



54th Annual
General
Meeting

2 - 4 JUNE 2013 SOFIA BULGARIA

GIRP ANNUAL REPORT 2012 - 2013



the vital link in healthcare

European Association of Pharmaceutical Full-line Wholesalers
Groupement International de la Répartition Pharmaceutique

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1. MESSAGE FROM THE PRESIDENT

Dear Colleagues,

A great budgetary disaster is unfolding in many Euro zone countries that have agreed to slash spending, wages, and living standards to meet the demands of fiscal austerity. One facet of this story that has received far too little attention, however, is the effect the measures have on their healthcare systems.

Austerity derives from the Greek 'austeros', for harsh or severe; but, in the area of health care, this is much worse as it has a direct impact not only on business but on the actual lives and well-being of people.

The effects of austerity on health care are both immediate and far reaching. Deep cuts in public health spending including medicines clearly worsen the suffering caused by the prolonged economic crisis. This in turn is leading in some countries to an unraveling of one of the great achievements of modern Europe: the health care system.



GIRP takes this situation very seriously and works where possible to support members by raising the matter at the European level. We have worked hard in the last twelve months to raise the profile of the wholesale distribution sector. We have been communicating the results of the study on the distribution sector from the six European countries selected – France, Germany, Italy, Netherlands, Spain and United Kingdom. The study was commissioned by GIRP and carried out by the Institute for Pharmaeconomic Research (IPF), a scientific research institute based in Vienna.

One of the main results on the study showed how wholesalers play a critical role in pre-finance almost the entire market of medicinal products and how they secure cash flow for social insurers. From the countries subject to the study, the findings were remarkable in that full-line wholesalers pre-finance on average €10.2bn over a period of 41 days.

Another German study conducted by Prof. Thomas Wilke – “value creation by the pharmaceutical wholesaling industry by means of superior delivery capacity when compared with direct sales by the pharmaceutical industry” showed from the data of 106 pharmacies that an absolute minimum of 4,707 pharmaceutical orders per year are needed. With a hospitalisation rate of only 1 % due to medication non-availability, at least 47.1 people per pharmacy per year would have to be admitted to hospital on these grounds alone. Thus, the value added by the delivery capacity of the pharmaceutical full-line wholesale sector, interpreted as the non-occurrence of these admissions, is at least 138,275 € per pharmacy per year (based on average costs per hospital stay in Germany). If this figure were to pertain to all the 21,000 non-hospital pharmacies in Germany, the result value is around 3 billion euro.

It is on this basis that we can highlight that wholesalers are important contributors to the healthcare system and its financing. Measures aimed at reducing costs for medicines distribution should be balanced against its overall contribution. We have been highlighting this message at the highest levels in European circles and stand ready to work with members at national level to support their goal of communicating the same messages towards their national governments.

While the struggle against headwind from austerity and other budgetary cuts continues wholesalers are facing other challenges. But the other challenges equally present possible opportunities.

Wholesale distributors are ‘innovators’ in terms of finding new, creative and cost effective ways of delivering services and products to customers and patients. Any wholesaler which does not look beyond the core job of product delivery will find it increasingly hard to secure growth in coming years. It is for this reason why wholesalers are actively looking to add value throughout supply chain with enhanced service levels. Services in the areas of e-health, patient compliance and home care are potential growth drivers and cost savers for healthcare systems.

It seems to be without question that the winners will be wholesalers that can effectively reinvent themselves by developing new ways to support their pharmacy customers, which will help them be proactive rather than reactive in identifying and exploiting current and future opportunities. However, to take the ultimate prize of success it is not as simple as reinventing oneself as a wholesaler. The key to achieving growth in our sector is to find new services which can be price-tagged and properly remunerated. It is for this reason why we have established a number of project groups to allow members to come together to explore ways in which to raise the level of awareness of the services offered and try to identify means by which wholesalers can find ways to be remunerated for their new services.

GIRP is also committed to playing a greater role in raising the profile of our members in the area of corporate social responsibility and good conduct. During the last twelve months we have developed and approved a brand new GIRP code of conduct as part of our good governance drive and furthermore developed and adopted a GIRP statement regarding the corporate social responsibility of our members. The papers prove to our stakeholders and targets how as a sector we are committed to higher standards and to making a contribution to society at large. We have also been increasingly engaged in European Commission initiatives in the area of corporate social responsibility through the European Innovative Partnership on Active and Healthy Ageing, in addition to our work in the context of the Commissions corporate social responsibility platform on access to medicines in small markets.

Finally, as always I would like to take this opportunity to thank all GIRP members and our many colleagues in the European institutions and stakeholder associations for their contributions to our achievements. I very much look forward to our continued collaboration.



