European strategic stockpile

factsheet

- ☐ Problem Statement
- ☐ Policy recommendations
- ☐ Examples

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Preventing shortages

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Problem Statement

It is good practice for manufacturers, hospitals and the military to ensure good inventory levels to buffer demand fluctuations for medicines. However, during Covid-19, many Member States introduced counterproductive stockpiling measures that disrupted industry supply chains, threatened patient access and undermined EU solidarity. Disproportionate stockpiling requirements post-Covid-19 at national and/or EU level would further increase market consolidation and supply risks. Pharmaceutical companies already implement internal inventory policies (stocking critical materials needed to produce for demand variations) that covers API, bulk and finished products as part of their efforts to increase security of supply. Ill-conceived stockpiling medicines will generate the waste and destruction of medicines, which should be avoided as much as possible. Therefore, Medicines for Europe supports Commission policies to tackle national hoarding and other disproportionate restrictions to the free movement of goods and welcomes the structured dialogue to design EU-wide policies for resilient supply chains.

Medicines for Europe recognises the positive role that emergency reserves can play in crisis situations provided they are proportionate, based on industry recommendations for good stock management, aligned with the principle of EU solidarity and economically sustainable. However, EU stockpiling is challenging for multisource medicines because of licenses and different languages. Additionally, an EU stockpile is not suitable to address national shortages.

Policy recommendations

Regarding a possible future EU strategic reserve, we encourage the Commission to carefully design this policy together with medicine manufacturers.

Recommendations for fair, sustainable and practical stockpiling:

- European Strategic stockpiling should be **targeted** (based on a risk assessment to determine medicines or therapeutic focus areas) and **proportionate** (the size of the stockpiling should be defined per product to avoid overstocking waste).

- A stockpiling method should be adopted to absorb unforeseen market surges for a clear list of **essential medicines** for specific health emergency risks. Any European reserve should avoid distorting the normal functioning and sustainability of the Internal Market and prevent the wasteful destruction of unused medicines.

- **Facilitate the movement of stock** from one country to another within EU, especially for medicines approved under national procedures (referred to as DCP or MRP medicines – around 90% of medicine registrations in Europe) and avoiding expensive and time-consuming re-packaging.
  - Flexibility to accept eLeaflets and multilingual packages.
  - Flexibility to accept different pack sizes at national level based on Marketing Authorization.

- **Reduce the regulatory complexity** of managing a reserve of products which may have national licences (MRP/DCP) and labelling requirements.

- Establish clear **responsibility for the costs** associated with acquisition, distribution, storage and maintenance of these medicines.

- **Avoid the wasteful destruction** of medicines.

- Establish a **transparent process** to purchase these medicines, identifying who will place orders, purchase the goods, hold the reserve, call off deliveries and under which conditions these medicines can be used.

- Any European reserve should avoid distorting the normal functioning and sustainability of the Internal Market.

Examples

- Evidence from **Finland**, which has a stockpiling requirement for certain medicines, shows a decrease in the number of tender bidders inversely correlated with the months of obligation for stockpiling, leading to the consolidation of manufacturers and therefore contradicting the security objective of stockpiling.

- **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 key to prevent death or admission to hospital.
  - 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.