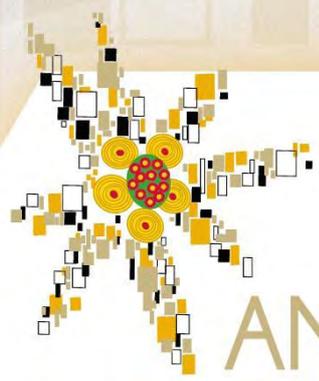




# GIRP

THE VITAL LINK IN HEALTHCARE



ANNUAL  
**55<sup>th</sup>** GENERAL  
MEETING

1-3 JUNE / VIENNA, AUSTRIA

## GIRP ANNUAL REPORT 2013-2014

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

## TABLE OF CONTENTS

1. MESSAGE FROM THE PRESIDENT.....	3
2. MESSAGE FROM THE DIRECTOR GENERAL .....	5
3. GIRP MISSION AND OBJECTIVES .....	8
4. GIRP KEY PRIORITY AND ACTION AREAS.....	9
5. FINANCIAL REVIEW .....	10
6. GIRP MEMBERSHIP .....	11

## 1. MESSAGE FROM THE PRESIDENT

Dear Colleagues,

Our business is rooted in the reality of modern health and society taking its constraints and opportunities along at the same time.

In any given year GIRP tries to bring a greater degree of harmony to the business of wholesale distribution and the services it offers with European legislation and the policy agenda.

Patients need access to safe, high quality and genuine medicines at the right time and right place. That is where GIRP members come into play. However, this also requires the regulation of the activities of the supply chain participants.

GIRP calls on to European and national authorities as well as other stakeholders to work together to find solutions to ensure sustainable access to medicines while allowing business operators to deliver returns for their stakeholders.

GIRP maintains a strong continuous channel of communications with public authorities to develop together a policy that has at its heart the vision of a sustainable healthcare system.

With this in mind the past twelve months have been very busy for GIRP and our work has focused on many key important issues that impact the business of our members.

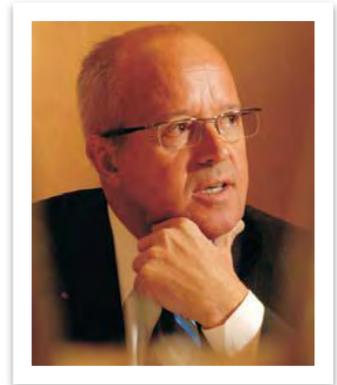
With good governance always a key theme in our activities, the reporting period has involved us evaluating GIRP's strategy. Our Managing Board and Board have taken a hands-on approach to the evaluation exercise. After many meetings our Managing Board presented in April 2014 the outcome of their efforts to the Board. We succeed to develop a draft Vision, a 2020 Objective and a Membership Commitment. These will be presented to our upcoming General Assembly and if approved, altogether will assist GIRP deliver results for members in the years ahead. However, the reporting period ahead will involve us looking more closely at structural and governance matters and resources needed for a sustainable and successful association for members fit for years ahead.

We committed to the positive future development of the association and the sector we represent. Our driving value is to take ownership of the association and take proactive steps which best serve the interests of the membership as a whole. We take direct actions to promote the development of our sector in new innovative areas of healthcare products and service delivery as deployed by our members. We have created new groups which tackle key new areas of services development of our members to offer them a platform to come together to assist them deliver services where the patient is placed first. We are committed to the further development of such groups and will respond quickly to the evolving needs of members.

We are also fully committed to serving members with targeted actions. Over the years it became increasingly necessary to develop a dedicated group for national associations with 2013 playing host year to the first Directors of Associations meeting. The meeting allowed national association directors to come together and learn from one another about how best to deal with common challenges and seize new opportunities which serve their association and members in the best possible way.

Due to the high number of legislative and regulatory developments, our work has majorly focused on the impact of such development on the sector.

