Recommendations on ways to address medicines shortages

Patients are the most affected by medicines shortages. These recommendations aim to address the issue of medicines shortages, in order to soften their impact on patients and improve availability.

1. **Information sharing:**

   - GIRP recommends a medicines **shortages list and an early warning system involving all supply chain stakeholders, from manufacturers, wholesalers, pharmacists to prescribers and the national competent authorities, about the existing and anticipated shortages.**

   - GIRP recommends shortages of medicines in an EU Member State also to be made transparent at EU level, to allow for solving or at least mitigating said-shortages by imports from other Member States.

2. **Pharmaceutical full-line wholesalers' buffer stocks and ensure the continuity of supply:**

   - A distinction should be made between pharmaceutical wholesalers/distributors and **pharmaceutical full-line wholesalers**, who ensure the continuous availability of all medicines they can procure within the limitations of the legal framework and market conditions.

   - System failures can be dealt with through the full implementation, effective monitoring and enforcement of Article 81, paragraph 2 of the Directive 2001/83/EC, as amended[1].
     Article 81 paragraph 2 should be interpreted and set-out in national legislations in a way that places **independent or separate obligations on both Marketing Authorisation Holders (MAH) and pharmaceutical full-line wholesalers**. This is why national legislation should also provide for and duly enforce an auditable **right to be supplied for pharmaceutical full-line wholesalers to be appropriately and continuously supplied** by MAHs with the full range of products in order to **fulfill the needs of patients in the Member States in an appropriate manner.**

   - Legislation must **separately oblige MAHs / manufacturers and pharmaceutical full-line wholesalers to ensure appropriate and continued supply** of medicines to pharmacies and persons authorised or entitled to supply medicines to patients.

   - Compliance to **PSOs should be enforced on EU Member State level.**

   - **Additional safety stocks for essential medicines** should be held on national level.

   - If there is a justifiable need to impose supply quotas for medicinal products due to a national shortage, pharmaceutical full-line wholesalers should be made aware of their respective allocated quantities in advance (no "black-box" quotas with unknown amounts of products allocated) to allow optimised allocation of the available quantities of mediciens. Supply quotas in general are

[1] The provision states that "The holder of a marketing authorisation for a medicinal product and the distributors of the said medicinal product actually placed on the market in a Member State shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered"

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highly problematic and based on legal grounds should be abolished. The practice of supply quotas cannot be reconciled with Public Service Obligations (PSOs) or Public Service Functions and are therefore rather contributing to the occurrence of shortages than avoiding them.

- Optimise the legal and economic framework which enables manufacturers to increase medicines production in the EU for EU markets.

- Collecting data with the only aim to prevent shortages of medicines should be exempted from competitive restrictions by law.

3. **Temporary controls of parallel exports** for specific listed medicinal products **may be considered suitable** if they:

   - apply **only** to medicinal products for which **a shortage is likely or certain to occur and if the medicinal product is part of the essential medicines list**;[2]

   - are established by a medicines agency or an independent third-party which can verify the potential for a shortage of a particular product;

   - are established through transparent and auditable **criteria that are known in advance having been confirmed following a consultation of all supply chain stakeholders**;

   - **take into account the possibility of substitution or the availability of alternative treatments** in the Member State concerned;

   - **are revised on a regular basis taking into account** the latest occurrences or risks of **shortages of essential medicines** for public health.

   Measures have to be proportionate to the prevention of shortages, transparent and communicated in time.

   Measures should be open to be contested before court / administrative bodies by all stakeholders.

   Parallel exports for all medicinal products included on the list should be carried out under the supervision of the National Competent Authorities (NCAs).

[2] https://www.who.int/medicines/publications/essentialmedicines/en/