chains and reduce the risk of shortages at the European level.

Medicines supply chains are built to provide the right products, at the right place, time, and quantity. However, supply chains are complex and involve many actors. Marketing authorization holders (MAHs) implement a broad range of measures to reduce and mitigate supply chain risks. Ensuring the supply of medicines to patients who need them remains a core priority for EFPIA and its members.

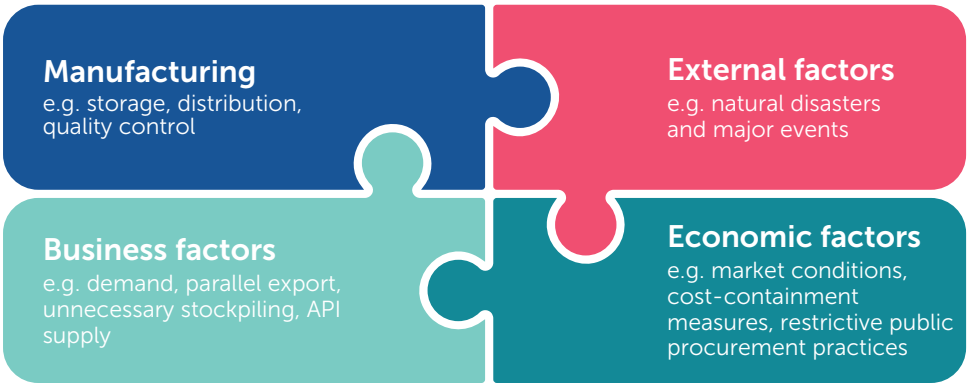
This paper summarizes the innovative pharmaceutical industry's proposals to minimize the impact of medicine shortages in the context of the revision of the General Pharmaceutical Legislation (GPL), the European Commission's (EC) Communication on Shortages, the multiplication of national-level stockpiling requirements, and the Critical Medicines Act, announced by the EC for March 2025. Addressing this multifaceted challenge requires a collaborative approach, with all stakeholders contributing to solutions and enhancing cooperation through regular dialogue.

Political context

The EU has been confronted with extensive medicine shortages over the past few years. The COVID pandemic unveiled the reciprocal dependency between EU and non-EU countries for the supply of key medicines and active pharmaceutical ingredients (APIs). Although the reasons for shortages are multi-factorial and complex, the focus has been on increased dependencies on a few countries for key strategic products. As this has gone up in the EU political agenda (fuelled by the increasingly complex and unstable geopolitical situation), it has also become an important focus of discussion among Member States, leading to a multiplication of uncoordinated national-level initiatives to increase national strategic autonomy in the pharmaceutical supply chain.

At the European level, the European Commission (EC) adopted Regulation (EU) 2022/123, which provided for a 'reinforced role for European Medicines Agency (EMA) in crisis preparedness and management for medicinal products and medical devices', and expanded its mandate to monitor and mitigate shortages at the EU-level. This was followed by the publishing of the Pharmaceutical Package revising the existing legislation on pharmaceuticals through a Directive and Regulation in April 2023. This proposal, referred to as General Pharmaceutical Legislation (GPL) in this document, introduces several measures to address medicines shortages. In October 2023, the EC published a Communication on addressing medicine shortages in the EU. The Communication presents several medium, and long-term initiatives to reduce and mitigate medicine shortages. Some of them have been implemented since, such as the publication of the Union List of Critical Medicines, the launch of the Critical Medicines Alliance, and the execution of a pilot exercise to assess the vulnerabilities of a set of critical medicines. The momentum created by these initiatives and the support from several Member States has led President von der Leyen to propose a Critical Medicines Act in her recent Political Guidelines for the next European Commission.

