GIRP

Reflection on medicines stockpiling and increased buffer stock at pharmaceutical full-line wholesaler/full-service healthcare distributor level

In the context of the study commissioned by the European Commission on the evaluation and impact assessment of the EU general pharmaceutical legislation, GIRP would like to share additional reflections on the issue of costs for medicines stockpiling and increased buffer stocks at the pharmaceutical full-line wholesaler/full-service healthcare distributor level.

Following the discussions on stockpiling measures to increase the security of supply and availability of the required medicines for patients, costs should be assessed as inventories generate costs related to their creation, maintenance, and turnover of the stockpile. In this short paper, we discuss some of the options for stockpiling with a particular focus on the cost considerations. Moreover, there are many cost components that need careful consideration when assessing stockpiling and increased buffer stocks. In the annex to this paper, we set out a comprehensive list of possible cost components. Consideration should be made to each component when referencing new stockpiles or increased buffer stocks as some costs will be one-off fixed costs while others will be reccurring or ongoing.

Potential contributions of pharmaceutical full-line wholesalers/full-service healthcare distributors to mitigate short term supply interruptions

Several EU Member States have transposed Article 81 (2) of Directive 2001/83/EC by placing separate Public Service Obligations (PSOs) on pharmaceutical manufacturers and pharmaceutical full-line wholesalers. Unfortunately, few countries have linked a 'right to be supplied' from pharmaceutical manufacturers to the PSO for full-line wholesalers (see here full overview). As outlined in our suggestions to improve the current EU general pharmaceutical legislative framework (see here), the PSO combined with the right to be supplied from the pharmaceutical industry would place the pharmaceutical full-line wholesalers/full-service healthcare distributors in a better position to mitigate shortages in case of short-term supply interruptions through buffer stocks; respectively buffer availability guarantee (pharmaceutical law, remuneration/margin defined by national level) for a period of approximately 2 weeks.

At the onset of the COVID-19 pandemic, when EU Member States closed their borders, patient suffering was avoided thanks to the buffer stocks held by pharmaceutical full-line wholesalers/full-service healthcare distributors. A study carried out in France (where the right for full-line wholesalers to be supplied by the pharmaceutical industry is enforced), showed that pharmaceutical full-line wholesalers, thanks to their buffer stocks, absorbed a large part of shortages and only 1 out of 3 product shortages (72h stock-out time in France) hit pharmacies. Although the holding of buffer stocks/buffer availability guarantee comes with a cost for our sector (see below), it is by far the most cost-effective way to prevent unavailability of medicines for patients caused by short-term supply interruptions.

Rotating dynamic vs static stockpiling

An important criteria for the cost of stockpiles is if they are rotating or static.

1. Emergency stockpiles for crisis situations: Products' shelf lives vary by the type of product. Stockpiles can be partially dynamic but also require holding stocks which do not rotate as they are dedicated to specific emergency/crisis situations and therefore need to be held as part of a static stockpiling approach (stockpiling of masks prior to the COVID-19 pandemic or iodine tablets more recently). If stocks are not managed on a rotating basis with 'normal' inventory, they have

a high risk of expiration. This leads to their disposal generating unnecessary additional costs, complete loss of the initial investment and triggering a negative environmental impact. A static stockpile with no rotation of stock might therefore result in a large volume of expired stock that needs to be replenished again adding additional costs for their creation, maintenance, and turnover of the stockpile. It also needs to be defined who covers the cost of expired products and who pays for their disposal.

2. Increased buffer stocks by 2 weeks for critical or essential medicines, which could be integrated via rotation into pharmaceutical full-line wholesaler/full-service healthcare distributor rolling stocks, thus reducing the risk that products expire. This could be carried out on FEFO (First Expired First Out) basis – **dynamic stockpiling**. Naturally, the Remaining Shelf-Life (RSL) of products differ according to the type of product. However, buffer stocks can be organised in a way that the products are continuously used and replenished but the length of storage, the expiry date of products and the potential safe disposal of unwanted medicines need to be considered. Increased buffer stocks held at wholesale level need to be purchased at ex-manufacturer prices from the pharmaceutical industry (providing that there is the right to be supplied), which increases the capital costs. This is one of the main reasons (other than available warehouse space) why the establishment of larger stockpiles at the level of pharmaceutical full-line wholesalers/full-service healthcare distributors above 2 weeks is highly challenging (due to currently insufficient margins while also holding a pre-financing function for the healthcare supply chain).