We have invested a significant amount of time and resources into developments related to the preparation of the delegated acts of the Falsified Medicines Directive. Connected with this we have also been investing considerable resources into the establishment and deployment of a European Medicines Verification System (EMVS) as proposed by the European Stakeholder Model (ESM) backed by the major supply chain organizations representing the relevant constituencies of the supply chain – European Association of Euro Pharmaceutical Companies (EAEPC), European



## GIRP ANNUAL REPORT 2013-2014

Federation of Pharmaceutical Industries and Associations (EFPIA), Pharmaceutical Group of the European Union (PGEU) and GIRP. No doubt the following year will demand even more attention and hard work towards developing this project and securing the buy-in of our members into the project at national level.

We have also been very active with supporting the implementation of the European Good Distribution Practice Guidelines at national level which will equally form a part of our work in 2014 and 2015.

Major efforts were focused on lobbying activities associated with the revision of the European Unions' Medical Devices legislation. The considerable energy invested has still not yielded the desired outcome and this issue will therefore continue to be a dominating matter for the agenda for the coming 12 months.

The revision of the Medical Device legislation poses a major threat to our sector. Our strong lobbying efforts at EU level have helped bring issues of importance to distributors to the attention of the legislator however the package of measures proposed remain extremely worrying and lobbying efforts must now focus at national level as ultimately it is the Member States that approve the legislation.

As President of GIRP it is my role and duty to underline the importance of members' lobbying actions at national level and the response needed to developments at EU level. At GIRP we have a unique opportunity to influence the executive at an early stage and are committed on all occasions to do so as effectively as possible. However, once the dossiers pass to the European Parliament and Council the role of members becomes increasingly important. It is therefore important that coordinated approaches to our lobbying activities and call on members to support this approach.

I mentioned earlier our strategic review. An important outcome was our Managing Board and Board proposal for the establishment of the Public Affairs and Policy Committee (PAPC). This committee is now open to members to nominate participants who will work with GIRP to develop common and coordinated approaches to lobbying activities. We call on members for their active contribution to the work of this new committee and support its activities when coordinating future lobbying activities.

Our relation with our supply chain partners goes from strength to strength. The last year can be credited with significant progress made in terms of relationship with industry. We held a successful reception between the members of our Advisory Council Supply Chain Solutions (ACSCS) and the Brussels based representatives of some of the major manufacturers. The reception was very positively perceived by the industry representatives who expressed a clear desire to develop a closer relationship with our sector and learn of the collective portfolio of our members in tailored industry services. The event was considered an eye opener for the industry as many were clearly unaware that GIRP members offer non-core services.

Since this time last year we have seen changes in the representation of members, I would like to take this opportunity to thank those members who are departing us for their great work and dedication to GIRP over the years. Their support remains highly appreciated and can be credited to many of our keys successes. All departures signify new arrivals. We are delighted to welcome new representatives of members. We look to them to renew their organisations' support and dedication to GIRP, we look to them for leadership and strength to drive forward our common agenda and deliver on our new vision and objective while supporting our actions to deliver on our commitment to members.

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,

Since our last annual report the European institutions have been extremely active. Policy, legislative and regulatory issues of direct importance to our sector have been fast moving. Many long running issues have increased pace of progress, some dossiers have been finalized and many new issues have come to the table.

Despite the upcoming European Parliament elections and with the mandates of European Commissioners' coming to an end in autumn 2014, the European institutions still remain active. While we will witness a lull in activity of the European institutions over summer and autumn, our work will continue and our preparation for the new institutional mandates will advance.

We can look back on some major successes during the reporting period. It is for this reason, I would like to focus on 2 matters where we can confidently claim success and use the opportunity to congratulate ourselves on the achievements of both GIRP and GIRP's members.

The first of such has been our activities in relation to the Delegated Acts of the Falsified Medicines Directive (FMD). Since the adoption and publication of the FMD in 2011, the European Commission has been busy assessing the impact of the envisaged measures and preparing the Delegated Act related to the technical specifications and modalities for verification of safety features which will be applied to the vast majority of prescription medicines from the beginning of 2018 onwards.