Causes of medicine shortages



Shortages predominately affect off-patent medicines:

Shortages of in-patent medicines account for **4% of all reported shortages**

Figure 1: *Shortages affect both innovative and generic medicines - yet only 4%[1] of them occur for patented products. The root causes of supply shortages vary from case to case and are often multiple.*

Modern medicines encompass a wide spectrum, from small molecules to large, complex biologics, vaccines, and other biologicals, each with distinct characteristics and development needs. Several steps are required to take the right therapies to the right patients. Medicines available in hospitals and pharmacies today begin their journey up to 36 months before, when manufacturers start planning production based on demand forecasts. Then, the right raw and starting materials need to be sourced, and the manufacturing, distribution, and transportation needs to be planned. Hence, it is important to understand, from an early stage, which products need to be delivered, in what amount, when, and where. The manufacturing process usually starts 6 to 12 months before the therapy reaches the patients. Some products require much longer lead times, such as large molecules or complex multivalent vaccines (18 to 36 months)[2]. Hence, manufacturers need to ensure that the production capacity will meet the forecasted demand. Therefore, it is critical to have adequate local patient demand information.

The internal market rules are a fundamental pillar for the EU. They allow medicines to be freely moved across the Union; however, in case of demand forecast, MAHs do not have any visibility on whether products supplied in one country will be later allocated to a different country from other actors in the supply chain.

Medicines are then packed and labelled according to the destination country's specific requirement and then distributed to hospitals, local pharmacies, wholesalers, distributors, or local health authorities. The principle of EU solidarity is fundamental to facilitate the adequate allocation of medicines - without national safety stock restrictions- where patients need them. Hence, the need to change from national to one EU approach where collaboration with the industry is key.

The report, Future-proofing pharmaceutical legislation[3], commissioned by the EC, sheds light on the root causes of medicine shortages in Europe, the main ones being quality and manufacturing issues, followed by commercial reasons, unexpected changes in demand, and regulatory issues. However, according to a recent internal survey by EFPIA, it was found that the most frequent root causes of medicine shortages in the 2022/2023 period were unexpected increased demand, followed by manufacturing and quality issues.

1 *IQVIA Shortage Transparency Platform Beta Version, status as per 17.Feb. 2023*

2 *https://www.vaccineseurope.eu/media-hub/position-papers/vaccines-europe-analysis-of-vaccine-production-lead-times/*

3 *https://op.europa.eu/en/publication-detail/-/publication/1f8185d5-5325-11ec-91ac-01aa75ed71a1/language-en*

INDUSTRY'S ACTIONS TO STRENGTHEN SUPPLY CHAINS

Pharmaceutical companies demonstrated the resilience of their global supply chains during the COVID-19 pandemic by:

- Enhancing their manufacturing and supply capacity for the required essential medicines in reduced periods,
- Triggering pandemic preparedness plans, and
- Cooperating and coordinating with the relevant health authorities,
- All while operating with little visibility of real demand

What makes supply chains resilient?

Resilience: A system's capacity to withstand, adapt, and recover from disruptions while maintaining routine functions.

Transparency
on demand allows to plan timely

Global supply chain
allows to mitigate risks through diversified sourcing and cross regional back up

Flexibility
allows to adjust capacity and allocate medicines to the countries that need them with agility

Digitalisation
allows to better FORECAST needs and demand; detect risks and shorten response

Manufacturers are committed to maintaining the supply of medicines to patients in need and are therefore continuously implementing measures to reduce potential supply disruptions, when possible and appropriate. These include:

- **Demand forecast and stock management:** Investing in advanced technology and capabilities to forecast demand and management of stocks.
- **Quality management:** Advancing good manufacturing practices, increasing quality management maturity of individual manufacturing facilities, and strengthening internal operating procedures to reduce risks inherent to any step of the manufacturing process. Usually, **our sector relies on in-house manufacturing or on closer relationships (long-contractual agreements) with API suppliers[4],** which reduces the risk of disruptions significantly.
- **Proactive risk management:** Using multiple sources for raw materials wherever appropriate to ensure that alternative sources are immediately available, adopting supply continuity plans, updated business contingency plans, and fit-for-purpose shortage prevention plans.
- **Leverage technology:** Leveraging science and digital to improve internal quality, safety, and manufacturing processes to increase and optimize capacity.
- **Active engagement:** Engaging in an active dialogue with authorities to improve the security of supply.

4 *According to internal EFPIA surveys with member companies*

WHAT CAN THE EU DO? PROPOSALS FOR ACTION

We all have a responsibility to ensure supply chains are resilient. Authorities and regulators can enhance the security of medicines supply through effective policy implementation. However, **policy solutions need to be fit for purpose, targeting the specific root causes of shortages**. Manufacturers' resources should be spent on getting the right medicines to patients, not on bureaucratic processes. Any measures considered should be risk-based, proportionate and provide efficient, workable solutions that serve public health needs.