René Jenny
President

2. MESSAGE FROM THE DIRECTOR GENERAL

Dear Members,

Ahead of next year's European Parliament elections and with the mandates of European Commissioners' coming to an end in 2014, the European institutions have been more active than ever before in terms of proposing and adopting new legislation and regulation. We have seen that many of the recent developments are core to our sectors concerns, while others less so, but increasingly some appear at first glance to be non-impacting but on closer scrutiny are of major relevance.

All of GIRP's activities are guided by our core principle – ensuring supply chain safety and thereby patient safety. However, recently we had to fight several pieces of legislation which would have added disproportionately to our cost and workload without any major contribution to patient safety. The most striking example is certainly the **new GDP guidelines**.

In spring 2010, we first made our members aware of new GDP guidelines being drafted by a working group of GMP/GDP inspectors, striving to implement the concepts of Good Manufacturing Practice (GMP), in the guidelines covering the distribution of medicines. Since then, we have alerted our members about the eventually very negative impact of the new provisions in case they are not changed. When the information became public we participated through an extensive contribution to the consultation and encouraged all GIRP members to approach their drafting group members, medicines agencies and health ministries' to explain the huge, unnecessary expenditures which would be caused, if the draft GDP guidelines on which the consultation was based would become the guiding principles of medicines distribution. In a meeting with the inspectors working group at the European Medicines Agency as well as in meetings with the European Commission services, we were able to avoid several provisions which would have severely compromised the operation and processes of our members, as well as skyrocketing costs without any clear benefit for product and patient safety and ultimately would have put the smooth running of the supply chain in peril. Just to mention a few, but the most striking examples we were able to avoid are:

- The permanent presence of the Responsible Person combined with the impossibility to delegate tasks and to have a Responsible Person per warehouse,
- the requirement for active humidity steering in wholesalers' warehouses,
- the tracking of physical journey of products,
- the requirement to deliver into the hands of customers, which would have made night deliveries impossible,

Finally, on 8th March 2013 the new GDP guidelines were published and a lot still needs to be done until their entry into force on 8th September 2013. However, our sector is committed to delivering medicines respecting the highest possible standards to guarantee their safety, security and efficiency in the supply chain. Our members will comply certainly to the requirements imposed on them through the new GDP guidelines despite the significant investments involved in times of economic hardship.

In order to assist our members to swiftly implement the new provisions, GIRP will organise a first workshop on quality and risk management, including the process of corrective and preventive actions (CAPA) still prior to the Annual General Meeting in Sofia. Further workshops in this direction will be held if our members deem it useful for their business.

We will promote these new standards equally towards our supply chain partners and insist that inspections are carried out on all supply chain participants with the same level of scrutiny as this will be done for our sector.

One of the examples where we have only discovered the relevance of an upcoming legislation through careful screening of the legal proposals, which from the outset did not seem to have an impact on our sector, are the proposed **Regulations on medical devices and in vitro diagnostic medical devices**. The proposed Regulations follow the recent tendency in EU regulation to place increased market surveillance obligations on distributors, however, without specifically addressing their limited role and responsibility. Wholesale

distributors can only be held responsible for ensuring the maintenance of the quality and safety of a product throughout the distribution chain and not the safety of the product itself.

Therefore, we currently urge the Members of the Committee on Environment, Public Health and Food Safety to amend the proposals of the European Commission in this respect and warmly thank our members for their support with their good contacts to the Members of the European Parliament from their countries.

The GIRP office will keep abreast of the developments and report on developments as the proposal pass through the legislative machinery and will call upon its members once again for the votes in the European Parliament and the Council.

GIRP also continues its very intense collaboration with PGEU (European pharmacist association), EFPIA (European pharmaceutical industry association) and EAEPC (European parallel distributors association) to develop the **European Stakeholder Model (EMS)**, which is aimed at a stakeholder-led implementation of the Falsified Medicines Directive and the yet to be defined Delegated Acts.

The statutes of the ESM are in their final stage and subsequently will be open for adoption by each of the stakeholders' organisations.

The close collaboration with the other stakeholder organisations during the past two years has also led to an exchange on other problems in the supply chain such as the increasing difficulties with medicines shortages. GIRP as the vital link in health care is in an ideal position to provide the platform for an open dialogue, thereby increasing collaboration, transparency, responsibility and accountability of all supply chain stakeholders.

Finally, I would like to express a warm thank you to all our members as well as to our President and our team in the office for the continuous support and dedication.



Monika Derecque-Pois
GIRP Director General

3. GIRP MISSION AND OBJECTIVES

GIRP – “Groupement International de la Répartition Pharmaceutique Européenne” – is the European umbrella organisation of pharmaceutical full-line wholesalers. It represents the national associations of over 750 pharmaceutical full-line wholesalers serving 31 European countries, including major pan-European pharmaceutical wholesaling companies. Through their network of operational facilities, GIRP members employ about 140,000 people and serve over 170,000 pharmacies and other healthcare professionals dispensing medicines to the public.

