



## **GIRP POLICY PAPER**

### **I. GIRP The European Association**

'Groupement International de la Répartition Pharmaceutique' or in English 'European Association of Pharmaceutical Full-line Wholesalers' – is the international umbrella organisation of pharmaceutical full-line wholesaler's in Europe. Founded in 1960, GIRP represents the national associations of pharmaceutical wholesalers with over 400 pharmaceutical full-line wholesalers serving 17 European countries (including every member state of the EU) as well as the 3 major Pan-European Pharmaceutical Wholesaling companies (Alliance UniChem, Celesio, Phoenix) and a group uniting cooperatives in 6 European countries (SECOF) as Full Members. GIRP also includes Associated Professional Members who represent the pharmaceutical full-line wholesaler associations/ companies in Eastern Europe and the New Independent States, as well as Associated External Members who are companies who have an interest in the activities of our association. GIRP members employ about 70.000 people and distribute medicines with an annual value of around 70 billion Euro.

Above all, GIRP is a communication platform and focal point between its member organisations and all players in the health-care sector, providing information and co-ordinating informed opinions on all matters relevant to the efficient and safe distribution of medicines throughout Europe.

GIRP strives to safeguard the wholesaling system, ultimately to meet the needs of the patients in Europe.

### **II. Self-understanding of the European full-line wholesalers**

Pharmaceutical wholesalers are the vital link, ensuring the safe and continuous supply of medicines between manufacturers and pharmacies, and ultimately to the patients.

The European pharmaceutical wholesalers have built and maintained a very efficient distribution network which is highly reliable, extremely rapid, is active 365 days a year and fosters a cost-effective supply chain management system that protects product integrity and quality.

One of the aims of the Single Market is to ensure the free circulation of medicines in order to guarantee to all European citizens equal access to medicines of the highest quality and at the most competitive price. Full-line wholesalers contribute to this ideal by linking the hundreds of manufacturers to over one hundred thousand pharmacies for the benefit of the many millions of patients in Europe, making sure the medicines needed are available when and where they are needed.

Full-line wholesalers hold up to 80,000 products of which only a small proportion actually makes a profit. The slow moving - but often vital - medicines are held as a sometimes life-saving service in order to quickly provide the complete needs of the patients. Such a service is only available from the full-line wholesaler, whose objective is not cherry picking but fulfilling its vital role towards responsible health care distribution.

European pharmaceutical full-line wholesalers are prepared to implement immediate recall procedures on behalf of manufacturers and Member State health authorities in order to withdraw defective products from the market. Emergency plans are in place, ensuring that all pharmacies are alerted and products are recalled and disposed of when necessary for safety reasons, thereby protecting the patient.

Full-line wholesalers also care for the collection and destruction of out-of-date medicines and provide

valuable information services which can create new opportunities, monitor costs and lead to improvements in patient care.

Due to the significant investments in technology, the European pharmaceutical wholesalers can offer a very high level of service as well as automated product handling. This makes full-line wholesaling arguably the most efficient and cost effective sector of any industry.

The differences between national policies on healthcare - its funding, availability, and balance of trade implications - are kept in perspective when working at the pan-European level, and by constantly focusing on the healthcare supply interests of the Community.

The European pharmaceutical wholesalers are in favour of deregulation as long as it is carefully handled in order not to destroy the highly efficient structures that exist within the health care system and as long as all patients' needs are protected.

Full line Wholesalers provide a host of added value services to ensure that the patients' needs are met in the most complete, efficient and cost effective method possible. No other distribution system is able to provide such a unique service.

### III. Political targets of GIRP

#### ***Completing the internal market***

The pharmaceutical wholesalers see the completion of the internal market as one of the most important tasks for the European Union Member States. A European market with over 380 million customers in the current EU countries- as in the United States and Japan - is the way to the successful economic development of industry and trade. It will guarantee progress in the creation of jobs, solve social problems by increasing the income of the social systems, and strengthen the competitiveness of Europe.

The members of GIRP strongly support their national governments in the attainment of this aim. European regulations such as the Good Distribution Practice (GDP) or the Wholesaling Directive 92/25/EEC are the first steps for the European pharmaceutical wholesalers towards the completion of the internal market.

#### ***Free movement of pharmaceuticals***

The proceeding harmonisation of the legal regulations within the European Union is the basis for major pharmaceutical wholesalers to start cross-border mergers and acquisitions and there are today several Europe-wide operating wholesalers. However, due to the different health care systems, different pharmacy structures, different prescription behaviours of doctors and consequently, different product ranges in each country, the wholesale business is still a national or regional business. Furthermore, the small and medium sized enterprises play an important role in the supply to the market and the maintenance of local competition.

Today, pan-European wholesale distribution of pharmaceutical products is still not feasible. Despite essential progresses, the European pharmaceutical market place is still split into fragmented national markets on the wholesale and retail trade level.