In the context of the current initiatives by the EU and Member States' authorities and based on the key issues highlighted by the COVID-19 pandemic[5] that need to be addressed to minimize any shortages of critical medicines, we propose the following policy recommendations:

I. Develop a Harmonized EU Shortage Prevention and Mitigation System

The development of a harmonized EU shortage prevention and mitigation system, based on a standard definition of medicine shortages, a common methodology to identify critical medicines, and an interoperable IT European monitoring/ notification system.

1. Endorse a harmonized definition and reporting of shortages through an interoperable IT monitoring/notification system

Regulation (EU) 2022/123 provides for a more exhaustive definition of 'Shortage', including a reference to 'Supply' and 'Demand' (see box below).[6] In order **to ensure a consistent and workable definition of medicine shortage in all Member States, the definitions of shortage, supply, and demand must be incorporated into the new Regulation for the GPL** to enable coherence with the other regulation as well as data exchange and comparison.

'Shortage' means a situation in which the supply of a medicinal product that is authorized and placed on the market in a Member State does not meet the demand for that medicinal product in that Member State, whatever the cause. **'Supply'** is the total volume of stock of a given medicinal product that is placed on the market by a marketing authorization holder or a manufacturer. **'Demand'** is the request for a medicinal product by a healthcare professional or patient in response to clinical need; the demand is satisfactorily met when the medicinal product is acquired at in appropriate time and in sufficient quantity to allow continuity of the best care of patients.

Support for the **linkage between EMA's European Shortages Monitoring Platform (ESMP) and the European Medicine Verification System (EMVS)**. The interoperability with the EMVS will provide time data to assess the dimension of a shortage (national or EU) and will make it possible to identify evidence-based and targeted

5 The five key issues are 1) The importance of a preparedness plan for critical medicines and the need for regulatory flexibility; 2) The need for understanding and transparency of patient demand at national/subnational level; 3) the need for timely (current and forward looking) epidemiological data; 4) the need for transparency of the supply chain; and 5) the need for solidarity between Member States.

6 https://eur-lex.europa.eu/eli/reg/2022/123/oj

solutions to tackle the issue. The information stored in the EMVS provides timely intelligence regarding the number of packs for all prescription products being supplied by manufacturers on the various Member States' markets, the number of packs dispensed in national pharmacies and hospitals, the number of packs exported (and/or imported), as well as on the level of stocks present in the supply chain at Member State level.

In addition, **a harmonized shortage reporting system should include a two-month notification period for temporary disruptions,** rather than extending it to six months as companies cannot reliably predict issues so far in advance. Longer notification periods will flood the system with unnecessary reports, masking real shortages. Instead, standardizing the definition and reporting of supply interruptions across the EU will streamline efforts to address actual shortages. Additionally, when alternative pack sizes of the same product are available, notifications should not be required to prevent unintended shortages due to medicine hoarding.

2. Adopt a risk-based approach focused on Critical Medicines

A harmonized list of critical medicines at EU-level can strengthen a consistent and coordinated EU-wide approach by aligning methodology, clinical relevance, and market coverage. Supply constraints, however, vary across therapeutic areas and manufacturing processes, so tailored measures are essential. MAHs, other supply stakeholders, and authorities must collaborate to address these challenges holistically. **A unified definition of Critical Medicines, established at both Member State and Union levels through a standardized methodology that evaluates therapeutic indication and availability of alternatives, will further enhance consistency across a single Union list of Critical Medicines.**

However, not all critical medicines are the same, and a 'one size fits all approach' is neither future-proof nor adapted to the realities of innovative medicines. Radionuclides, ATMPs, plasma-derived, and vaccines, which could become the critical medicines of the future, cannot be placed in the same basket as other traditional/mature products. Their manufacturing, storage, and transportation require specific conditions that limit the implementation of traditional measures used to mitigate shortages (i.e. stockpiling).

Furthermore, EFPIA supports the development of a **fit-for-purpose shortage prevention plan (SPP) and shortage mitigation plan (SMP) limited to critical medicines to ensure effective shortage management**. Requiring these plans for non-critical medicines would divert resources and funding for the mitigation of critical medicines. Data for the SPP and SMP should be aligned with the ESMP requirements to ensure consistency.

