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Medicine shortages and national stockpiling requirements in the EU

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Executive Summary

- Stockpiling is not a solution to medicine shortages.
- Extensive, uncoordinated and disproportionate national stockpiling requirements have unintended consequences:
    - Additional costs and complexity for manufacturers reduce the economic viability of low price and/or low volume medicines, aggravating market consolidation, increasing the risk of shortages and threatening patient access to medicines.
    - Prevent manufacturers from reallocating stocks from one EU member state to another to mitigate a shortage because stockpiles can only be used in that national market. Medicines are manufactured to serve patients not hoarding.
    - Create a false sense of security about the ability to mitigate a major shortage. During the Covid-19 pandemic, the demand for certain intensive care unit medicines increased by 900%, the paediatric amoxicillin surge in 2022-23 increased demand by 500%. Only a rapid reaction by manufacturers combined with regulatory flexibility can tackle this level of demand surge.
- The European Commission should strengthen its monitoring of national measures and regulate disproportionate national stockpiling across the EU and as required by the EU Internal Market. National stockpiles are clearly aimed to hoard medicines at the expense of EU solidarity for patients.
- Instead of stockpiling, the EC and Member States should tackle the root causes of medicine shortages by:
    - Reducing regulatory complexity through streamlining, and digitalisation to improve stock re-allocation across the EU by MAHs. This includes systemic regulatory simplifications and flexibilities in packaging and labelling (harmonisation of pack sizes and replacement of the paper leaflet by an e-leaflet), use of epidemiological data to forecast demand, and the use of the European Medicines Verification System by the national authorities for supply and demand monitoring. The latter would also improve the visibility and predictability of market needs, allowing manufacturers to better prevent and mitigate shortages.
    - Strengthening generic medicine markets through medicines pricing and procurement reforms and including security of supply criteria to national pricing and reimbursement policies to create healthy competition, economic sustainability, market stability and predictability.
- Solidarity-based initiatives, such as the European Voluntary Solidarity Mechanism, when implemented well, can provide a viable alternative in emergency situations.

Strategic reserves at European level co-funded by the EU and Member States, could play a beneficial role in mitigating shortages in emergency situations, while avoiding distortion of the normal functioning and sustainability of national markets. To be successful, the EU Strategic Stockpile mechanism needs to have clear rules for use and be based on industry recommendations for good stock management practices, aligned with the principle of EU solidarity, and be economically sustainable.

1. 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 supply chain disruptions, pharmaceutical companies implement various internal inventory policies (contingency stocks of critical materials needed to provide for demand variations) that cover API, bulk and finished products as part of their strategy to guarantee the security of supply.

At the same time, in their attempts to prevent and mitigate stockouts, many European authorities are **introducing extended, unpaid stockpiling obligations** on Marketing Authorisation Holders (MAHs) in their respective markets. The most recent example is the introduction of a 6-month stockpiling obligation for medicines in Germany.

In response to the pressing challenge of medicine shortages, the Medicinal Product Supply Shortage Control and Improvement Act (ALBVVG) was adopted in Germany on 27th July 2023. This legislation introduces a significant stockpiling obligation, compelling marketing authorisation holders (MAHs) participating in discount contracts for off-patent medicines to maintain a six-month supply for the German market. This regulation will divert essential medicines, such as life-saving antibiotics, from covering the needs of patients in other EU Member States toward German stockpiles. The increase in stocks reserved for the German market would seriously affect the availability of (often lifesaving) medicines in other Member States, in particular in CEE countries, which are already experiencing difficulties in securing sufficient supplies. In the case of antibiotics, German annual consumption, together with the 6-month stockpile would amount to the annual consumption in 11 EU countries combined - Bulgaria, Poland, Romania, Croatia, Czech Republic, Estonia, Latvia, Lithuania, Hungary, Slovakia and Slovenia.[1] That is equivalent to one quarter of the total consumption of the whole EU. As an illustrative example, to fulfil this stockpiling requirement, antibiotic manufacturers need to increase production by 120%, resulting in antibiotics for the German market dominating the 45% of the total volume consumed in Europe. Increasing production by that much is not feasible when manufacturers are already producing at maximum capacity. The only option is to allocate existing manufacturing capacities towards Germany, creating supply risks for other European markets, making this a beggar-thy-neighbour policy, and thereby leading to unintended and disproportionate costs, making the market conditions even worse.

