Position paper on the recognition of a distinct system of wholesale distribution licenses for pharmaceutical full-line wholesalers

GIRP welcomes the initiative of the European Commission to revise the European Union (EU) general pharmaceutical legislation to adapt the regulatory framework to an ever-increasingly complex environment and to the learnings of over two years of COVID-19 pandemic. In view of the objectives announced by the European Commission and taking into consideration the challenges posed by the current regulatory framework, GIRP sees this revision as a unique opportunity to ensure adequate, comprehensive, and effective access to healthcare for patients across the EU.

GIRP already presented a set of recommendations[1] for the European Commission to consider for a balanced revision of the EU general pharmaceutical legislation that recognises the public service role fulfilled by pharmaceutical full-line wholesalers to ensure the continuous supply of medicinal products to all patients.

GIRP would like to provide further elements of reflections on the role of pharmaceutical full-line wholesalers in the pharmaceutical supply chain and on the necessity to streamline the system of wholesale distribution licenses to better reflect the reality of the activities carried out by full-line pharmaceutical wholesalers and the obligations entrusted to them in accordance with EU and national legislation. The intent is not to exclude nor limit the activity of other licensed wholesale distributors (short-line wholesalers) but recognise by law the core services provided by pharmaceutical full-line wholesaler who, in compliance with their Public Service Obligations or Public Service Function, carry and distribute the complete assortment of products in range and depth within the frame set by the authorities and the market - regardless of the price and subsequent margin and regardless of the quantity procured to retail pharmacies, hospitals and dispensing doctors and this regardless of their location, or dimension - and continuously ensure product availability to patients through their pharmacists within a matter of hours.

A. Different licensing systems for different types of wholesale distribution

The wholesale of medicinal products is an activity regulated according to Directive 2001/83/EC,[2] and requires the possession of a wholesale distribution authorisation to ensure the quality, integrity and authenticity of the products. Member States are bound to 'take all appropriate action to ensure that only medicinal products in respect of which a marketing authorization has been granted in accordance with Community law are distributed on their territory'[3] as well as to guarantee that 'the wholesale distribution of medicinal products is subject to the possession of an authorisation to engage in activity as a wholesaler in medicinal products'.[4]

This obligation to establish a system of wholesale distribution authorisations requires Member States to adopt a dedicated system but does not define the modalities thereof. Consequently, in most of the European Union Member States, the implementation of these provisions was thus limited to a single wholesale distribution license, which does not distinguish between different types of wholesaling.

However, in practice, this system does not capture the essence of the activities carried out by pharmaceutical full-line wholesalers which fundamentally differ from other forms of distribution activities in the healthcare sector. Indeed, whereas pharmaceutical full-line wholesalers distribute a complete assortment of medicinal

[1] GIRP 'Reflections on elements to be considered by the European Commission in the evaluation and revision of the general EU pharmaceutical legislation' (December 2021) https://girp.eu/sites/default/files/2022-03/Elements%20to%20be%20considered%20in%20the%20revision%20of%20the%20general%20EU%20pharmaceutical%20legislation.pdf .
[2] Consolidated text: Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L 311, Article 77.
[3] *Ibid.*, Article 76.
[4] *Ibid.*, Article 77.

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products with a dedicated depth of stock and are able to distribute in a very short time span, short-line pharmaceutical wholesalers (by comparison) focus on the distribution of a selected (limited) assortment of medicinal products, but do not necessarily provide the added-value services brought by full-liners and are not serving as a "one-stop-shop" for pharmacies and persons authorised or entitled to dispense medicinal products to the public.

Pharmaceutical full-line wholesalers, bound by the PSOs they respond to, store, handle and distribute all authorised products including low-priced medicines, which often generate a loss in income. Pharmaceutical full-line wholesalers are committed to continuously delivering all products, with the highest standard of quality, safety and integrity as needed by the patient within a matter of hours, regardless of the medicines' price – which is a responsibility not carried out by other distributors. Therefore, pharmaceutical full-line wholesalers, alongside pharmacists, are the warrantor of patients' fair access to all medicines.

B. Recognising different supply chain responsibilities for the benefit of patients

This practical distinction is yet at the cornerstone of the pharmaceutical supply chain and guarantees the adequate distribution of medical products as both models are complimentary: pharmaceutical full-line wholesalers and pharmaceutical short-liners serve inherently different purposes that are reflected in the practice and in the legislation of some European Union Member States where a separate licensing system is in place.