II. Improve Understanding and Transparency of Patient Demand and Drivers of Shortages

Improved transparency across the supply chain has the potential to increase resilience and prevent shortages. Leveraging data available from the European Centre for Disease Prevention and Control (ECDC) and other systems such as the National Medicines Verification Systems (NMVS), IRIS, SPOR and other sources into the European monitoring system will dramatically expand authorities' visibility and thereby their capacity to take appropriate action.

3. Improve transparency and understanding of patient demand, through timely (current and forward-looking) epidemiological data and regular and early dialogue with authorities

Increased transparency and understanding of patient demand, through timely (current and forward-looking) epidemiological data: the ECDC should aim for the timely release of modelling data covering the needs of patients, National immunization Programmes, and hospital capacity in the Member States. This should also combine any such forecasting data with real data on usage (medicines consumption and vaccine administration), and other relevant data that can provide information on supply. **Regular dialogue with authorities is key to preventing situations where MAHs are requested to provide additional supplies of medicines with little to no time in advance.**

4. Use of the European Medicines Verification System (EMVS) for medicine shortage prevention and monitoring of stocks

As mentioned in Recommendation 1, **the data stored in the EMVS could also provide timely intelligence regarding the number of packs for all prescription products supplied by manufacturers on EU markets**, the number of packs dispensed in national pharmacies, the number of packs exported (and/or imported), as well as the level of stocks present in the supply chain at country level. The real-time information in the EMVS data repositories can be analysed according to very granular timeframes (per day, per week, per month, etc.) as well as per region (postal codes). Wholesalers and traders, as well as national competent authorities, have access to the data stored in National Medicines Verification Systems. A shared analysis of the EMVS data could be part of a regular dialogue between EU and national competent authorities, MAHs, and other supply chain stakeholders. This would allow collaboration to anticipate and effectively address supply chain-related issues. The notification process entails promptly informing authorities about the occurrence and extent of shortages, including relevant details such as affected products, anticipated duration, and potential causes. Transparent notification of shortages enables regulatory bodies to assess the situation comprehensively and implement timely interventions to mitigate the impact on patients (i.e. using the EMVS system to track real-time supply issues).

III. Enhance Supply Security Through EU-own Strategic Reserves and Regulatory Flexibility

EU-coordinated efforts are necessary to improve the resilience of supply chains and reduce the risk of shortages. Policy solutions need to be fit for purpose, targeting the specific root causes of shortages. The use of safety stocks should be proportionate and only used in exceptional cases, adopted with the necessary regulatory flexibilities.

5. Adopt contractual tools to increase the security of supply in the form of EU-own Strategic Reserves

Safety stocks are only one of many strategies to prevent shortages and should be tailored to respond to specific and actual risks to ensure sustainability. Stockpiling is the less efficient measure to take to prevent and mitigate shortages. As well explained by EMA, "*The stockpiling of medicines results in a disrupted supply chain. Stockpiling can prolong the duration of a shortage, precipitate a shortage or result in an inequitable distribution to patients*."[7]

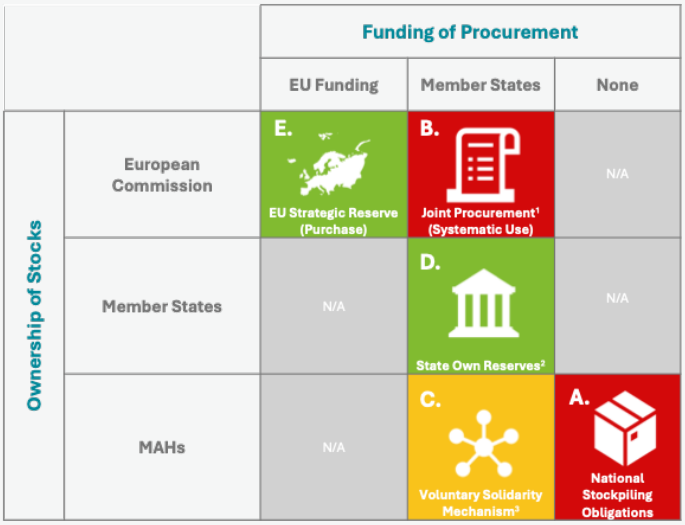
Safety stocks should be proportionate and only used in exceptional cases, **focusing on critical medicines with a high risk of vulnerability in their supply chains, when other measures cannot be applied. The size of safety stocks must be proportionate to the specific risks and needs of a medicine**. Like in any other industry, manufacturers generally manage safety stocks to absorb fluctuations of demand and supply, except for medicines produced on a make-to-order basis due to their technical requirements (plasma-derived, radionuclides, several ATMPs, etc).