This particular Delegated Act can be said to be one of the most important developments for our sector in the last two decades. We have worked tirelessly to ensure that the impact of this Delegated Act protects the legal supply chain from the infiltration of falsified medicines with the least possible burden on our members. We have collected data, prepared arguments, lobbied and demonstrated at every occasion possible the most proportionate measures for our sector to meet the objective of the legislation. Over the last number of years GIRP members were faced with 3 possible scenarios for meeting the terms of the directive:

1. No checking of the safety feature at the level of the wholesale distributor
2. Random checking of the safety feature at the level of the wholesale distributor when there is a higher risk of receiving a product that may be falsified
3. A full checking of the safety feature of all packs at the level of the wholesale distributor.

The implication of each scenario requires no detailed explanation – the impact is obvious. Clearly, the latter scenario can be considered a doomsday one from the perspective of wholesale distributors attracting a cost impact of approximately EUR 600 million (estimated on data provided by GIRP members) for the sector. While the first option has no cost impact it prevents pharmaceutical wholesalers from being vigilant and ensuring that only genuine medicines are circulating in the legal supply chain. After considerable lobbying efforts, the European Commission informed at the end of January 2014 that the second option will be taken into consideration and confirmed in April 2014 that the European Commission will foresee that wholesale distributors have to verify the safety features when the product is not obtained from the marketing or manufacturing authorisation holder or when the product is returned by another wholesale distributor or a pharmacy. While the detailed wording to be used in the Delegated Act remains to be decided, the European Commission has orally confirmed that also the safety features of products



obtained from a person or entity authorised/mandated by the marketing/manufacturing authorisation holder will not require checking.

Though costly at an estimated EUR 36 million and comprising a bit above 3% of the RX products in Europe, it is by far the preferred option and will enable wholesale distributors to avoid that falsified medicines enter the legal supply chain.

Together with our supply chain partners – European Association of Euro Pharmaceutical Companies (EAEPCC), European Federation of Pharmaceutical Industries and Associations (EFPIA), Pharmaceutical Group of the European Union (PGEU) - we have been hugely consumed with the development of the European Stakeholder Model (ESM) project for a European Medicines Verification System (EMVS). Progress on a number of issues has been achieved, though overall progress will need to accelerate in the near future. Specific progress has been made on the development of the European-Hub; a road-map set for the EU Hub's connection to the German medicines verification system (securPharm); positive indications from other stakeholders (especially from EGA - the European umbrella organisation of the generic industry) about joining the ESM project and first discussions with the Council Of Europe's European Directorate for the Quality and Safety of Medicines (EDQM) about possible supervision of the European system have taken place.

As the European Commission has finally announced a stakeholder led model for the establishment and management of the repository systems, the ESM has been given a motivation injection. The ESM must and will now act in terms of motivating national stakeholders to move forward with establishing national medicine verification systems. As a committed ESM partner, we call on GIRP's members to play their part at national level and proactively start to discuss with national stakeholder partners the approach forward. As the Delegated Acts are expected to be published by the start of 2015 and become effective 3 years thereafter (2018) there is no time to lose. The European Commission has warned stakeholders that no transitional period is envisaged, if even legally allowed. Therefore, pressure is now on all stakeholders to take responsibility to join forces with a view to being fully compliant with the applicable laws of the FMD and Delegated Acts at the time of their coming into force.

We will continue to work with our members and remain willing to assist all efforts at national level to move forward with national projects.

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. When pitched against the first draft of the GDP guidelines and the version which become effective as of 8<sup>th</sup> September 2014, GIRP has been able to point to a highly successful lobbying outcome on a number of important aspects of the new GDP guidelines. Our lobbying achievements were quantified, using GIRP members cost estimates, in savings of up to one billion euros. However, while the GDP guidelines have been published and successes in terms of lobbying referenced, there are many issues which still present significant challenges for members in terms of implementation, with the requirement to transport products according to storage conditions being among the most troublesome. It is for that reason we are engaged with members by offering dedicated workshops on areas where members require support, such as on Corrective and Preventative Action (CAPA) and Quality Management and Quality Risk Management System issues. Where possible, for instance on the issue of transportation, we are working with our European partners in the supply chain with a view to developing a common interpretation or approach to this aspect.