Regrettably, Germany is not alone in its attempts to secure a stock of medicines for its own market at the expense of neighbouring countries. Table 1 below provides an overview of various safety stock obligations imposed on supply chain operators in Europe, highlighting the diverging national stockpiling requirements currently in place.

[1] Based on IQVIA data calculations on market share.

Table 1 Safety stock obligations imposed on supply chain operators in the EU.

Types of safety stock requirement	Country and details
None	**Ireland, Italy, Slovenia**. Although there is no formal requirement to stockpile, the MAH is subject to strong availability requirements (safety stock obligations) in **Slovakia** and **Lithuania**. New stockpiling obligations are under preparation in **Austria**, which would require MAHs to ensure a safety stockpile of around 50 substances for 4 months.
On a permanent basis (imposed on the MAH)	The current national safety stock requirements in **France** call for the MAH to build up a stock of at least four months' supply for medicines qualifying as medicines of major therapeutic interest (see more info in Annex 1) In **Finland**, authorities manage and financially compensate the mandatory reserve supplies held by pharmaceutical companies for 1500 products. Since July 2020, the medicines must be stocked in Finland, and the stock size corresponds to sales for 3-, 6- or 10-months' use (referring to the sales in the previous year). In **The Netherlands**, a safety stock of 2.5 months for all prescription-bound medicines, of which 6 weeks at the supplier and 4 weeks at the wholesaler is proposed (Annex 1). In **Portugal**, companies must keep a 2-month stock of medicines and 4-month stock of critical medicines for which the MAHs are allowed to increase the price to the highest price in the reference countries and are exempted from paying regulatory fees (Annex 1). According to the National Economic Supply Act in **Switzerland**, The Federal Council may require stockpiling of certain essential goods after agreement with the companies (corresponding to 3 to 4 months average sales). **Germany:** pharmaceutical companies must keep a 6-month stock for medicines that enter discount agreements. **Czech Republic:** companies must keep a 1–2-month supply of all medicines (including reimbursed medicinal products). MAHs will also have to provide products that have a fixed payment from the public health insurance or a maximum price, for the needs of patients in the Czech Republic. **Austria** (from 25.02.2025): MAHs are obliged to keep a 4 month of average demand of stock, based on the Austrian active ingredient list (i.e., 48 APIs, 721 KPU – 63% generics). The demand is based on a monthly average for the last 12 months (quantity delivered). There are exemptions to cover an increased demand (25%), if an export ban is put into effect, in case of a force majeure, if the MA is terminated, and in case of restriction by BASG. There are also annual quantity reporting obligations, also in case of falling short of the required shortage quantity. **Poland**: For all reimbursed products in retail 3-month stock obligation
General obligation mentioned in the law, without specification	Spain and Italy: for reimbursed medicines.
Imposed on the wholesaler	Various wholesaler obligations in Belgium, France, Germany, Portugal, in Netherlands, Denmark.

	New proposal in the **Czech Republic**: Distributors must inform the Ministry of Health about stocks of "limited availability" products.
Imposed on the pharmacist/hospital	**Germany** – 2 months stockpiling for hospitals **Austria:** hospitals are required by law to have an average storage range of medicines of at least 14 days. **Finland:** hospitals are required by law to have a stockpile corresponding to ten months' consumption of hospital products (e.g. antibiotics). New proposal in **Czech Republic**: pharmacists cannot order "limited availability" products, and their orders shouldn't exceed the average number of packages issued in 1 calendar week in the last 3 calendar months.
Other	UK (in the context of Brexit) – UK (Essential Medicines Buffer Stock from 2009 – 2019 (see Annex 1)) **Austria:** the Compensation Regulation Act imposes costs to be covered by the public when: additional costs incurred for storage, up to a maximum of 5% of the ex-factory price per proprietary medicinal product, and when costs in the amount of the 3-month Euribor rate plus 0.25 percentage points, calculated on the ex-factory price per pharmaceutical specialty.