However, stockpiling fails to address the real root causes of shortages and may create a false sense of security about medicine availability in cases of shortages. **Disproportionate national stockpiling requirements can be detrimental to the real needs of other countries, particularly if those safety stocks are blocked and multiple countries enforce them simultaneously.** If the current trend of national stockpiling requirements across the EU continues, it could have serious unintended consequences for patient access, both in Europe and globally.

Therefore, if policymakers see no other option but to adopt safety stocks, this should be done at a European level in alignment with the solidarity principle, **instead of** disproportionate national-level requirements and not layering them together. **European safety stock policy, in the form of contractual EU-owned strategic reserves (see Figures 2 and 3), is more efficient than national-level requirements, minimizing costs and optimizing**

7 *Good practices for industry for the prevention of human medicinal product shortages, page 12, recommendation 9.*

supply allocation through cross-border flows. European strategic reserves should be flexible (i.e. multi-country packs) to move stock to where patient demand is and not overlap with national stockpiles. Only then can stocks help to increase supply chain resilience.



A. National Stockpiling Obligation: Legally bound requirement where manufacturers assume the cost of the stock at the expense of fines or other forms of penalties, which are usually triggered when the stock is below a specific threshold. Stocks are usually required in a finished form and, in the worst cases, bound to be kept within the borders of a Member State. This form is less practical and most likely to produce negative consequences to patients in other countries.

B. Joint Procurement of Stocks: Procurement of stocks organised by multiple countries or through EU-level authorities where the participation of countries should be voluntary. The ownership of the stocks belongs to the procurement body and is usually placed in one or multiple countries (purchasing countries). However, joint procurement is not an instrument that necessarily leads to greater predictability in consumption. There have been instances where forecasted demand through joint procurement did not align with actual uptake, resulting in disagreements between the parties involved.

C. State Procurement of Manufactured-Own Stocks: Legally bound requirement where Member States secure the purchase the stocks while being kept by the manufacturer. This form of stock management fits the purpose of the Voluntary Solidarity Mechanism (VSM). However, stocks should be kept at unfinished/ bulk level to facilitate their distribution. Early dialogue with manufacturers is essential for adequate management of the stocks and quick response in case the VSM is needed.

D. State Own Reserves: The procurement of stocks is done through individual Member States and the stocks are owned by them. This form of stock management facilitates the predictability of demand for manufacturers and, as long as enough manufacturing lead time is considered, it doesn't create additional burdens. This form is also eligible for VSM if implemented together with regulatory flexibilities (i.e. ePI and EU packaging).

E. EU Own Strategic Reserves: The procurement and ownership of stocks belong to the European Commission. A strategic reserve is a contract between manufacturers and the Commission rather than a legally bound requirement. The stocks are kept in one or several EU/EEA countries and are estimated according to the countries' needs.

Figure 2: *EFPIA's mapping of forms of ownership and funding of procurement of stocks. 1. Only acceptable under exceptional circumstances. 2. Eligible for VSM. 3. Need for early dialogue with MAH.*

EFPIA PRINCIPLES FOR SAFETY STOCKS

In the cases where safety stocks were considered an appropriate tool to prevent/mitigate shortages, EFPIA recommends the following conditions:

Funding and Ownership

Safety stocks should be kept either through EU-owned Strategic Reserves or State-owned Reserves, with a preference for the former. Stocks should be purchased by stockpiling contractors rather than be required by a legally bound obligation which would only exacerbate shortages. In either option, the stocks are usually kept at Member States' facilities. However, if stocks are managed by the manufacturers, the cost incurred should be paid by governments, as costs for creating and maintaining stockpiles are substantial (i.e. storage capacity, often in strict cold-chain conditions + resources to manage rotations).