Certainly, the activities of the EMEA are a significant step forwards through the development of a central European-wide registration.

Nevertheless, it is still virtually impossible to buy pharmaceuticals in one member state of the EU and put them on the market in another state without relicensing, repackaging and relabelling. We still have 15 separate national markets.

The free movement of pharmaceuticals is still not a reality and it remains a national business.

Significantly more effort will be necessary in order to harmonise all regulations concerning the pharmaceutical market and abolish existing trade barriers. This can only be achieved with the active support of the Member States, the registration authorities and the pharmaceutical manufacturers.

### ***Good distribution practice***

Wholesale Members of GIRP operate within the EC Wholesale Directive and the Guidelines on Good Distribution Practice. These are regularly reviewed and updated as good practice and technology develops. Consequently, manufacturers and pharmacists have confidence in the full-line wholesaler's ability to maintain the quality and integrity of medicines within the distribution chain and thus safeguard the patient.

### ***Margins***

Given the existing variations in national pharmaceutical markets in terms of product range, pricing and reimbursement systems, pharmacy structures, geographic conditions and per capita wealth it is not possible to make a realistic comparison of distribution margins. Furthermore, contrary to the interventions in the manufacturer's prices, national regulations on trade margins and consumer prices do not hinder the free movement of pharmaceutical products, and therefore, efforts towards deregulation at a European level are considered unnecessary. Pharmaceutical wholesalers generally operate on a small net percentage of the sales price of the products they supply. This margin varies between one country and its European neighbours, as a result of differing health care policies and also the different services and performances provided by pharmaceutical wholesalers and pharmacies. Therefore on a national level there exists different margin systems as well as different reimbursement and price systems. The regulations on margins in Member States have the common task of guaranteeing all patients in the respective Member State the best access to medicinal products. It would be a violation of the principle of subsidiarity if the Community authorities were to start to intervene in these national regulations.

Full-line wholesaling is an extremely competitive business and as a result is very efficient and cost effective. It has to compete with cherry picking short-line wholesalers, who have no public service liability responsibilities and do not provide the range of added value services or an immense product portfolio. This portfolio includes a high percentage of slow moving products, which are delivered in small quantities under the same responsive service as that available to profitable high volume medicines. Full-line wholesalers are the vital link between manufacturers and pharmacies and are not immune from the effects of government legislation. Cost containment measures applied to manufacturers or to pharmacists have a knock-on effect and wholesalers are equally affected due to the national systems on margins.

Full-line wholesalers work on extremely low margins in a highly competitive industry and consequently any attempt to cut distribution costs by legislation will simply result in reducing the full-line wholesalers comprehensive range of products as they simply will not be able to carry the already loss making products. The patient will therefore suffer and the Government will often be faced with higher costs for alternative medicines.

### ***The pharmacist's role***

The legislation of all Member States includes, for reasons of pharmaceutical quality and safety of supply, the rule that medicinal products are to be sold and handed out to patients in principle through pharmacies only. Differences exist between countries regarding the question of whether exceptions are allowed or not. Despite this common conviction, the exclusive distribution through pharmacies is still not acknowledged at a European level. The reason for this gap in the European legislation is not missing competence of the Community or the principle of subsidiarity. The question "where, by whom and under which conditions are medicinal products allowed to be sold and handed out to patients" is essential, not only from the aspect of accessibility of medicines, but also with regard to the quality of medicinal products.

The pharmacy monopoly, which as a principle exists in all Member States, includes prescription-only-medicines as well as OTC drugs. This principle should also be included into Community legislation leaving the exceptions to national responsibility. All pharmaceutical provisions regarding the quality of

drugs as well as prescription requirements and patient information are useless if they can be circumvented by unclear distribution channels. The clear regulation of the distribution channel manufacturer - the pharmaceutical wholesaler - public pharmacy is therefore an essential precondition for the free and safe trade in pharmaceuticals within the European Union.

### ***Electronic commerce***

Electronic commerce is rapidly changing consumer behaviour patterns in a wide variety of areas and generally speaking, such innovation is supported.

#### ***Business to Business (B2B)***

All European pharmaceutical wholesalers represented by GIRP member associations are quick to apply modern techniques to their business operations in order to reduce overheads and improve efficiency in this extremely competitive market sector. Pharmaceutical wholesalers were early adopters of EDI and nowadays above 90% of all orders in Europe are processed by EDI. Pharmaceutical wholesalers in Europe are working on business to business E-commerce solutions in order to further improve the supply chain efficiency.

#### ***Business to Consumers***

There are areas where additional safeguards are required in order to protect the consumer and the supply of medicines is one such area. Of course, consumers seek health-care information on the internet but the actual willingness of European consumers to purchase healthcare products from the internet is not proven. Like all responsible health care professionals, GIRP has major reservations against the selling of medicines on the internet.

