Procurement and security of supply

factsheet

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Problem Statement

Since the 2009 financial crisis, European Member States have introduced policies to reduce medicine prices to balance healthcare budgets. These cost-containment measures have typically taken the form of reference pricing (internal or external), mandatory price reductions, procurement practices, rebates, clawback or a similar contribution system and payback measures. Across Europe, the current procurement practices have generated a number of undesired effects, namely reduced competition, price erosion, supply constraints (e.g. need to have stock in house to bid) and consequently medicine shortages. On top of this, most procurement processes do not take into account the unique characteristics of pharmaceutical manufacturing operations (e.g. lead times, accurate volumes, etc.), do not promote an adequate number of participating suppliers in tenders and do not guarantee competition as soon as market exclusivity period ends. Developing optimal procurement practices is an opportunity to create healthy competition and guarantee patient access to medicines, by increasing the number of manufacturers in the market and thereby reducing the risk of medicine shortages.

Optimization of the procurement process to ensure security of supply

- Adjusting the number of procurement winners according to the market, product and country characteristics
  - Multi-winner tenders are preferred to guarantee multiple manufacturers in the market and prevent supply issues.

- Using selection criteria that consider other factors than price and ensure fair competition by implementing MEAT criteria.
  - These criteria should not put any access barriers in place for generic, biosimilar and value added medicines.
  - Procurement criteria should consider product-specific characteristics.
  - Procurement criteria that consider other factors than the lowest price should ensure fair competition, such as:
    - Environmental criteria
    - Supply reliability and manufacturing resilience criteria
    - Product characteristics criteria
  - The non-price tender criteria should award a bonus, where the weight attributed to these criteria reflects the policy objectives.

- Guaranteeing that the procurement processes reopen after the entry of the first multisource medicine to ensure a competitive and predictable supply to patients.

- Using extended lead times that guarantee a predictable supply of medicines to patients.
  - Lead times should be adapted to the product characteristics as well as the requested volumes to be supplied, to guarantee a predictable supply.

- Preventing disproportionate penalties to encourage a sustainable supply of medicines to patients.
  - Penalties should be proportionate to the contract value to ensure competition in the procurement process.
  - Before the application of penalties, there should be some flexibility to find solutions for the interruption in supply.

- Accurate estimates of volume and volume commitments to be provided should guarantee a continuous supply.

To ensure **access to medicines for patients**, tenders should ensure **competition** in the long-term by:

Adjusting the **number of tender winners** to the **product, market** and **country** characteristics

Allowing reasonable and sufficient **lead times**, adapted to **volume** and **product characteristics**

Agreeing on **proportional penalties** for supply disruptions and being flexible when demand goes beyond the agreed tender contract

Re-opening tenders for **off-patent medicines** as soon as the patent expires

Adopting a holistic view and consider **additional relevant criteria** to ensure the **best value for money**

Example good practice

Italy:

- Regional authorities are now obliged to re-open the supply agreements within 60 days after entrance of the biosimilar medicine to the market.
- If there are more than 3 competitors on the market, it is mandatory to select 3 preferred products.

Germany:

- By law, there needs to be 6 months between the award of a tender and the first delivery, ensuring sufficient lead time.

Relevant documentation

- https://www.medicinesforeurope.com/wp-content/uploads/2019/04/M-Best-procurement-practices-position-paper_final-version.pdf
- https://www.medicinesforeurope.com/wp-content/uploads/2020/08/31072020_procurement-principles-letter-final.pdf
- https://www.medicinesforeurope.com/wp-content/uploads/2018/05/Hospital_Tendering_Infographics_V.1.4_Final.pdf