Scope

Critical medicines which have been subjected to a proper assessment and whose supply chain has been deemed to have a high risk of vulnerability. However, it should exclude certain categories of products like, for example, immunization therapies, some vaccines and plasma-derived products, personalised medicines or products with fast-track approval, because of their manufacturing/distribution specificities.

Volume

The volume of stocks required should take into account the totality of stock available in the distribution chain (use of EMVS to understand the size and location of stocks). The number of months' worth of stocks needs to be discussed in relation to expected or projected demand, based not only on epidemiological data but also on clinical practice and contractual obligations for every supplier (tender win or exclusion from the market). **It should be realistic and feasible, depending also on the shelf-life of the product.**

Presentation

Finished or unfinished level depending on the stock ownership.

- If there is no option, and the stock is held by the manufacturer, it should be produced in a minimum number of presentation(s) only (which become the "reference products"/correspond to the biggest country/ countries to keep inventory flowing smoothly).
- In the case of EU-owned Strategic Reserves, a single presentation should be used to facilitate distribution, particularly in times of crisis.

Standstill

EU-owned Strategic Reserves must be associated with a standstill on national measures (no additional national requirement on top of EU requirements).

Stock level

Regardless of the form of ownership, in particular if there is a national stockpiling requirement, it is agreed that at any given time, **the actual stock can be below the target stock without penalties, taking into consideration that safety stocks may need to be consumed during a shortage in a given Member State**. In this case, the manufacturer will do its utmost to replenish it as soon as possible. As a principle, safety stock is there to be used when needed, hence, at a given time, the **stock can be below the target for a time before being replenished**. Managing a safety stock needs consumption of capacity to be sustainable.

Time to build

Sufficient lead times to allow the build-up of stockpiles without jeopardising supply to other countries around the globe.

Flexibility

It is imperative that authorities facilitate the use of reference products in other countries, enable flexible changes to the manufacturing supply, adopt ePI, and tend to a standardized EU/multi-country package. As well as the flexibility, according to the solidarity principle, to allocate the stocks where needed without penalties (if held by manufacturers) that strain the supply chains.

Stock management/off-loading

Mechanisms need to be put in place to ensure timely rotation & avoid wastage. Stocks also need to be carefully managed to ensure that the product is maintained in good condition.

Roles and responsabilities

Rules clearly defined between stakeholders and appropriate communication flow to be able to address specific circumstances. Furthermore, there is a need to clarify the use of unregistered products.

Figure 3: *EFPIA's principles for safety stocks.*

As a way forward, EFPIA calls for a Critical Medicines Act to end national stockpiling requirements at finished product level and, as alternatives:

- To ensure that safety stockpiles are effective and proportional to their purpose, establish minimum thresholds for the entire EU region, including specific thresholds by product category according to the identified vulnerabilities of critical medicines' supply chains; and
- Leverage EU solidarity mechanisms between Member States that would allow MAHs to quickly redeploy inventories, therefore avoiding uneven distribution of stocks.

6. Enable timely and agile changes to manufacturing processes and supply chain

Authorities should enable changes to manufacturing processes and the supply chain to avoid unnecessary barriers caused by regulatory requirements that can create or worsen shortages. **It is crucial to ensure that changes are enabled by flexibility in terms of quality evidence and processes**, particularly for biological products. Enabling changes is essential to enhance supply security, in particular if coordinated internationally (such as via ICMRA PQKMS and EMA reliance).

7. Leverage ePI and regulatory flexibilities

The use of electronic Patient Information (ePI) would allow greater flexibility and faster allocation of supplies to the countries that need medicine and contribute to the reduction of shortages. A pragmatic implementation is needed, starting with a quick transition from paper to electronic product information for products administered by healthcare professionals (HCPs), including vaccines in light of multiple positive pilot experiences already in place. The use of ePI will also provide patients with the most updated information in real-time. Flexibilities should facilitate the reallocation of medicines stock from one Member State to the other while avoiding resource-consuming repackaging/relabelling. For example, adopting standardized EU/multi-country packs and harmonising labeling would increase resilience by enabling companies' abilities to distribute medicines.