While it is always a pleasure to raise and address successful matters, it is only fair to turn to more challenging issues. The revision of the medical devices legislation has become one of our most difficult files in the reporting period. Without doubt our team has committed almost incalculable time into raising awareness of the problems faced by distributors as result of the European Commission proposals (on obligations for distributors) and the failed subsequent efforts to have the extremely worrying obligations removed at the level of the European Parliament. Today, we are faced with a troubling future regulatory obligation for all members carrying medical devices and in-vitro medical devices. That concern involves the requirement to check that each product is accompanied by the relevant

## GIRP ANNUAL REPORT 2013-2014

product information and is also accompanied by the required EU declaration of conformity [added by the Greek Presidency in 2014]. Clearly, the burden placed on the shoulders of distributors is disproportionate to the desired outcome of the European Commission and presumably the legislator, however, despite some limited results, successfully communicating the message at European and national levels has remained elusive.

Lobbying on matters such as the medical devices legislation is an extremely important part of our daily work at GIRP. Too often the importance of joint and coordinated lobbying at EU and national level is overlooked and at times even has caused some frustration between GIRP and some of our members. It is however important that we all act in a coordinated way, with each party taking care of the angle it can best tackle. It is only when we are coordinated and active can we achieve great lobbying success for our sector. Shoulder to shoulder, GIRP and all of our members can reduce the burden for the business, while ensuring patient safety as an ultimate goal, as a result of legislative and regulatory developments.

We have tried to cover these, and many other issues throughout this annual report. You will read in detail our main activities over the last year.

We will strive for higher and higher levels of success and excellence in the coming period.

On a final note, I would like to express a warm thanks to all our members as well as to our President and our team 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 32 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>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 the conditions for determining the risk based verification system.</p> <p>Work with GIRP's supply chain partners namely EAEP, EFPIA and PGEU (and EGA) 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 minimised.</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 outside the EU boundaries.</p> <p>Continue to provide support with individualized service for GIRP members in dealing with unique national problems and the creation of 'company clusters' for specific interests.</p> <p>Drive forward the initiative to focus information flow by convening a regional meeting 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>Re-establish and develop new contacts with the European Commission, European Parliament, European Medicines Agency (EMA) and other pertinent international organisations. Particular focus on following the European Parliamentary elections in 2014.</p> <p>Establish better contacts to the Heads of Medicines Agencies.</p> <p>Continue to establish new contacts with manufacturers, pharmacists, patients and payers directly and through their representative associations.</p> <p>Continue with thematic discussions with supply chain partners on issues such as medicines shortages, access in small markets, etc.</p> <p>Continue with the 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 are promoted to authorities and stakeholder groups and reflecting this in GIRP's 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>Run dedicated (fee paid) training sessions for GIRP members on specific operation topics.</p> <p>Implement outcome of strategy evaluation 2014.</p> <p>Establish new manufacturer membership category.</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 2013 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/groups.

“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 40 Full Members consisting of 26 national associations in Europe (the two national associations of Greece – PAPW and OSFE – have one common voting right), five companies acting as national associations for the purpose of country representation in GIRP (Pelion SA from Poland and Distica hf. from Iceland, while Medika d.d., Oktal Pharma d.o.o. and PHOENIX Farmacija d.d. are representing Croatia together), six major pan-European pharmaceutical wholesaling companies (Alliance Healthcare Germany, Celesio, COFARES, Mediq, Oriola-KD, and PHOENIX) 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

##### ARGE Pharmazeutika

Arbeitsgemeinschaft des Pharmazeutischen  
Großhandels  
Prof. Heinz Krammer  
Palais Schlick, Türkenstraße 25/16  
AT - 1090 Vienna

Tel: +43 1 409 44 86  
Fax: +43 1 409 44 87  
Email: office@argeph.at

##### Belgium

##### NVGV – ANGR

Association Nationale des Grossistes-  
Répartiteurs en Spécialités Pharmaceutiques  
Mr. Stijn Terryn  
8, Avenue Ed. Van Nieuwenhuysse  
BE – 1160 Brussels

Tel: +32 2 788 0546  
Fax: +32 2 788 0547  
Email: st@comeos.be

## Bulgaria

### BATEL

Bulgarian Association of Pharmaceutical  
Wholesalers  
Mr. Dimitar Dimitrov  
8, Han Asparuh Street  
BG – 1463 Sofia

Tel: +359 244 217 20  
Fax: +359 889 118 589  
Email: office@batel.bg

## Croatia

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### Medika d.d.