It is quite essential that there must be the realistic involvement of a doctor and a pharmacist with full access to the patient's medical history in order to check on the suitability of the medicine and to check for drug interactions before any prescription is provided.

It should also be born in mind that the widespread introduction of electronic commerce in pharmaceuticals will undoubtedly have an adverse impact on the accepted distribution of medicines, resulting in a reduced level of service to the community and increased costs, as the profitable range of products are lost to cherry picking activity.

It is necessary to keep the balance between:

- the use of new E-commerce technologies,
- the ongoing change of the relationship between manufacturers, wholesalers and pharmacists and
- the protection of the patient

Therefore the supply of medicines has to be limited personally to pharmacies and when specific national rules are given - doctors.

### ***Freedom of therapeutic choice and self medication***

The doctor's freedom to decide which medical treatment is appropriate is one of the most important principles. He is the only one who is able to prescribe the right medicament and he is responsible for treatment. It is therefore one of the most important tasks of the pharmaceutical wholesalers to offer all pharmaceutical and medicinal products to the pharmacy so that doctors can prescribe without restriction - restrictions which could arise due to unavailability.

There is also the right of the patient to buy pharmaceutical products for self medication which ought not to be hindered by insufficient rules or restricted supply. The customer's freedom with regard to self-medication should only be limited by the pharmacist's guidance given in order to guarantee a successful treatment. The members of GIRP - full in line with the above mentioned principles.

Austria	Arbeitsgemeinschaft des pharmazeutischen Großhandels - ARGE Pharmazeutica
Belgium	Association Nationale des Grossistes-Répartiteurs en Spécialités Pharmaceutiques (NNGV - ANGR)
Denmark	Denmark Forenigen af medicingrossisters-Association of Pharmaceutical Wholesalers (MEGROS)
Finland	APTEEKKITAVARATUKKUKAUPPIAAT r.y. (ATY) Association of Pharmaceutical Distributor
France	Chambre Syndical de la Répartition Pharmaceutique (CSRP)
Germany	Bundesverband des pharmazeutischen Großhandels (PHAGRO)
Greece	Panhellenic Association of Pharmaceutical Wholesalers and Qualified Pharmacist (PAPW)
Ireland	Pharmaceutical Distributors Federation (PDF)
Italy	Associazione Distributori Farmaceutici (ADF)
Luxembourg	Groupement des Grossistes Répartiteurs Luxembourgeois en Produits Pharmaceutiques (GGRP)
Netherlands	Bond van Groothandelaren in het Pharmaceutische Bedrijf (BG Pharma)
Norway	Norsk Medisinaldepot AS
Portugal	Associação de Grossistas de Produtos Químicos e Farmacêuticos (GROQUIFAR)
Spain	Federación Nacional de Asociaciones de Especialidades Farmacéuticas y Productos Parafarmacéuticos (FEDIFAR)
Sweden	Läkemedelsgrossistföreningen Swedish Association of Pharmaceutical Wholesalers
Switzerland	Verband Schweizerischer Spezialitäten Grossisten (VSSG)
United Kingdom	British Association of Pharmaceutical Wholesalers (BAPW)

Alliance UniChem

Celesio AG

Phoenix Pharmahandel AG & Co.

SECOF Sociedad Europea de Cooperacion Farmaceutica s.a.



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### Executive Summary

'Groupement International de la Répartition Pharmaceutique' or in English 'European Association of Pharmaceutical Full-line Wholesalers' – is the international umbrella organisation of pharmaceutical wholesaler's associations in Europe.

GIRP strives to safeguard the full-line pharmaceutical distribution system, ultimately to meet the needs of patients throughout Europe.

The European pharmaceutical full-line wholesalers have built and maintained a very efficient distribution network which is highly reliable, extremely rapid, is active 365 days a year and fosters a cost-effective supply chain management system that protects product integrity and quality and guarantees all European citizens equal access to all medicines of the highest quality and at the most competitive price.

Only pharmaceutical full-line wholesalers carry the full range of medicinal products, including slow moving but vital medicines. Their objective is its vital role towards citizens and society in providing responsible health care distribution.

Wholesale Members of GIRP operate within the EC Wholesale Directive and the Guidelines on Good Distribution Practice. These are regularly reviewed and updated as good practice and technology develops.

Pharmaceutical wholesalers generally operate on a small net percentage of the sales price of the products they supply. This margin varies between one country and its' European neighbours, as a result of differing health care policies and also the different services and performances provided by pharmaceutical wholesalers and pharmacies.

Pharmaceutical wholesalers were early adopters of EDI and nowadays above 90% of all orders in Europe are processed by EDI. Pharmaceutical wholesalers in Europe are working on business to business E-commerce solutions in order to further improve the supply chain's efficiency. E-commerce will inevitably change the relationship between manufacturers, wholesalers, pharmacists, and patients. Therefore additional safeguards are required in order to protect the consumer by specific rules to limit the supply of medicines personally to pharmacies and doctors.