IV. Create an Environment that Strengthens EU Manufacturing & Commercial Base

To incentivize the pharmaceutical industry to manufacture critical medicines within the EU, it is essential to explore both solutions derived from EU legislation and innovative approaches. These efforts should not only encourage the production of medicines but also support the maintenance of the existing value chain capacity in Europe. Additionally, these measures must consider and support a balanced implementation of the EU Green Deal through a resilient supply chain transition plan based on robust science, ensuring a level playing field in environmental and manufacturing standards without disproportionately impacting innovation.

8. Reduce bureaucratic hurdles and adopt smart regulation (balance implementation of the Clean Industrial Deal)

In line with EFPIA's Competitiveness Strategy for European Life Science, better regulation is crucial. Actively identifying and implementing measures to **reduce bureaucratic hurdles that impede innovation and efficiency is essential**. This includes optimizing existing structures, simplifying administrative processes and reporting requirements, enhancing regulatory clarity, and promoting faster approval timelines for Life Sciences R&D and manufacturing projects. Special attention should be given to implementing the green and digital agendas to ensure that these transitions occur alongside improved innovation capacity and sector competitiveness. Furthermore, EFPIA supports a balanced implementation of the Clean Industrial Deal. This means a resilient supply chain transition plan based on robust science that ensures a level playing field in environmental and manufacturing standards and doesn't disproportionately impact innovation. To that end, specific measures should be reconsidered given their negative or disproportionate impacts. This includes the Urban Wastewater Treatment Directive (UWWTD), and the proposed ban on the use of PFAS for medicine production.

Hence, a Critical Medicines Act should provide that competent authorities responsible for enacting, implementing, and enforcing provisions of existing and future EU legislations on food, chemical, and environmental protection conduct an impact assessment evaluating to what extent these provisions affect the security of supply of critical medicines in the EU. This assessment should be complemented at national level with an evaluation of the impact of economic policies, such as cost-containment measures, on the sustainability of supply.

9. Invest in Existing Infrastructure and Incentivize the Future

Ensure that recommendations aiming at reshoring manufacturing of critical medicines in the EU also aim at i) supporting positive conditions for existing EU manufacturing and ii) incentivizing future manufacturing of new innovative (critical) medicines in the EU. This means attracting investment in modern manufacturing and supporting infrastructure through smart regulation, in line with the Draghi report's call to increase and focus R&D investment.[8]

Any future legislation (i.e. Critical Medicines Act) geared towards increased localisation of production of essential medicines (not necessarily innovative) in the EU should carefully consider its impact on global supply chains as it could distort the global market in several ways.

10. Adopt Value-based Procurement Guidelines

EU value chains of critical medicines should be reinforced through the adoption of value-based procurement guidelines that consider broader criteria than price, including environmental standards and supply sustainability. The EC should develop and monitor the implementation of European guidelines on public procurement in all EU Member States based on the 'Most Economically Advantageous Tender (MEAT)' criterion and ensure multiple tender winners. However, this should not lead to pricing, reimbursement, and procurement policies conditional upon supply security or EU manufacturing. These measures not only do not comply with EU/World Trade Organisation (WTO) rules and EU commitments via many Free Trade Agreements (FTAs), and also diminish EU competitiveness.

V. Enhance Global Supply Chain Resilience

As far as innovative medicines are concerned, Europe's supply chain for most innovative products is not strategically dependent on developing countries but requires a global supply chain.[9] As the EU is the largest exporter of finished medicines globally,[10] patients across the world depend on Europe for the supply of medicines. Given this and a challenging geopolitical backdrop, it is important to collaborate internationally to support and increase global supply chain resilience.

FTAs and Mutual Recognition Agreements on Pharmaceutical Good Manufacturing Practices (GMP MRAs) remain important tools. At the multilateral level, a holistic WTO agenda on trade and health would complement bilateral partnerships. Tariffs on medical goods, including upstream inputs, have a cumulative negative impact -increasing the cost of production and reducing patient access[11] - so policymakers should commit to reducing or not imposing them.