More details on the country specific stockpiling measures are available in* **Annex 1: Examples of safety stock obligations imposed on supply chain operators .

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.

2. Exacerbating the problem, inhibiting solutions

The Technopolis Study on Medicines shortages[2], requested by the European Commission, confirmed that shortages are often localised in one country, and can usually be offset by other market players without substantial volume loss. However, current procurement practices and short-term cost-containment measures, rapidly increasing inflation, combined with burdensome and costly regulatory processes, drive consolidation of multisource supply and manufacturing, and reduce the number of marketing authorisation holders or manufacturers able to supply medicines to patients.

Any stock management strategy has immediate effect on cash flow immobilisation, financial costs linked to the capital needed to prepare the stock and economic costs linked to logistics and warehouse space. In this context, national stockpiling requirements imposed on manufacturers, where medicines are stored to address potential future needs, will aggravate financial and economic sustainability, and will consequently increase market consolidation with an increasing risk of shortages, hindering supply and patient access to medicines.

[2] European Commission, Directorate-General for Health and Food Safety, Jongh, T., Becker, D., Boulestreau, M. 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

There is also a notable variance in the definitions related to stockpiling (e.g. "stockpiling, safety stock, reserved inventory etc.) between the industry and the public authorities leading to misinterpretation and misunderstanding of the capacities and extensive existing internal inventory control measures taken by the industry.

Evidence from Finland shows a decrease in the number of tender bidders inversely correlated with the number of months of obligation for stockpiling, leading to a consolidation of supply. This was also highlighted in the Technopolis Study on Medicines shortages, which makes a clear correlation between national stockpiling requirements and a higher number of reported shortages[3]. Economic success in the generic medicines market requires competitive manufacturing costs and cost-efficiency at every level. Therefore, higher safety stocks are constrained by economic, logistical, and environmental limitations. Since most shortages are localised and stockpiling requirements imposed on manufacturers are unpaid, thus aggravating market concentration, stockpiling medicines does not represent a suitable method to obtain security of supply and it could instead result in contrary effects.

Uncoordinated and extensive stockpiling requirements for multisource medicines entail plenty of risks and **shortcomings**, of which we highlight the following:

- Stockpiling would signify increase the risk to generate a considerable waste and consequent destruction of medicines, especially for products with a short shelf-life. For antibiotics, destruction may also present an additional risk of antimicrobial resistance (AMR) development.
- Increased stockpiling requirements will increase costs and can force companies to reassess products in their portfolios and accelerate withdrawal decisions of certain products caused by unsustainability, where these requirements are not compensated by proportionate reward or guarantees from the market side.
- The geographical availability of the stockpile can be different from patients' needs and medicines shortages locations, threatening patient access to medicines. As a consequence of stockpiling nationally or regionally, the supply chain flexibility to allocate medicines to markets in need is restricted.
- In case where demand forecasts are not accurate, stockpiling would not safeguard needs either by over or underestimation of the buffer stock needed, resulting in either shortages or waste.
- Stockpiling entails a significant cost for medicine manufacturers, limiting capabilities to invest in other important activities in support of Public Health and Patients (such as R&D to develop new generic medicines).

These risks were recognised in the HERA AMR feasibility study on stockpiling, which found the financial feasibility of an increase of private-sector inventories to be low.[4] The study concluded 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."

[3] European Commission, Directorate-General for Health and Food Safety, Jongh, T., Becker, D., Boulestreau, M. 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

[4]European Commission, European Health and Digital Executive Agency, 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

3. Recommendations

Addressing the root causes of medicine shortages and increasing security of supply.

Medicine shortages are a multi-factorial issue that has multiple root causes. The stockpiling obligations do not address the real root causes of shortages of generic medicines such as the regulatory complexity, lack of competitiveness and market consolidation following decades of cost-containment policies. Addressing these root causes is only possible through comprehensive measures described in Table 1.

