POSITION PAPER

of the Pharma Deutschland e.V.

on the New EU Stockpiling Strategy

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Introduction

Pharma Deutschland explicitly welcomes the European Commission's initiative to develop a coherent EU strategy for strategic stockpiling. Considering growing geopolitical uncertainties, increasingly frequent supply crises, and global supply chain dependencies, a coordinated European approach may be necessary. At the same time, it must be acknowledged: stockpiling is not a cure-all. It must be designed in a targeted, differentiated, balanced and realistic manner – with special attention to the specific characteristics of medicinal products. Furthermore, the significant personnel and financial resources required from the involved companies must be appropriately compensated.

1. Avoid Fragmentation – Think Stockpiling on a European Scale

National solo efforts in stockpiling medicinal products, as currently seen in several Member States, are not suitable to ensure supply security across Europe – on the contrary: they lead to market distortions, supply shifts, and shortages in neighbouring countries. This creates uncertainty for companies and causes conflicting objectives in cross-border supply. Coordination is insufficient – both between Member States and across administrative levels. In addition, both national and European stockpiling obligations may result in scarce medicinal products already on the market being withheld from third countries where they are most urgently needed, simply because they are formally stockpiled within the EU (for example, due to the market withdrawal of competitors in third countries). This socially inequitable consequence of stockpiling requirements vis-à-vis third countries must be addressed through exceptions that allow for greater flexibility—provided that European supply security is not compromised.

Recommendations:

- Assessment of existing national stockpiling regulations by the EU Commission for proportionality and internal market compliance.
- Development of a unified EU framework with minimum standards, clear definitions, and coordination requirements (e.g. limiting national stockpiling obligations to a maximum of two

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months and only for EU-defined critical medicines). Avoid imposing preventive stockpiling obligations for medicinal products that are not affected by supply shortages.

- Harmonization of stockpiling obligations, considering economic feasibility and sector-specific factors.
- Establishment of a central European solidarity stockpile with coordinated flexible rotation and redistribution to avoid national redundancies and market fragmentation.
- Transparent and binding rules distinguishing between stockpiling for crisis vs. routine supply.
- Enable flexible redistribution and create regulatory flexibility regarding packaging and labeling requirements (e.g. through multi-country packs). This enhances solidarity among Member States and increases flexibility and control over stockpiled critical medicines.
- Despite minimum standards and clear definitions, there must be room for flexible action – particularly to ensure timely responses to the often sudden occurrence of supply shortages in the future.

2. Differentiated, Risk-Based Stockpiling

Strategic stockpiling must not be generalized. It should focus on clearly defined, particularly vulnerable medicines – based on risk analyses, seasonal demand, and technical storage capabilities. Stockpiling can at most serve as a supplementary, not a primary, tool to ensure supply.

Recommendations:

- Focus on critical medicines with proven supply vulnerabilities, fragile supply chains, or crisis relevance.
- No stockpiling of products with technical storage constraints (e.g. ATMPs, radionuclides, plasma-based products).
- Differentiated planning depending on the type of medicine (e.g. shelf life of vaccines, seasonal demand, patient-specific manufacturing).
- Align stockpile volumes with real demand – e.g. vaccine quantities based on actual public willingness to vaccinate.
- Introduction of product-specific thresholds and caps at the EU level.
- Enable stockpiling at bulk level to improve redistribution and production flexibility.
- Use retrospective market data for demand estimation.

3. Involvement of the Private Sector – Including SMEs and Midcaps

Pharma Deutschland's member companies see themselves as active partners in strategic and balanced stockpiling. Close and early coordination with industry is essential for successful implementation – both in selecting criteria for critical medicines and emergency stockpiles and in executing logistical processes.

Recommendations:

- Establish coordination forums at EU and national levels with binding industry involvement.
- Ensure representative consideration of SMEs and midcaps in regulatory and financial requirements.
- Avoid one-sided obligations without technical feasibility or economic viability.

4. Financing Models

Stockpiling requires significant investments in storage, personnel, administration, and tender management. Stockpiling ties up significant capital, and the risk of wastage due to expired, unused medicines—particularly in the case of volatile products with difficult-to-predict demand—must be urgently considered. Without reliable incentive and compensation systems, sustainable industry participation is not feasible.

Recommendations:

- Development of mixed-financing models (e.g. cost-sharing, compensation surcharges, tax incentives).
- Offset the economic burden for companies – especially smaller providers.
- Safeguard against expiration risks through return or compensation mechanisms.
- Link stockpiling to national pricing and reimbursement systems by requiring Member States to implement exemptions from national pricing regimes for EU-defined critical medicines that are subject to a European stockpiling obligation.

5. Digital Coordination and Governance

The multitude of national measures and systems hampers efficient inventory management. A European strategy must rely on digitalization, transparency, and governance.

Recommendations:

- Establish a tiered governance model with clear allocation of roles between EU, national, and regional levels, as well as defined tasks and responsibilities for industry stakeholders.
- Use digital platforms for real-time tracking of national and international safety stocks and their shelf lives. For critical medicines, actual consumption data (e.g. from hospitals or end users) should also be centrally recorded—provided this can be done automatically.
- Preventive, centralized tracking of stock levels along the supply chain is strongly discouraged. Such tracking would only be meaningful if all inventory levels (at manufacturers, national warehouses, wholesalers, and pharmacies) were captured promptly and with high granularity. This level of effort should only be undertaken in the event of an actual shortage and on a case-by-case basis.
- Utilize existing databases (e.g. for AMR monitoring, the European Medicines Verification System, and the European Shortage Management Platform) to support evidence-based decisions. Avoid creating parallel structures.
- Require TRIS notifications for national measures to prevent overlapping regulations.

6. International Cooperation

Supply chains are global. National and European solo efforts hinder supply security during crises and exacerbate shortages.

Recommendations:

- Cooperation agreements with third countries on the manufacturing, storage, and logistics of critical products.
- Use international platforms such as WHO, G7, or OECD to align common standards and crisis mechanisms.

Conclusion

Pharma Deutschland supports the European Commission's aim to advance a resilient, future-oriented stockpiling strategy. Successful implementation requires unified European standards, an intelligent, risk-based approach, and consistent involvement of the sectors concerned – including SMEs and midcaps. Companies must not be left alone with the necessary personnel and financial burdens. Especially in vulnerable areas, this could otherwise lead to market exits. However, stockpiling must not be a substitute for preventive supply policy. Moreover, fragmentation and unilateral national approaches, by contrast, jeopardize the shared goal of ensuring reliable access to essential medicines for people across Europe – even in times of crisis, as every stockpiled medicine is, at least initially, withheld from the market.