GIRP's reflections on elements to be considered by the European Commission in the evaluation and revision of the general EU pharmaceutical legislation

Pharmaceutical full-line wholesalers, referred to in the current legislation as wholesale distributors, provide customised solutions to meet a diverse range of supply chain needs beyond their core activity of pharmaceutical full-line wholesaling which consists of the purchase, warehousing, storage, order preparation and delivery of medicines.

Pharmaceutical full-line wholesalers carry and distribute the complete assortment of products in range and depth within the framework set by the authorities and the market to meet the needs of those with whom they have normal business relations and deliver all medicines in their geographical area of activity on the same day/within less than 24 hours. Pharmaceutical full-line wholesalers provide working capital and extended financing services, funding of stock and receivables of pharmacies and health care professionals.

As they are in a unique position connecting crucial supply chain stakeholders, pharmaceutical full-line wholesalers have an in-depth view of the flow of medicines in the supply chain. Thus, they provide in addition to the full product range also a full range of services to all partners in the supply chain, including manufacturers, pharmacies, hospitals, nursing homes, patients (through their pharmacies) as well as to governmental institutions and society.

For the purpose of this exercise, and as our proposals revolve around their core activity as pharmaceutical full-line wholesalers, we will refer to them as such to avoid all and any confusion.

In the evaluation and revision of the general pharmaceutical legislation, GIRP calls on the European Commission, the European Parliament, and the Council to:

I. Addressing medicines shortages

1. Work toward strengthening existing obligations for supply chain actors and a **better framework for the accurate implementation and enforcement of Article 81, paragraph 2 and 3 of Directive 2001/83/EC in Member States legislation.**

2. Ensure the accurate interpretation of this provision in national legislation, in a way that places obligations on both Marketing Authorisation Holders (MAH) and pharmaceutical full-line wholesalers, and most importantly provide **for an enforceable (by NCAs) right for pharmaceutical full-line wholesalers to be appropriately and continuously supplied by MAHs with the full range of products,** to fulfil the needs of patients in an appropriate manner.

   Full effective implementation can ensure that **appropriate levels of stocks** are maintained at wholesale level to help mitigate medicines shortages. Such measures must be remunerated.

3. **Abolish unjustified supply quotas** based on legal and ethical grounds. Supply quotas can only be justified in case of a shortage of an essential medicinal product and the calculation of the allocation scheme must be transparent to pharmaceutical full-line wholesalers and to NCAs in advance, to allow optimised allocation of the available quantities of medicines. So-called "black-box" quotas with unknown amounts of products allocated must be prohibited. MAHs may only apply quotas upon notifying NCAs of a shortage. The practice of supply quotas is incompatible with Public Service Obligations as they can force wholesalers in turn to apply quotas to pharmacies, potentially increasing the likelihood of shortages.

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4. Introduce a legal basis for an **EU-wide early warning system for anticipated/potential and verified/confirmed shortages for critical medicines**, involving all supply chain stakeholders, from manufacturers, pharmaceutical full-line wholesalers, online and community pharmacists to prescribers, the national competent authorities and EMA for coordination at EU level. This system should include the **obligation of early notification of shortages by MAHs** to pharmaceutical full-line wholesalers (in addition to NCAs) and the access for wholesalers to data provided by MAHs to NCAs for early notification of shortages.

   Recently, some supply chain actors have promoted the **European Medicines Verification System (EMVS)** as a solution for monitoring of medicines shortages. We would like to briefly outline why the EMVS, built to protect patients from falsified medicines, cannot provide an overview of national stock levels and even less so, serve as an indicator of demand.

   On the supply side, the deficiency of the EMVS lies in **a huge overestimation of available supply levels** as the data contained therein will – due to multi-market packs among other reasons - always be significantly higher than the number of packs actually shipped to the national markets. Most importantly, however, data about products decommissioned from the system **in no way show the national demand**. Leaving aside the many cases when products are currently not decommissioned - especially in case of a shortage – there are no products available to be decommissioned and therefore the figures would be highly misleading and lead to **wrong conclusions on demand with a detrimental impact on patients' access to medicines.**

   For more information, please follow this link.

