



the vital link in healthcare

**GROUPEMENT INTERNATIONAL DE LA REPARTITION PHARMACEUTIQUE
EUROPEAN ASSOCIATION OF PHARMACEUTICAL FULL-LINE WHOLESALERS**

Commissioner Byrne
Dr. Fernand Sauer, Head of Unit C
DG Health and Consumer Protection
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Brussels, 25th September 2004.

Concern: - Reflection process on achieving good health for all across the EU

Dear Commissioner Byrne,
Dear Dr. Sauer,

Referring to your letters dated 14th July 2004 and 19th July 2004, I would first of all like to thank you for inviting GIRP, the European Association of Pharmaceutical Full-line Wholesalers, to join your reflection process on "enabling and achieving Good Health for all".

As you know, GIRP is the umbrella organisation of pharmaceutical full-line wholesalers' in Europe. Our members provide, several times daily to all European pharmacies, all necessary medicines for the citizens in Europe and share the commitment to constantly further develop and improve health systems aiming at ensuring the quality and safety of products and services. GIRP members employ about 100,000 people and distribute medicines with an annual value of around 80 billion Euro.

Pharmaceutical full-line wholesalers are the vital link between manufacturers and pharmacies, and ultimately the patients as they ensure that the medicines are readily available at everyone's local pharmacy 24 hours a day, 365 days a year. Pharmaceutical full-line wholesalers, represented by GIRP, handle the total range of pharmaceutical products that can be prescribed by doctors in Europe.

GIRP and its members fully recognise the macroeconomic impact of good health in the European Union. Therefore we highly welcome DG SANCO's reflection process and gladly contribute to this consultation on "achieving good health for all across the EU".

In this respect, we would like to bring some comments and suggestions on the two documents to your attention.

GIRP strongly appreciates the Constitutional Treaty provisions, which reinforce the European Union mandate in the health sector. We also recognise health as a factor of macroeconomic growth and therefore fully support the positioning of health in the centre of the European Union policy-making.

GIRP embraces the outcome of the Review of the Community Code relating to medical products for human use (2004/27/EC) which sets high standards of quality and safety for medical products and guarantees the continuous and appropriate supply of medicines to pharmacies and ultimately to European patients.

GIRP finally warmly welcomes the European Commission's support to cooperation schemes between Member States who need to coordinate their policies and programmes. Concurrently, GIRP wishes to be involved in new mechanisms for cooperation between patients and health professionals as our role is to provide the constant, vital link between the manufacturers and the pharmacists and therefore ultimately to the patients in Europe.

In this respect the outcome of the new High Level Group on Health services and medical care is of high interest to GIRP as well as the work of the European Centre for Disease Prevention and Control (ECDC). Our association would welcome the opportunity of sharing our know-how and experience in the area of emergency response capacity, including transmission of alerts and information flows. Moreover, we would exchange best practices in the field of the just in time availability of medicines with the European administration as well as with all partners in the supply chain in order to create an interlinked, well functioning network, which is prepared for emergencies.

GIRP offers to support the reflections of the High Level Group on Health services and medical care with information and opinions on issues related to the provision and access to medicines.

Furthermore our association proposes to contribute to the ECDC especially in the fields of early warning and response systems (EWRS) and would gladly participate in exchanging information, expertise and best practices with the Centre. Finally, GIRP members are ready to discuss the development and implementation of joint actions at EU level for emergency recalls or delivery of medicines.

As a whole, GIRP fully supports the European Union commitment to the principles of transparency, participation of stakeholders, effectiveness and coherence for all EU initiatives.

1. Enabling patient's choice

GIRP favours the Commission's commitment to 'enable citizens to make the right choices for their health and would like to specially emphasise two aspects which are of strong interest to us.

a. Access to medicines

By delivering the full-range of medicinal products available, several times a day, to all pharmacies in Europe, full-line wholesalers guarantee the freedom of prescription of the General Practitioner, the freedom of the pharmacist to substitute the medicines by a generic product (depending on the national legislation) and when self-medication is concerned, the freedom of choice of the patient, advised by the pharmacist.

GIRP members are committed to delivering all medicines when and where they are needed in adequate quantities and in appropriate conditions so that the continuous supply of medicines is ensured - in every pharmacy - wherever it is located. GIRP members endorse public service obligations (be they enforced into national legislations or not), thus contributing to the health and safety of European citizens.

GIRP therefore highly welcomes the new European pharmaceutical legislation, confirming the obligation of continuous and appropriate supply and the possibility for Member States to implement public service obligations on manufacturers as well as on wholesalers. GIRP strongly favours the new provision introducing an obligation for manufacturers to ensure the regular flow of medicines to wholesalers, who on their behalf have to ensure continuous and timely deliveries to pharmacies/hospital pharmacies.