Table 1 Drivers of medicines shortages and proposed solutions

Problem Area	Problem description	Proposed measures
Reducing regulatory complexity to support the agility of the supply chain	The management of regulatory requirements brings about additional difficulty to an already complex supply chain for medicines, and can lead to stock-outs and delays in getting products to the market. In situations where shortages need a quick fix, the regulatory rigidness leads to substantial delays in sourcing products thus inhibiting the resolution of the problem. A complex and rigid regulatory environment also increases the overall costs of bringing and maintaining the products on the market. 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. Supportive policy and regulatory measures are needed to increase the agility of the supply chain without lowering the EU quality and safety standards. This is possible through reducing the regulatory complexity via streamlining, digitalising regulatory processes and making the regulatory systems fit the digital age.	• **Facilitate the re-allocation of stock** from one country to another within the EU, especially for medicines approved under national procedures (referred to as DCP or MRP medicines – around 90% of medicine registrations in Europe) and **avoid expensive and time-consuming re-packaging**. Some Nordic countries already enable this flexibility provided a medicine is already approved in another EU market. This simple change could significantly reduce the medicine shortages in many EU countries. • Investment and cooperation with industry on **digitalisation of regulatory data systems** (EU and nationals) and **interoperability with other relevant systems** (i.e. Shortages reporting, European Medicines Verification System) are critical to support the resilience of the supply chain. • Recognise the digital leaflet **(electronic product information – ePI**) as the main source of product information. Removing the obligation to provide the paper version of the leaflet in the package will allow industry to re-allocate medicines faster to meet patient need. ePI will

		also equip patients with the most updated information, more quickly than the paper leaflet can. It is critical that ePI is implemented for all medicinal products and not only for centrally approved products, in order to enjoy the full benefits of this important digital tool. • **The variation reforms** should drastically reduce the burden of administrative changes that are not linked to safety, quality, and efficacy standards, but only with bureaucracy and paperwork. • **Move towards a broader adoption of multi-country packs and labelling harmonisation to increase manufacturing and distribution resilience.**
Ensuring a competitive market and predictability of demand	Maintaining competitiveness and demand predictability is vital amidst mounting challenges. Existing strict pricing rules prioritise short-term cost-cutting over market adaptability, contributing to market consolidation in European regions. External factors, like the COVID-19 pandemic and the Ukraine conflict, have worsened matters by driving inflation, disproportionately impacting this sector with its narrow profit margins and price regulation limitations. To address these issues effectively, sustainable pricing and a reimbursement environment that attracts more manufacturers to foster a resilient supply chain is needed. 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.	• 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. • Implement **new sustainable pricing and reimbursement models** for generic medicines that ensure healthy market competition and prevent the undesired effects of existing pricing mechanisms, allowing patients to continue having access to a broad range of therapeutic options as well as guaranteeing that generic competition remains healthy in the long term. These new pricing models should be resilient and reflect the competitive situation, allowing companies to adjust prices based on inflation. • **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. • EU legal guidance on medicines procurement as an alignement tool to improve procurement practises. • Revise and adjust the application **of national cost containment measures** that discourage generic medicine manufacturers from entering or staying on the market.

More information on the Medicines for Europe recommendations can be found in the position paper on best procurement practices and factsheet on market and regulatory reforms to ensure availability and resilience of the supply chain.

Stronger EC monitoring of national stockpiling policies to avoid internal market disruption for patients in other EU countries.

Excessive stockpiling obligations pose threats to the flow of goods within the EU internal market thus jeopardising the security of supply and ultimately access to medicines across Europe. Therefore, the **European Commission should closely monitor the proportionality of national stockpiling requirements and ensure that the normal functioning and sustainability of the internal market is not distorted**.

This monitoring should be done through various measures available to the European Commission:

- The EC should enter into dialogue with the Member States to actively discourage excessive and unpaid national stockpiling obligations.
- The EC should utilise appropriate policy instruments to conduct the monitoring of national regulations which can jeopardise access to medicines. For example, Member States should, in accordance with Article 5 of Directive (EU) 2015/1535[5], notify the European Commission when adopting national technical regulations which may pose technical barriers to trade, so that the Commission can assess MS compliance with the freedom of movement of goods. This obligation is not always met, as seen in the case of the German stockpiling law, where no notification was made to the European Commission. To avoid these discrepancies, the EC should reinforce the notification requirement and be ready to impose penalties for non-compliance.