5. Any system aiming to monitor shortages should take the service-level from the pharmaceutical **industry and full-line wholesalers into account as a reliable indicator of a potential shortage** well ahead of the problem reaching the patient. The service-level data consists in the percentage of order fulfilment or the percentage of warehouses out-of-stock in one market.

6. GIRP supports the idea of tapping into existing structures through making use of national systems already in place, providing market signals by involving all supply chain stakeholders and elaborating a method to aggregate data at EU level.[1]

7. Establish a legislative base for harmonising the significant differences in shortages reporting and monitoring across the EU Member States and implement **EU-wide harmonised categories for root causes of shortages** in Member States shortages databases, which also comprises the APIs of medicinal products included in the list, as well as the root cause of shortage for said-APIs.

8. Implement risk mitigation plans for MAHs, designed in cooperation with the authorities and all supply-chain stakeholders.

9. The list of critical medicines in short supply must be regularly updated in a proportionate manner.

[1] See paper Improving the availability of medicines – shortages monitoring systems for public health emergencies

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II. Improving accessibility by advancing the EU Single Market for Medicines

10. Ensure the **free-flow of medicines within the EU Single Market** and foresee in future legislation a framework which only allows temporary restrictions to the free movement of medicines through controls on parallel trade **if it is in conformity with the Treaty of the European Union, the obligations laid by directive 2001/83/EC and the framework elaborated by the European Commission when Member States establish export controls.**

11. In that respect, the **paper on obligation of continuous supply to tackle the problem of medicines as agreed by the Ad-hoc technical meeting under the Pharmaceutical Committee on shortages of medicines 25 May 2018** should be enshrined in the European legislative framework and enforced at national level.

12. The issue of **pricing and reimbursement for centrally (EMA) registered products should be separated from the availability of centrally registered products on national markets**. In case of a detachment of pricing and reimbursement, products could be immediately placed on the market (with an EU or a multi-country package including all necessary national requirements) after the centralised marketing authorisation has been granted. Pharmaceutical manufacturers should be able to set an **ex-factory price of their medicine for the whole EU market**. Due to the principle of subsidiarity, Member States would subsequently have to decide upon the public price and the reimbursement of the product. Derogations should be applied for Member States where the access to the market is not possible prior to a reimbursement decision.

13. In the event of a shortage, swift dispatch across the EU is possible through resorting to **multi-market packaging or foreign-language packaging**.

14. The European Commission should set out a **roadmap for advancing a true single market for medicines**.

III. Strengthening supply chain resilience

15. Acknowledge the **critical public service role and function of pharmaceutical full-line wholesalers** through recognition, as part of the **pharmaceutical critical infrastructure** that allows wholesalers fulfil their obligations of continuous and equitable distribution of medicines to patients in the EU, even more so in times of pandemics, crises, or force majeure.

16. Evaluate the capability of pharmaceutical full-line wholesalers as the **providers of the right infrastructure for stockpiling measures** for emergency preparedness, with **appropriate remuneration** and a balance between European and national stockpiles

17. Foresee a **general revision of the wholesale distribution licensing system** and introduce a distinction between full-line wholesalers carrying out a public service obligation or function and other distributors, storing and distributing by choice only a selective range of products.

18. Pharmaceutical full-line wholesalers must, within the framework of their responsibility, **guarantee a demand-oriented and continuous supply of all medicinal products** (demanded) by customers with whom they have a constant business relationship, fulfil a PSO vis-a-vis pharmacies and persons authorised or entitled to supply to the public, have a right to be supplied (right to claim supplies from MAHs) to comply with their PSO, be able to deliver, within a defined number of hours, to customers in a catchment area thereby fulfilling critical entity obligations.

19. Other distributors, such as short-line wholesalers or specialised distributors, would have limited obligations but would not be entitled to a right to claim supplies as they would not need to fulfil a PSO.

20. Consider the need for **financial viability of pharmaceutical full-line wholesalers** to improve the long-term resilience of healthcare systems and work with MSs to promote measures, such as the application of a sustainable remuneration for the full-service healthcare distribution sector.

ABOUT GIRP

GIRP, the European Healthcare Distribution Association, is the umbrella organisation for full-service healthcare distributors in Europe. It represents the national associations of over 750 pharmaceutical wholesalers serving 33 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.

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