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9 EFPIA (2020). EU strategic resilience in pharmaceuticals: global value chains and innovation. Available at: https://www.efpia.eu/news-events/the-efpia-view/blog-articles/eu-strategic-resilience-in-pharmaceuticals-global-value-chains-and-innovation/

10 https://oec.world/en/profile/hs/pharmaceutical-products

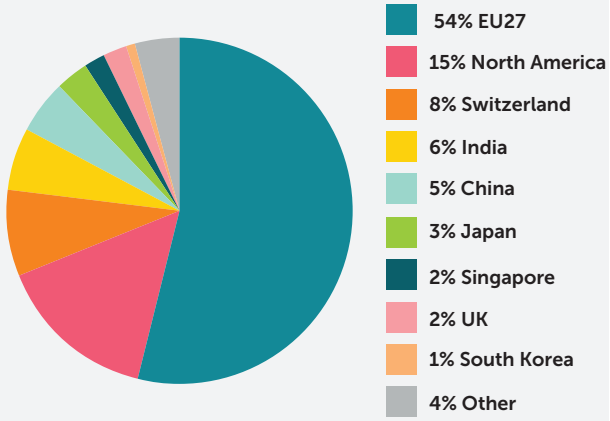
11 https://geneva-network.com/research/how-tariffs-impact-access-to-medicines/

One key positive strategy to support resilience is by **diversifying international supply chains, facilitating the movement of healthcare goods, and regulatory cooperation,** via partnership agreements with key trading partners (e.g. the United States, United Kingdom, Switzerland, Japan, Korea, Canada). Any criteria to evaluate and prioritize potential partners for diversification should build on existing EU agreements, the scale of trade in medicines with the EU, and support fair competition and a level-playing field.

€363 billion (EFPIA total):
The value of pharmaceutical production in Europe in 2022

€158 billion:
Trade surplus of medicinal and pharmaceutical products in 2023*

64% of APIs are manufactured in Europe (EU-27, Switzerland, UK)**



** EFPIA, The Pharmaceutical Industry in Figures, 2024, https://efpia.eu/media/2rxdkn43/the-pharmaceutical-industry-in-figures-2024.pdf*

*** EFPIA survey conducted in April 2021. Number of APIs (biological and chemical) sourced or manufactured per region of origin (irrespective of value/volume). A total of 16 EFPIA member companies submitted their input to the survey referring to in-patent and off-patent medicines*

11. Diversify international supply chain partnerships

In line with the recommendations in the Draghi Report,[12] **the EU should seize the opportunity to develop strategic international partnerships to solidify and bolster the EU's international trade position in pharmaceuticals** with countries including the US, in wider Europe, and in the Asia-Pacific region. Partnerships should focus on key objectives and shared commitments including:

- **Facilitating cross-border movement of medicines and vaccines:** Trade partners are needed to ensure medical goods and inputs are available when needed and that products reach patients faster in a crisis
- **Removing barriers to trade:** Lowering trade barriers can open markets in other countries by creating a level playing field for products. Reducing or eliminating tariffs on medical goods supports internationally integrated supply chains.
- **Regulatory cooperation:** Convergence efforts between regulators should facilitate patient access and remove friction and costs. This includes expanding the scope of some existing EU MRAs and negotiating new MRAs with partner countries with strong GMP standards (i.e. United States, United Kingdom, Turkey) in order to support resilience.
- **Diversifying supply networks:** Supporting companies' abilities to diversify production through various measures.
- **Safeguarding innovation:** Future-proofing resilience means sharing lessons on skills development and technological advances in production and supply, including AI and data use. It also means collaborating against negative practices such as forced technology transfer.
- **Upstream dependencies:** Collaborating on raw materials and equipment to address shared risks for supply chain vulnerabilities. Manufacturers can adapt capacity but without addressing upstream vulnerabilities, there is a higher risk of disruptions in supply chains.

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There is no simple solution, and the way forward consists more of a blend of adjusted measures than a one-size-fits-all approach. Any future policy solution needs to be designed and implemented proportionally to the risk, giving due consideration to the unintended effects brought by the measure and above all supported by strong evidence on the nature of the shortage. Furthermore, any recommendation needs to reinforce both companies' ability to supply patients and the industry's competitiveness. This is a delicate balance to achieve in a complex milieu where information is scarce, and where any well-intended measure also has the potential to hinder access of patients to medicines.

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