Dioničko društvo za trgovanje lijekovima i  
sanitetskim materijalom  
Mr. Jasminko Herceg  
Capraška 1  
HR – 10000 Zagreb

Tel: +385 1 2412 555  
Fax: +385 1 2371 441  
Email: jasminko.herceg@medika.hr

### Oktal Pharma d.o.o.

Mr. Marijan Škiljević  
Utinjska 40  
HR – 10020 Zagreb

Tel.: +385 1 6595 777  
Fax: +385 1 6595 701  
Email:  
marijan.skiljevic@oktal-pharma.hr

### PHOENIX Farmacija d.d.

Ms. Jasna Turkalj  
Ozaljska ulica 95  
HR – 10000 Zagreb

Tel: +385 1365 0111  
Fax: +385 1365 0110  
Email: j.turkalj@phoenix-farmacija.hr

## Czech Republic

### AVEL

Association of Czech Full-line Wholesalers  
Dr. Pavel Brauner  
Pelinkánova 7  
CZ – 16200 Prague

Tel: +420 602 737 048  
Fax: +420 602 737 048  
Email: brauner@braunerandpartners.cz

## Denmark

### MEGROS

Association of Danish Pharmaceutical  
Wholesalers  
Ms. Liselotte Johansen  
Brandstrupvej 4  
DK - 2610 Rødovre

Tel: +45 44 57 11 40  
Fax: +45 44 57 11 03  
Email: Liselotte.Johansen@tmj.dk

## Estonia

### ERHL

The Estonian Association of Pharmaceutical  
Wholesalers  
Ms. Jana Laasalu  
Vae 16, Laagri

Tel: +372 650 1901  
Fax: +372 650 1900  
Email: janalaasalu@hotmail.ee

EE – Harjumaa

## 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](mailto:aty@aty.fi)

## France

### CSRP

Chambre Syndicale de la Répartition  
Pharmaceutique  
Mr. Emmanuel Déchin  
47 Rue de Liège  
FR – 75008 Paris

Tel: +33 1 42 94 01 25  
Fax: +33 1 42 94 19 84  
Email: [emmanuel-dechin@orange.fr](mailto:emmanuel-dechin@orange.fr)

## Germany

### PHAGRO

Bundesverband des pharmazeutischen  
Großhandels  
Ms. Bernadette Sickendiek  
Charlottenstraße 68  
DE – 10117 Berlin

Tel: +49 30 201 88 448  
Fax: +49 30 201 88 454  
Email: [phagro@phagro.de](mailto:phagro@phagro.de)  
Email:  
[bernadette.sickendiek@phagro.de](mailto:bernadette.sickendiek@phagro.de)

## Greece

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### PAPW

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](mailto:papw-gr@otenet.gr)

### OSFE

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](mailto: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](mailto:kuttel@phoenix.hu)