More European solidarity and voluntary stock sharing.

Medicines for Europe supports the EC proposal for the **European Voluntary Solidarity Mechanism** and sees it as an **important alternative to national stockpiling**. Reallocation of stocks between countries is the most suitable

[5] Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September laying down a procedure for the provision of the information in the field of technical regulations and of rules on Information Society Services.

solution for most medicine shortages occurring in the EU, since most shortages occur in a single country. Moreover, a well-functioning mechanism of voluntary allocation would make national stockpiling at individual Member State level unnecessary while also fostering the spirit of openness and solidarity between countries.

To make the proposed mechanism a reality, Member States should have a thorough understanding of their individual medicines stock across the pharmaceutical supply chain to be able to offer medicines in case of critical shortages in another country. To do so, Member States need to use the data stored in existing data repositories such as the European Medicines Verification System (EMVS). By providing real-time information on the availability of medicines across the EU, the EMVS data should become a structural part of the proposed Solidarity Mechanism and should be used under the proposed matchmaking platform. In addition, stock sharing should be accompanied by the adoption of regulatory flexibility to facilitate quick and efficient reallocation of products between Member States.

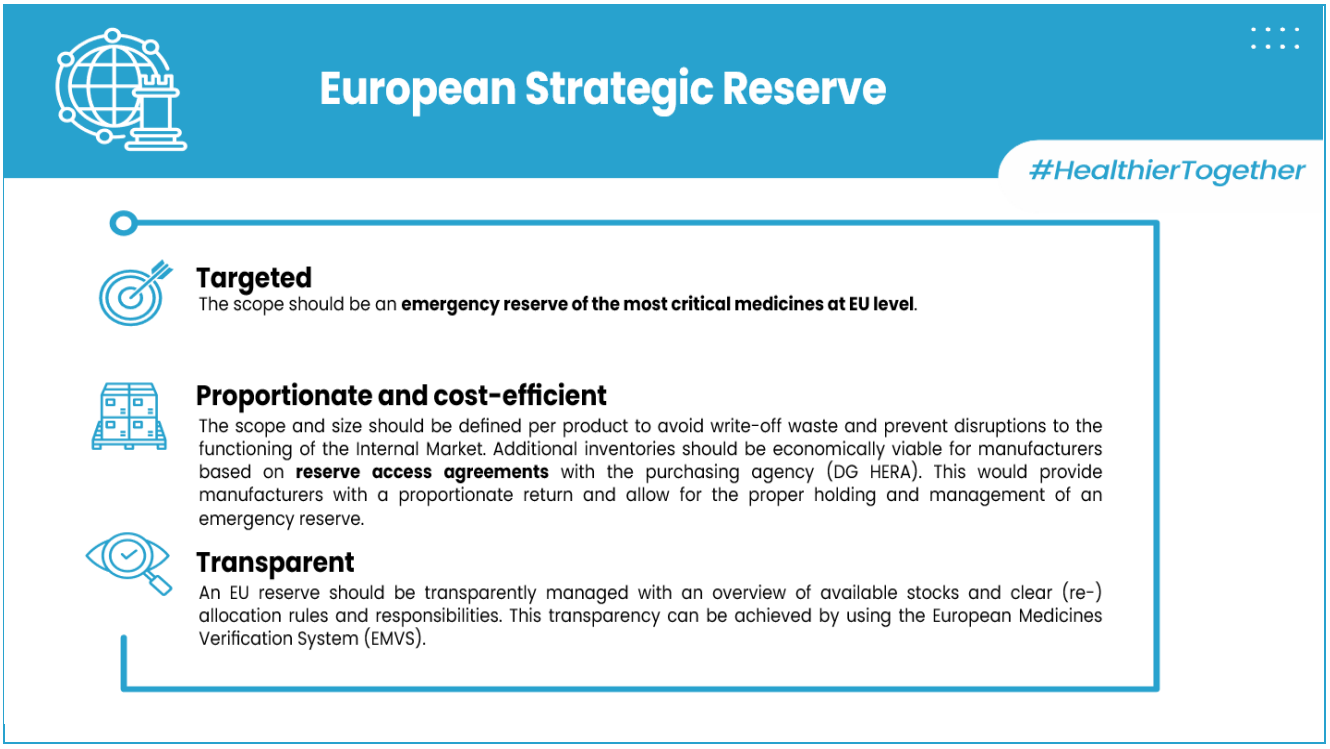
An alternative to national stockpiles: EU stockpiling of multisource (generic) medicines.