The aim of GIRP is to define the principal functions of pharmaceutical full-line wholesalers and pharmaceutical integrated supply chain providers whose actual core business is full-line wholesaling. GIRP promotes its members role in the interests of public health and defends a common policy for ensuring the safe and continuous supply of all registered medicines to patients in Europe.

In the performance of their public service role GIRP members absolutely guarantee the highest levels of quality, integrity and excellence. GIRP members are the trusted supply chain partners of manufacturers, pharmacists, healthcare professionals and, above all, patients for ensuring continuous access to safe medicines. GIRP members are the vital link between our trusted supply partners. Should this vital link break, the safe and continuous supply of medicines cannot be guaranteed.

GIRP maintains a permanent contact with its members and to achieve our aims, examines and studies common professional issues relative to the wholesale trade, the handling and the safe delivery of pharmaceuticals to the patients.

GIRP formulates, ensures, promotes and defends opinions and measures relative to the scope of activities at national, European and international level. GIRP offers its members individual as well as collective support services and assistance that affects their business on a daily basis. We work with the national associations and companies to help them with unique issues at national level by providing advice, information, statistics and other data. Our aim is to tailor our services to the key priorities and challenges of our members.

4. GIRP KEY PRIORITY AND ACTION AREAS

Legislation & Regulation	Membership	Networking & Communications	Refining strategy
<p>Closely monitoring the implementation of Falsified Medicines Directive (FMD) and developments in relation to the adoption of the Delegated Acts.</p> <p>Continue to get across GIRP's views on the Delegated Act, the impact that it will have on members' activities – highlighting a risk based verification of medicine packs at the level of wholesale distributors.</p> <p>Work with GIRPs supply chain partners namely EAEPC, EFPIA and PGEU on the development of the European Stakeholder Model (ESM) approach to the implementation of the FMD and subsequent Delegated Act.</p> <p>Work with the European institutions to ensure the impact of the draft Regulations for Medical Devices and in-vitro diagnostics is minimized.</p> <p>Closely monitor and report on other legislative and regulatory developments such as general product safety, data protection regulation, etc...</p>	<p>Continue to drive forward an agenda for increased GIRP membership and ensure greater geographical coverage of GIRP.</p> <p>Continue to provide support with individualized service for GIRP members in dealing with unique national problems.</p> <p>Drive forward the initiative to focus information flow by convening GIRP regional meetings and a meeting of associations' directors.</p> <p>Support members with the implementation of the Falsified Medicines Directive at national level.</p> <p>Support members with the establishments of National Medicines Verification Organisations (associated with the European Stakeholder Model).</p> <p>Support members with the implementation of the European Good Distribution Practice Guidelines</p> <p>Support members at national level with issues of a European dimension.</p>	<p>Continue to build on existing and establish new contacts with the European Commission, European Parliament, European Medicines Agency (EMA) and other pertinent international organisations.</p> <p>Establish better contacts to the Head of Medicines Agencies.</p> <p>Continue to establish new contacts with manufactures, pharmacists, patients and payers directly and through their representative associations.</p> <p>Continue with thematic discussions with supply chain partners.</p> <p>Continue with establishment and active development of the range of new project groups headed by project champions recruited from the GIRP Board.</p> <p>Implementation of the revision of the GIRP corporate identity including new website.</p>	<p>Ensure that value added services of GIRP's members is promoted to authorities and stakeholder groups and reflecting this in GIRP strategy.</p> <p>Establish and run new project groups for issues of interest to a cluster of members rather than thematic working groups.</p> <p>Establish a new Directors' of associations meeting.</p> <p>Run dedicated (fee paid) training sessions for GIRP members on specific operation topics.</p> <p>Review ongoing implementation of GIRP strategy.</p> <p>Commit 20 additional man days to the marketing of the ESM for uptake of project at national level.</p>

5. FINANCIAL REVIEW

The Association is financed through contributions of all members for which in return they receive specific advice and consultancy services such as tailor-made services which are delivered to individual members to support them in the promotion of their role of ensuring the safe and continuous supply of all registered medicines to patients in Europe. Furthermore, the Association is financed through delegate contributions / fee to events and sponsorship.

The annual accounts for 2012 are submitted in accordance with the legal stipulations and held at the associations registered office.

6. GIRP MEMBERSHIP

Currently, GIRP comprises the following categories of membership:

GIRP “Full Members” are the national associations of pharmaceutical full-line wholesalers in Europe as well as major European pharmaceutical wholesaling companies.

“Associated Members” are pharmaceutical full-line wholesalers that are members of their national association, but also wish to have direct representation within GIRP or associations of pharmaceutical full-line wholesalers outside the EU and EEA.