## GIRP ANNUAL REPORT 2013-2014

<b>Iceland</b>	<b>Distica hf.</b> Gylfi Rútsson Hörgatún 2 IS - 210 Garðabæ	Tel: +354 412 7500 Fax: +354 412 7510 Email: gylfi@distica.is
<b>Ireland</b>	<b>PDF</b> Pharmaceutical Distributors Federation Mr. Sean Coyle Glandore House, 33 Fitzwilliam Square IE – Dublin 2	Tel: +353 1 202 48 55 Fax: +353 1 202 48 55 Email: sean.coyle@united-drug.ie
<b>Italy</b>	<b>ADF</b> Associazione Distributori Farmaceutici Mr. Giuseppe Scrofina Via Milano, 58 IT – 00184 Roma	Tel: +39 06 487 01 48 Fax: +39 06 478 249 43 Email: scrofina@adfsalute.it
<b>Latvia</b>	<b>LZLA</b> Latvian Association of Pharmaceutical Wholesalers Mr. Mārcis Rutulis Ulbrokasiela 23 LV – 1021 Riga	Tel: +371 6771 8702 Fax: +371 6771 8780 Email: lzla@latnet.lv
<b>Luxembourg</b>	<b>GGRLPP</b> Groupement des Grossistes Répartiteurs Luxembourgeois en Produits Pharmaceutiques Mr. Jules Clement 60, Rue de la Vallée LU – 2661 Luxembourg	Tel.: +352 45 07 07 Fax: +352 45 63 46 Email: jules.clement@hanff.lu
<b>Netherlands</b>	<b>BG Pharma</b> Mr. Geo Aldershof Bezuidenhoutseweg 12 NL – 2594 AV Den Haag	Tel.: +31 70 349 01 53 Email: aldershof@vno-ncw.nl
<b>Norway</b>	<b>Norwegian Association of Pharmaceutical Wholesalers</b> c/o Norsk Medisinaldepot AS Mr. Arne Øverby Sven Oftedalsvei 10, Postboks 183 - Kalbakken NO – 0903 Oslo	Tel.: +47 24 05 30 00 Fax: +47 24 05 30 01 Email: arne.overby@nmd.no

## GIRP ANNUAL REPORT 2013-2014

<b>Poland</b>	<b>Pelion S.A.</b> Mr. Jacek Szwajcowski Zbaszynska 3 PL – 91342 Lodz	Tel: +48 42 613 34 44 Fax: +48 42 613 35 35 Email: jacek_szwajcowski@pelion.eu
<b>Portugal</b>	<b>GROQUIFAR</b> Associação de Grossistas de Produtos Químicos e Farmacêuticos Ms. Marta Dos Santos Av. António Augusto Aguiar, 118-1 PT – 1050-019 Lisbon	Tel: + 351 21 319 38 60/7 Fax: + 351 21 319 38 69 Email: groquifar@groquifar.pt
<b>Romania</b>	<b>ADFR</b> Asociatia Distribuitorilor si Retailerilor de Farmaceutice din Romania Ms. Cristina Munteanu Str. Telega nr. 6, tronson A, et. 15, ap. 81 RO – Bucharest	Tel: + 40724220085 Fax: +40 21 301 1 74 75 Email: cristina.munteanu@adrfr.ro
<b>Serbia</b>	<b>Serbian Chamber of Commerce - Group of Pharmaceutical Wholesalers</b> Ms. Gordana Hasimbegovic Resavska 13-15 RS – 1000 Belgrade	Tel: +381 11 323 40 42 Fax: +381 11 323 0949 Email: gordana.hasimbegovic@pks.rs
<b>Slovakia</b>	<b>ADL</b> Association of Drugs and Healthcare Equipment Suppliers Ms. Jana Srníková Heydukova 1 SK – 811 08 Bratislava 1	Tel: +421 2 52 96 24 12 Fax: +421 2 52 63 11 88 / 87 Email: adl@adl.sk
<b>Slovenia</b>	<b>TZS</b> Slovenian Chamber of Commerce, Pharmaceutical Full-line Wholesalers Ms. Barbara Krivic Dimiceva 13 SI – 1000 Ljubljana	Tel: +386 1 5898 216 Fax: +386 1 5898 219 Email: barbara.krivic@tzslo.si
<b>Spain</b>	<b>FEDIFAR</b> Federación Nacional de Asociaciones de Mayoristas Distribuidores de Especialidad de Farmacéuticas y Productos Parafarmacéuticas	Tel: +34 91 562 40 25 Fax: +34 91 411 43 26 Email: mvaldes@fedifar.com