A feasible alternative to national stockpiling is the establishment of a **European Strategic Reserve at European level**. Led by the European Commission (HERA), this model could be beneficial in crisis situations and would avoid distorting the normal functioning and sustainability of the internal market, provided it is based on good stock management, aligned with the principle of EU solidarity, and economically sustainable. This is in line with the recommendations from the Technopolis study on medicine shortages, which states that holding a sufficient stock of medicines of major therapeutic interest can be an effective tool to protect against shortages, if done jointly (as in at EU-level) and when managed properly.[6] The beneficial role of a centralised safety stock for the most critical medicines was also highlighted in the findings of the Structured dialogue on the security of supply and in the HERA AMR feasibility study on stockpiling[7,8].

[6] European Commission, Directorate-General for Health and Food Safety, Jongh, T., Becker, D., Boulestreau, M. 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

[7] COMMISSION STAFF WORKING DOCUMENT: Vulnerabilities of the global supply chains of medicines. Structured Dialogue on the security of medicines supply, European Commission 2022, https://health.ec.europa.eu/system/files/2022-10/mp_vulnerabilities_global-supply_swd_en.pdf

[8] European Commission, European Health and Digital Executive Agency, 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



Given the complexity of the pharmaceutical supply chains and the specificities of the off-patent sector, several important conditions need to be in place for the European Strategic Stockpile to be effective. These include:

- Close collaboration and **two-way dialogue** between authorities and industry to ensure the most efficient stockpiling, based on a thorough risk assessment of products on the European critical medicines list.
- The implementation model for the European Strategic Stockpile should be designed in a way that allows for rapid access to reserve stocks in cases of critical shortages. Instead of keeping a physical centralised stockpile, a virtual stockpiling technique should be employed. The stocks (of final products or APIs) should be held by the industry (manufacturers, wholesalers, or distributors). A pilot project on, for example, critical antibiotics may be needed.
- Stockholders should be fairly compensated by the purchasing authority (e.g. DG HERA) for the storage and maintenance of these products.
- There should be a clear **commitment** from Member States on buying the stock for the European stockpile over the national stockpiling. This would enhance **coherence** between EU policies to avoid duplication of stockpiling and purchasing.
- To limit waste, strategic reserves need be available for stockholders to use in a continuous rolling system of stock allocation. At the same time, there should be clear rules in place for when, how, and under what conditions the reserve stocks can be used. A cost-effective method used by the United Kingdom that could serve as a model is described in Annex 1 under **Other stockpiling measures in the EU and beyond**.
- The data on demand and the availability of stock should be continuously collected via the European Medicines Verification System (EMVS) which provides information on the market-specific availability of

any prescription medicinal product in real-time or near real-time. This would allow for the stock to be allocated to the location where the local supply does not meet the local demand.[9]

- To achieve a quick and smooth allocation of products to the national markets, medicines supplied through the Strategic stockpile should be exempt from national packaging and labelling requirements. Use of Electronic Product Information (ePI) should be ensured.
- The setting-up of the Strategic Reserve should be accompanied by thorough preparation in the form of an open dialogue between the European Commission, Member States and the industry to define:
    - The scope and size of stockpiling.
    - The roles and responsibilities of various involved stakeholders. This includes purchasing the stock, placing orders, holding the reserve, facilitating and managing orders from local health authorities, requesting deliveries and determining under which conditions these medicines can be used. This should help clarify the tasks to be managed at country level and at EU level involving the relevant supply chain actors and should not disrupt the normal market functioning.