“External Members” are companies or organisations whose business interests are related to the pharmaceutical industry and the pharmaceutical distribution sector. They do not necessarily need to be based in the EU or the EEA. This category of membership is specifically dedicated to the representation of sponsors.

“Liaison Members” can join the association upon invitation and can be any company or organisation necessary for furthering the Association’s objectives.

6.1. Full Members

Currently, GIRP has 37 Full Members consisting of 26 national associations in Europe (the two national associations of Greece – PAPW and OSFE – have one common voting right), two companies acting as national associations for the purpose of country representation in GIRP (Pelion SA from Poland and PHOENIX Farmacija d.d. from Croatia), seven major pan-European pharmaceutical wholesaling companies (Alliance Healthcare Germany, Celesio, COFARES, Mediq, Oriola-KD, PHOENIX Group and United Drug) and two groups uniting pharmaceutical wholesalers in different European countries (SECOF – Sociedad Europea de Cooperación Farmacéutica – uniting cooperatives and Pharma Privat uniting privately-owned pharmaceutical wholesalers).

6.1.1. Full Member Associations

Austria

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Bulgaria

BATEL

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Denmark	MEGROS Association of Danish Pharmaceutical Wholesalers Mr. Iwan Alstrup Amagertorv 11, box 2111 DK – 1160 Copenhagen	Tel: +45 36 45 45 36 Fax: +45 33 14 19 33 Email: iwan.alstrup@tmj.dk
Estonia	ERHL The Estonian Association of Pharmaceutical Wholesalers Ms. Jana Laasalu Vae 16, Laagri EE – Harjumaa	Tel: +372 650 1901 Fax: +372 650 1900 Email: janalaasalu@hotmail.ee
Finland	ATY Association of Finnish Pharmaceutical Distributors Mr. Antti Vatanen P.O. Box 150 FI – 00251 Helsinki	Tel: +358 9 431 561 01 Fax: +358 9 431 561 05 Email: aty@aty.fi
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Germany	PHAGRO Bundesverband des pharmazeutischen Großhandels Ms. Bernadette Sickendiek Charlottenstraße 68 DE – 10117 Berlin	Tel: +49 30 201 88 448 Fax: +49 30 201 88 333 Email: phagro@phagro.de Email: bernadette.sickendiek@phagro.de

Greece	PAPW (common voting right with OSFE) Panhellenic Association of Pharmaceutical Wholesalers and Qualified Pharmacists Ms. Irene Markakis 34, Beranzerou Street GR – 104 32 Athens	Tel.: +30 210 522 7519 Fax: +30 210 522 1762 Email: papw-gr@otenet.gr
Greece	OSFE (common voting right with PAPW) Federation of Cooperative Pharmacists Mr. Andreas Galanopoulos 2-4, Pigis Street GR – 106 78 Athens	Tel :+30 1 38 04 634 Fax:+30 1 38 04 194 Email: osfe@otenet.gr
Hungary	HAPW Hungarian Association of Pharmaceutical Wholesalers Dr. Sándor Küttel Keleti Márton u. 19 HU – 2151 Fót	Tel.: +36-27-537-180 Fax: +36 27-537-167 Email: kuttel@phoenix.hu
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Romania

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Spain	<p>FEDIFAR Federación Nacional de Asociaciones de Mayoristas Distribuidores de Especialidades Farmacéuticas y Productos Parafarmacéuticas Mr. Miguel Valdés General Oràa, 70 ES – 28006 Madrid</p>	<p>Tel: +34 91 562 40 25 Fax: +34 91 411 43 26 Email: mvaldes@fedifar.com</p>
Sweden	<p>LDF Swedish Association of Pharmaceutical Wholesalers Mr. Hans Wahlén c/o Kronans Droghandel, P.O. Box 252 SE – 43525 Mölnlycke</p>	<p>Tel: +46 31 88 70 46 Fax: +46 31 33 85 100 Email: hans.wahlen@tamro.com</p>
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6.1.2. Full Member Companies/Groups

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Celesio AG

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United Drug PLC

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6.2. Associated Members

Currently, GIRP has six Associated Members which are pharmaceutical wholesaling companies/cooperatives active in Bulgaria, France, Russia, Serbia, Turkey and Ukraine.

Alba Ukraine

Alba-Ukraine

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Eurapharma

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6.3. External Members

6.3.1. Partnership Sponsor

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6.3.2. Associated Sponsors

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6.3.3. Supporting Sponsors

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6.4. Honorary Members

GIRP's Honorary Members are:

Dr. Jürgen Brink, GIRP Past President and PHAGRO Honorary President

Mr. Jeff Harris, GIRP Past President

Mr. Michael Watts, past Director of the BAPW, the British Association of Pharmaceutical Wholesalers

15th May 2013,



Monika Derecque-Pois
Director General