In 13 Member States,[5] pharmaceutical full-line wholesalers are, to varying degrees, bound to respond to PSOs and are under a much stricter regime than other pharmaceutical distributors. These more stringent legal requirements are thus determining factors of the business models of these operators and differentiate wholesalers that decide to fulfil more demanding obligations and respond to a function of public service from those that decide to only distribute a selected and limited range of products of their choosing.

This differentiation is however neither harmonised nor reflected in the legislation of all Member States. On the contrary, while pharmaceutical full-line wholesalers are *de facto* required to fulfil more stringent requirements on the basis of PSOs in thirteen Member States, they are fully recognised and protected as such by law only in two of them.[6] This discrepancy creates a hardly tenable situation in which the requirements imposed on pharmaceutical full-line wholesalers are not supported by a distinctive license that would acknowledge the essential service carried out by them in ensuring the adequate, permanent and timely supply of medicinal products, and thus being the vital link in the healthcare supply chain.

While this approach would recognise the unique role of the pharmaceutical full-line wholesalers, strengthens their obligations in the form of public service obligations and provide them with a right to claim continuous supplies from the pharmaceutical manufacturers, it does not prohibit, exclude or limit the activities of other wholesale distributors (such as so called short-line wholesalers) nor would it restrict the ability of marketing authorisation holders to provide their products directly to pharmacies and persons authorised or entitled to supply the public.

C. A system already implemented in several EU Members States

A situation in which distinct licensing systems exist for pharmaceutical full-line wholesalers and other distributors of medicinal products is already in place, for example, in Germany and Belgium and thus paves the way for a harmonised system on the EU level.

[5] Belgium, Croatia, Cyprus, Czechia, France, Germany, Hungary, Italy, Luxembourg, Portugal, Slovakia, Slovenia, Spain.
[6] Belgium and Germany.

In Belgium, according to the Law of 25 March 1964 on medicinal products, Article 1(20), a wholesaler-distributor is 'the wholesale distributor entrusted with public service obligations in respect of medicinal products for human and/or veterinary use'.[7] In Belgium, a public service obligation is understood as the 'obligation of wholesale distributors to guarantee at all times an assortment of medicinal products capable of meeting the requirements of a geographically determined territory and to ensure the delivery of the requested orders within a very short period of time throughout that territory'.[8] Thus, the legal regime governing the wholesale distribution authorisation of medicinal products distinguishes between the wholesaler/distributor of medicinal products and the pharmaceutical full-line wholesaler fulfilling the PSO hereinabove.

Likewise, in Germany, 'Full-line wholesalers of medicinal products are wholesale businesses that maintain a complete, manufacturer-independent assortment of pharmacy-only medicinal products which, in terms of depth and scope […]'.[9] The case of Germany is even more striking insofar as the distinct licensing system for full-line pharmaceutical wholesalers is embedded into the public service obligation: the fulfilling of the public service obligation and the full-line wholesaling license are construed as inseparable and indivisible, and are accompanied by a PSO for the manufacturers to supply the pharmaceutical full-line wholesalers, a so-called 'right to be supplied'.

As the above examples demonstrate, separated wholesale distribution licenses for pharmaceutical full-line wholesalers are already in place in the EU. GIRP strongly believes that a harmonised system on the EU level that would recognise and acknowledge the special position held by pharmaceutical full-line wholesalers by a distinct distribution licensing system not only is practically feasible but is necessary to guarantee that the demand of patients across Europe are met at all times.

In the light of the foregoing, GIRP calls on the European Commission to **create a distinct system of wholesale distribution authorisation for pharmaceutical full-line wholesalers fulfilling public service obligations.**

GIRP
European Healthcare Distribution Association
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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 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.

[7] Belgian Law of 25 March 1964 on medicinal products (Loi du 25 Mars 1964 sur les médicaments), Article 1(20). Translation provided by courtesy of GIRP.
[8] Ibid., Article 1(19).
[9] Medicinal Products Act in the version published on 12 December 2005 (Arzneimittelgesetz in der Fassung der Bekanntmachung vom 12. Dezember 2005), Article 52b. Translation provided by courtesy of GIRP.