4. Conclusion

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.

To ensure the prevention of shortages in the EU, as well as the protection of a competitive market and the predictability of demand, Medicines for Europe recommends:

- The EC and Member States should work closely together to reduce regulatory complexity through streamlining and digitalisation to improve stock re-allocation across the EU by MAHs, by using regulatory simplifications, or ad-hoc flexibilities in packaging and labelling, as well as the European Medicines Verification System.
- Revising national pricing and reimbursement and cost containment measures, to ensure sane competition, and the availability of generic medicines.
- Developing solidarity-based initiatives such as the European Voluntary Solidarity Mechanism, as well as strategic reserves led at EU level.

[9] The added value of using EMVS was recognised by the DG HERA study on stockpiling.

Annex 1: Examples of safety stock obligations imposed on supply chain operators

National safety stock in France

The European Commission sent a *reasoned opinion* to the French Government, challenging a draft decree establishing safety stocks for the national market of up to 4 months. The concerns and motivations of the European Commission were as follows:

- Aligned with the recommendations issued by the European Commission in the framework of the COVID crisis (ref. the EC Guidance on optimisation of supply of medicines), the EC will challenge national measures which can disproportionately affect the good functioning of the EU single market for medicines.
- In the absence of an increase in production capacity, up to 4 months of preventive stockpiling on the French market will affect the supply of medicines to other Member States: this impact is accentuated by the considerable size of the French market. For the EC, stock on a European scale would be an optimal solution (supported by RescEU) and national initiatives should be limited to moderate quantities.
- Even if a Member State has a margin of discretion to ensure the appropriate supply for national patients, the Commission questions the necessity of the draft decree and considers that it is disproportionate, particularly for medicinal products which are not of major therapeutic interest and that the concept of supply tension is not sufficiently defined and therefore proposes a monitoring of available stocks, supply and demand which seems to be a less restrictive alternative.

The recommendations from the European Commission to the French Government were to:

- Limit the obligation of preventive stockpiling to a maximum period of one month for a limited number of medicines, identified based on their therapeutic interest and data proving the risks of shortages, considering the availability of alternative treatments.
- Allow sufficient time for preparation.

The current national safety stock requirements in France need the MAH to build up a stock of at least two months' supply for medicines qualifying as medicines of major therapeutic interest intended for the French market and located on French territory or that of another EU country.

Stockpiling requirements in the Netherlands

In 2019, the former Minister for Healthcare and Sport in the Netherlands decided that there should be a 5-month stock for all medicines, spread through the supply chain (4 months at the supplier and 1 month at the wholesalers). The Dutch Association Bogin has been focusing on bringing the following messages forward:

- The importance of European alignment
- Stockpiling of 5 months for all medicines is a disproportionate measure
- The link between other policies impacting price and availability of medicines in the Netherlands

The Dutch government acknowledged that the proposal was disproportionate, that European alignment is necessary and that the medicines supply chain is very complex. The new proposal is for:

1. Safety stock of 2.5 months for all prescription-bound medicines, of which 6 weeks at the supplier and 4 weeks at the wholesaler
2. No national system to monitor supplies
3. Compliance will be further defined in collaboration with relevant stakeholders
4. The Ministry of Health to make € 25 million per year available to finance the safety stock.

5. Starting date of July 2022, as of 1 Jan 2023 IGJ will monitor. The MAH is not responsible for the occurrence of a medicine shortage in the following cases:
    a. caused by a distributor exporting/supplying medicinal products to another customer in another Member State and of which the marketing authorisation holders are not aware
    b. shortages caused by increased demand due to a shortage of an alternative medicine from another company
6. The necessity of the policy and alignment with Europe to be evaluated every two years

Stockpiling requirements in Germany

In its Law to Combat supply bottlenecks for off-patent medicines and to improve the supply of children's medicines (ALBVVG), Germany introduced a series of measures meant to avoid shortages of medicines.

