Press release

GIRP welcomes the ENVI committee vote on the own-initiative report on medicines shortages

Brussels, 13 July 2020

GIRP, the European Healthcare Distribution Association, welcomes today's ENVI committee vote on the own-initiative report on medicines shortages as a step towards addressing the issue at European level.

On the report, Bernd Grabner, GIRP President commented: *"Beyond the vote taken today, we welcome the Parliament's initiative of the report, recognising the importance of the issue and addressing it with a set of short, medium and long-term measures. Medicines shortages first and foremost impact patients and put their health at risk. It is also an increasing burden on the already fragile healthcare systems and is hampering the efficient operation of the supply chain. Due to the lack of availability of medicines, full-service healthcare distributors encounter difficulties ensuring the continuous supply of the full range of medicines."*

Mr Grabner continues: *"GIRP and European full-service healthcare distributors have long advocated for collaboration at European level involving all supply chain stakeholders and European authorities as well as Member States. We firmly believe the only way to mitigate the problem is to work together on a strong action plan and we look forward to collaborate with all parties involved to ensure the continuity of supply to European citizens."*

GIRP welcomes the call for an assessment of root causes in the approach to mitigate the issue as well as the call for the implementation of an early warning system to monitor shortages. GIRP also insists on the necessity to include all supply chain stakeholders, from manufacturers, full-service healthcare distributors, pharmacists, hospitals to prescribers and the national competent authorities. Early notification of potential and confirmed shortages by MAHs to full-service healthcare distributors (in addition to National Competent Authorities), is essential to optimize the allocation of available medicines.

Ms Monika Derecque-Pois, GIRP Director General explains: "*Full-service healthcare distributors have an important role to play in addressing the issue of shortages. They have proven time and time again during the COVID-19 crisis – and consistently beforehand – their efficiency in ensuring the continuous supply of medicines. In the thick of the crisis, full-service healthcare distributors developed coordinated contingency plans, allowing for the deployment of measures at short notice to respond to newly arising needs. Citizen, government, and patient confidence in the supply chain at community pharmacy level was fully maintained.* "

The continuity of supply and availability of medicines are key priorities of the European healthcare systems. Ensuring the availability of medicines for patients is therefore reflected in the EU legal framework governing the pharmaceutical sector, requiring supply chain partners to comply with it in accordance with Article 81 of Directive 2001/83. GIRP supports the call for full compliance with this cornerstone provision.

GIRP continues to call for clearer recognition of its members important stock keeping function, an inherent aspect of its contribution to continuity of supply. Full-service healthcare distributors invest substantial amounts of capital in maintaining a comfortable level buffer stock to ensure the availability of medicines to patients. This function is of strategic value to healthcare systems and can be further leveraged by them to ensure safety stocks at held as close as possible to patients in the countries.

Mr Grabner "*Full-service healthcare distributors are perfectly suited to support a European mechanism and to guarantee the timely and continues supply of healthcare products wherever they are needed, even in case of crisis. They are an integral part of the solution."*

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European Healthcare Distribution Association (GIRP) (website)

GIRP, the European Healthcare Distribution Association, is the umbrella organisation for pharmaceutical full-line wholesalers and distributors of healthcare products and services in Europe. It represents the national associations of over 750 pharmaceutical wholesalers serving 34 European countries, as well as major international and pan-European healthcare distribution companies. GIRP members employ over 140,000 people and distribute around 15 billion packs of medicines as well as a wide range of healthcare products per year. As the vital link in healthcare, they are committed to developing and providing innovative and efficient healthcare products and services to improve health and wellbeing of patients across Europe.

ANNEX 1

Link to GIRP Position paper on Medicines shortages in Europe and their impact on patients
Link to GIRP position paper on the potential use of data contained in the EMVS for shortages monitoring
Link to Catalogue of measures proposed by full-service healthcare distributors to ensure the continuous supply of medicines during the COVID-19 crisis

ANNEX 2

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].

[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

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 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.

pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered"

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

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).

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