Mr. Miguel Valdés  
General Oràa, 70  
ES – 28006 Madrid

## Sweden

### LDF

Swedish Association of Pharmaceutical  
Wholesalers  
Mr. Lars Schenatz  
c/o Tamro AB  
Importgatan 18  
SE - 42246 Hisings Backa

Tel: +46 31 88 70 46  
Fax: +46 31 33 85 100  
Email: Lars.Schenatz@tamro.com

## Switzerland

### Pharmalog

Swiss Pharma Logistics Association  
Mr. René Jenny  
Avenue de Tivoli 3, Case Postale 693  
CH – 1701 Fribourg

Tel: +41 26 347 41 58  
Fax: +41 26 347 41 40  
Email: info@pharmalog.ch

## United Kingdom

### BAPW

British Association of Pharmaceutical  
Wholesalers  
Mr. Martin Sawyer  
90 Long Acre  
UK – WC2E 9RA London

Tel: +44 20 7031 0590  
Fax: +44 20 7031 0591  
Email: msawer@bapw.net

## 6.1.2. Full Member Companies/Groups

### Alliance Healthcare Deutschland AG

#### Alliance Healthcare Deutschland AG

Dr. Thomas Trümper  
Solmsstraße 25  
DE – 60486 Frankfurt am Main

Tel: +49 69 79 203-0  
Fax: +069/79203-369  
Email: thomas.truemper@alliance-  
healthcare.de  
Website: www.alliance-healthcare.de

### Celesio AG

#### Celesio AG

Mr. Stephan Borchert  
Neckartalstraße 155  
DE – 70376 Stuttgart

Tel: +49 711 5001 401  
Fax: +49 (0)711.5001-1260  
Email: elke.reinhardt@celesio.com  
Website: www.celesio.com

### COFARES

#### COFARES

Mr. Carlos Gonzalez Bosch  
Ctra. Madrid-Irun, KM 11.800  
ES – 28049 Madrid

Tel: +34 91 740 87 02  
Fax: +34 91 740 87 95  
Email: cgonzalezbosch@cofares.es  
Website: www.cofares.es

## GIRP ANNUAL REPORT 2013-2014

### Mediq N.V.

### Mediq N.V.

Mr. Marc van Gelder/  
Mr. Arthur de Bok (as of 1/4/2014)  
Hertogswetering 159  
NL – 3543 AS Utrecht

Tel: +030 2821911  
Fax: + 030 2896650  
Email: marc.van.gelder@mediq.com  
arthur.de.bok@mediq.com.  
Website: www.mediq.com

### ORIOLA-KD Corporation

### Oriola-KD Corporation

Mr. Eero Hautaniemi  
Orionintie 5  
PO Box 8  
FI – 02101 Espoo

Tel: +358 10 429 99  
Fax: +358 10 429 43 00  
Email: eero.hautaniemi@oriola-kd.com  
Website: www.oriola.com

### PHOENIX Pharmahandel GmbH & Co. KG.

### PHOENIX Pharmahandel GmbH & Co. KG.

Mr. Reimund Pohl/  
Mr. Oliver Windholz (as of 31/1/2014)  
Pfungstweidstraße 10-12  
DE – 68199 Mannheim

Tel: +49 621 85050  
Fax: +49 621 85 40 31  
Email: G.HAGEN@phoenix-ag.de  
c.rupp@phoenixgroup.eu  
Website: http://www.phoenixgroup.eu

### Pharma Privat

### Pharma Privat

Mr. Lutz Geilenkirchen  
c/o Otto Geilenkirchen, Charlottenstr. 10-12  
DE – 52070 Aachen

Tel: +49 241 5192 259  
Fax: +49 241 5192 217  
Email: lutz.geilenkirchen@otto-geilenkirchen.com  
Website: www.pharma-privat.de

### SECOF

### SECOF

Mr. Olivier Bronchain  
Edificio Portico  
c/o Landwell - 8° plano  
Concejal Francisco Ballesteros, 4  
ES – 41018 Sevilla

Tel: +34 954 981 300  
Fax: +34 951 981 320  
Email: contact@secof.eu  
Website: www.secof.eu