Ownership and risks of stockpiles

The crucial question to be answered at the planning phase of stockpiling is who should own the product, who should manage the stockpiles and who carries the risk of the stock. Stockpiles can be either **owned** by the government (partially the case for crisis relevant products), the pharmaceutical manufacturer (e.g. products of a major therapeutic interest in France) or pharmaceutical full-line wholesalers/full-service healthcare distributors (e.g. in France, Germany, etc.) as part of their Public Service Obligation (PSO). Obviously, the physical location of a stockpile can be different from the one of the stock owners.

Stockpiles bear the **risk** of significant financial loss not only if products expire, but also if there is loss or damage, eventual recall and last but not least, costs for stock value loss (in case of price decreases), waste disposal and handling of expired, recalled, or unusable products.

Organisational / administrative reflections

Additional administrative and logistic costs might apply based on the conditions and to whom the safety stocks should be delivered.

Costs are higher, if the list of products to be stocked changes more frequently, because this requires higher efforts to administer the stocks.

It also needs to be decided under which conditions the emergency stocks will be supplied/released to the market, how they should rotate (e.g. FEFO) and how the rationalisation/allocation system would be organised in respect of market deliveries to ensue equitable access.

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Recommendations

Apart from stockpiles held by national governments, a cascading system of safety stocks to be held by MAHs and 2 weeks of buffer stocks (or buffer availability guarantees) held by pharmaceutical full-line wholesalers/full-service healthcare distributors integrated in rotating stock could be considered.

A pre-condition is an enforceable "right to be supplied" for pharmaceutical full-line wholesalers from the pharmaceutical industry, as an audited obligation for the pharmaceutical manufacturers to supply (see our recommendations for the overhaul of the pharmaceutical legislation) and legislative underwriting that the cost for the additional stock saving function as part of the PSO and right to be supplied will be covered at national level.

Stockpiles which surpass 2 weeks of 'normal' consumption cannot be financed by our sector within current remuneration/margin schemes and therefore should be held by the pharmaceutical manufacturers, 3PLs or pre-wholesalers on their behalf. A cascading system of stockpiles for products in primary packaging to be held on European (for use in all EU countries) or regional level and products in secondary packaging on national level should also be envisaged.

Brussels May 2022

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***Annex: Cost components*[1]**

Cost components to be considered for creation, maintenance, and turnover of stockpiles and increased buffer stocks:

1. **Warehousing**
2. **Organisational structure**
3. **Capital**
4. **Costs incurred due to expired products**

1. Warehousing:

- Property and business property taxes
- Energy
- Security
- Insurance
- Regulatory controls and inspections of inventory
- Maintenance & repair of facilities and equipment

Cold chain and narcotic products have increased handling and storage costs. The potential need to enlarge the warehousing space must also be considered.

2. Organisational structure (comprising staff costs):

- Product handling (goods receipt, transport to the storage location)
- Product storage
- Administration and documentation (inventory checks, expiry and breakage control)

Please note that cold chain and narcotic products also have higher administrative costs because of specific legal requirements and liabilities. The potential need to buy new material for the additional stockpiles should be taken into account as well.

3. Capital costs (in case of ownership)

Capital costs refer to the capital required to purchase and for accrued liabilities (for pharmaceutical full-line wholesalers/full-service healthcare distributors). The interest rate situation and the inflation rate must be taken into account. Capital investment is at risk if the products are not in a saleable state after being held in the stockpile. There is also a risk of price changes and therefore stock value loss.

4. Costs incurred due to expired products

- Capital investment loss
- Destruction
- Environmental impact

[1] Agile Stockpiles, IQVIA, 17/11/2020, https://www.iqvia.com/library/white-papers/agile-stockpiles#:~:text=Healthcare%20systems%20across%20the%20world,supplies%20in%20the%20pharma%20industry.

Consideration should be made however to each component when referencing new stockpiles or increased buffer stock as some cost will be one-off fixed costs while others will be reccurring or ongoing.

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