a) For paediatric medicines, the price rules will be relaxed, with the abolishment of fixed amounts and discount contracts.
b) The production of APIs in the EU/EEA will be taken into account in antibiotics tenders.
c) Price instruments for supply-critical medicines may be relaxed in the event of a market narrowing. If there are too few suppliers of important medicines, the fixed amount or price moratorium can be raised once by 50 percent. But after only two years, these increased prices can be again reassessed and reduced, prohibiting longer-term planning for generic manufacturers.
d) Pharmaceutical companies are required to hold 6 months of stock of discounted medicines. Hospital pharmacies must increase their stocks of parenteral medicines and antibiotics for intensive care, and wholesalers must increase their stockpile of paediatric medicines to four weeks.
e) The BfArM will play an increasing role, with the creation of an early warning system to detect imminent supply bottlenecks.

Measures to mitigate shortages in Portugal

In July 2023, Infarmed defined measures to support the availability of critical medicines, which are those that require or justify the adoption of additional measures to guarantee their maintenance on the market, to guarantee the provision of basic healthcare and considering their vulnerability in the supply chain.

Possible support measures include, for the purposes of determining the maximum price, the ex-factory price to be considered in Portugal may go up to the highest price in the reference countries or, if it does not exist in these countries, consider the medicine price in other European Union countries.

The MAH must however comply with the following minimum obligations:

a) Guarantee supply of the quantities necessary to satisfy consumption in the health system in the national territory;
b) Ensure the maintenance of a permanent stock level to guarantee adequate, regular and continuous market supply for a minimum period of four months;

Existence of a mechanism to communicate stocks in real time to INFARMED, I.P., that allows monitoring by that Authority.

Other stockpiling measures in the EU and beyond

- **UK strategic reserve**

From 2009 to 2019, the UK Government held a stockpile of approximately 400 essential medicines in the Essential Medicines Buffer Stock ("EMBS"). The list of medicines was drawn up by the DHSE, in conjunction with the NHS, and was designed to be ones most key to prevent death or admission to hospital.

This buffer stockpile was tendered under the following conditions:

- Awarded companies supplied stocks of medicines for one or more of approximately 400 lots of the essential/required medicines, which were purchased by the Department of Health.
- The awarded company was required to store the stocks of Department of Health-owned medicines in the UK over the duration of the tender (4 or 5 years).
- The awarded company was required to maintain a minimum shelf life for the relevant Department of Health-owned stock by releasing stock into the supply chain and replenishing with new stock.
- In the event of a supply shortage caused by a pandemic or other emergency, the company was required to release stocks into the supply chain for supply to UK customers and for delivery to the NHS, with the object of lessening any shortages of such medicines, and the contractor was required to purchase such stocks from the Department of Health for the purpose of such release.

- **Australia: 5-year Strategic Agreement with the Government**[10]

In the Strategic Agreement between the Commonwealth of Australia and the Generic and Biosimilar Medicines Association, signed in September 2021, a floor price or price increase is set for certain medicines. In exchange, the Responsible Persons must hold a minimum level of stock (4-6 months) for those medicines in Australia.

- **European Commission: rescEU stockpile of medical equipment**[11]

In March 2020, in the light of the COVID-19 pandemic, the European Commission created a strategic rescEU stockpile of medical equipment. It includes items such as intensive care medical equipment, personal protective equipment, vaccines and therapeutics and laboratory supplies.

The stockpile works under the following conditions:

- The stockpile to be hosted by one or several Member States (currently hosted by 6 EU Member States: Denmark, Germany, Greece, Hungary, Romania and Sweden). The hosting State will be responsible for procuring the equipment.
- The Commission will finance 90% of the stockpile. The Emergency Response Coordination Centre will manage the distribution of the equipment to ensure it goes where it is needed most.
- The initial EU budget of the stockpile is €50 million, of which €40 million is subject to the approval of the budgetary authorities.

[10] https://fedlex.data.admin.ch/filestore/fedlex.data.admin.ch/eli/cc/2017/308/20170601/en/pdf-a/fedlex-data-admin-ch-eli-cc-2017-308-20170601-en-pdf-a.pdf

[11] https://ec.europa.eu/commission/presscorner/detail/en/ip_20_476