## 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

Mr. Roman Efimenko  
100, Shevchenka Str. – Boryspil  
UA – 08300 Kiev Region

Tel: +38 044 490 3271  
Fax: +38 044 490 3271  
Email: office@alba.kiev.ua  
Website: www.alba.kiev.ua

### Eurapharma

### Eurapharma

## GIRP ANNUAL REPORT 2013-2014

Mr. Jean-Marc Leccia  
18 Rue Troyon  
FR – 9231b Sevrès

Tel: +33 (01) 46 23 56 56  
Email: jean-  
marc.leccia@eurapharma.com  
Website: www.eurapharma.com

### Farmalogist

### Farmalogist d.o.o.

Ms. Lovorka Nikolić  
Mirjevski Bulevar br.3  
SR – 11000 Belgrade

Tel: +381 11 33-15-001  
Fax: +381 11 33-15-010  
Email: lovorka@farmalogist.co.rs  
Website: www.farmalogist.co.rs

### KATREN

### KATREN, ZAO NPK

Mr. Leonid Konobeev  
Timakova street 4  
RU – 630117 Novosibirsk

Tel: +7 383 363 26 32  
Fax: +7 383 333 67 01  
Email: vatutina@katren.ru  
Website: www.katren.ru

### STING

### STING

Mr. Ivan Zdravkov  
6 Asen Yordanov  
BG – 1594 Sofia

Tel: +359 2 970 31  
Fax: +359 2 970 33 01  
Email:  
ivan.zdravkov@stingpharma.com  
Website: www.stingpharma.com

### TEKB

### TEKB

Mr. Evrim Baser  
Ömer Avni Mah. Prof. Tarık Zafer Tunaya Sok.  
Gümüşsuyu İş Merkezi No:14 K:3, Gümüşsuyu  
TR – 34427 Istanbul

Tel: +90 212 251 08 88  
Fax: +90 212 251 08 01  
Email: evrim.baser@tekb.org.tr  
Website: www.bizimeczane.com

## 6.3. EXTERNAL MEMBERS

### 6.3.1. Partnership Sponsor

#### IMS Health

Medialaan 38  
BE – 1800 Vilvoorde  
Tel.: + 32 2 627 32 11  
Fax: +32 2 649 67 75  
Email: egilissen@be.imshealth.com  
Website: www.imshealth.com

### 6.3.2. Associated Sponsors

#### INSIGHT HEALTH GmbH & Co. KG

Auf der Lind 10  
DE – 65529 Waldems-Esch

#### KNAPP

Günter Knapp Str. 5-7  
AT – 8075 Hart bei Graz

Tel.: +49 6126 95512  
Fax: +49 6126 95520  
Email: rlederer@insight-health.de  
Website: www.insight-health.de

Tel.: +43 316 4950  
Fax: +43 316 491395  
Email: gerald.hofer@knapp.com  
Website: www.knapp.com

### 6.3.3. Supporting Sponsors

#### **SSI Schäfer Peem**

Fischeraustr. 27  
AT – 8051 Graz  
Tel: +43 316 6096-713  
Fax: +43 316 6096-462  
Email: m.preiss@ssi-schaefer-peem.com  
Website: www.ssi-schaefer.de

#### **CAPPI**

8, Avenue Marceau  
FR – 8900 Auxerre  
Tel: +33 (0)3 86 51 06 98  
Fax : +33 (0)3 86 51 28 69  
Email: t.de.bie@ecor-lab.com  
Website: www.cappi.fr

#### **IBS Enterprise Italy Srl**

Piazza F.Caltagirone, 75  
It – 20099 Sesto San Giovanni (Mi)  
Tel: +39 02 947 558 10  
Email: elvio.andreello@ibs.net  
Website: www.ibs.net/it

#### **Sensitech Inc.**

Lireweg 42-52  
NL – 2153PH Nieuw-Vennep  
Tel: + 31 252 211 108  
Email: osimmonot@sensitech.com  
Website: www.sensitech.com

### 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