GIRP fully agrees to the fact that all partners in the supply chain have to ensure the appropriate and continuous supply of medicines in order to safeguard the supply of all medicines to the patients in Europe.

However, regarding the access to scientific and technological progress, i.e. the access to innovative products, we would like to emphasise that although the Central Authorisation procedure is working effectively, innovative products authorised by the EMEA are not available at the same time to all European citizens as they still cannot be distributed throughout Europe without being adapted to national requirements (vignettes, Pharmazentralnummer...). This adaptation requires a manufacturing authorisation, implying that the product responsibility is passed on from the original manufacturer to the new manufacturing authorisation holder. Therefore, despite the fact that theoretically innovative medicines are centrally registered, practically they cannot be accessed throughout Europe, hindering the fast access to medicines for all EU citizens.

GIRP therefore proposes to authorise wholesalers to adapt the centrally authorised medicines according to national market requirements (sticking the vignette or Pharmazentralnummer on the pack) and distribute these products Europe wide in order to guarantee the immediate access to innovative products for all European citizens.

b. Patient Information: health information, promotion and prevention

In order to enable EU citizens to 'make well-informed choices about their health and to promote their active participation in the health decision-making process', GIRP fully agrees to the importance of patient information.

GIRP recently answered the EMEA consultation process on this subject and appreciates the recommendation to raise the profile of the EMEA among the general public. GIRP also highly welcomes the focus on harmonised product information to patients, through health professionals and patients' organisations Europe wide.

As indicated to the EMEA, GIRP would be ready to participate in the promotion of good health through the services our members provide to pharmacies. GIRP fully encourages partnerships with health professionals, the industry, the EMEA and national health authorities to develop information to patients and would gladly contribute to the training of these partnerships.

PARTNERSHIP WITH OUR SUPPLY CHAIN PARTNERS

Within these two areas, GIRP and its members wish to further develop cooperation schemes with our supply chain partners, the manufacturers and the pharmacists for the benefit of the patients.

ACCESS TO MEDICINES: quality, safety and efficiency of the supply chain

In order to permanently ensure the quality, safety and efficiency of medicines throughout the whole supply chain, GIRP has set as one of the objectives of our future work the strengthening of the collaboration with our supply chain partners, as we strongly believe that increased cooperation will upgrade both the supply chain and its logical counterpart, the recall and emergency procedures.

Full-line wholesalers would be strongly in favour of an even closer collaboration amongst the supply chain partners.

- **Pharmaceutical manufacturers** could increasingly benefit from pharmaceutical wholesalers' excellent channel of communication towards the European pharmacies through trainings, product information, provisions of patient leaflets and other information material. Pharmaceutical full-line wholesalers, could through their network, forward manufacturers' information on products, product use and diseases (perhaps authorised by the EMEA or health authorities) to pharmacists who would then relay them to the patients, combined with their personal advise.
- Pharmaceutical full-line wholesalers are already closely collaborating with **pharmacies** in the field of information exchange and the setting-up of health education programmes. Full-line wholesalers already provide a wide range of training services to pharmacists and in some countries offer assistance in the provision of pharmacy specific information over the Internet to patients (allergies, flue...).
- Although not in direct contact with **patients**, GIRP members' welcome the idea to develop harmonised patient-tailored communication at European level. Pharmaceutical wholesalers could contribute to this idea by assisting the pharmacists with passing on the relevant information to the patients.

Within the European arena, GIRP supports and strongly opts for the continuation of the European Health Policy Forum, as we believe that the Forum is an ideal platform for exchange of views and open discussion in the healthcare sector.

2. Sharing knowledge & coordinating actions

GIRP fully recognises the fact that health and healthcare systems are under Member States' responsibility but also acknowledges the need for increased coordination and collaboration between Member States. Concerning the sector of pharmaceutical wholesaling for instance, national systems and requirements are very heterogeneous in respect of its legislation as well as in its implementation. GIRP therefore strongly believes in the public service role of wholesalers to timely deliver all medicines where they are needed, including low margins and slow moving, but vital medicines such as orphan drugs.

Furthermore, GIRP is already actively involved in cross-border cooperation especially regarding questions such as health threats and bio-terrorism preparedness.

a. Building a knowledge basis

GIRP welcomes the gathering and exchange of knowledge within the healthcare sector, as long as the confidentiality of certain kind of information is not undermined. Thanks to its position in the supply chain, GIRP would welcome increased partnerships within the supply chain partners and could serve as a channel for information on medicine use and distribution.

b. Protection of population health threats: pharmacovigilance, epidemics and bio-terrorism

GIRP members firmly believe in the need of good pharmacovigilance practices and feedback/reporting mechanisms from patients' associations and all members of the supply chain to national authorities and finally to the EMEA. GIRP therefore fully supports the idea of close collaboration between the supply chain partners, health professionals and patients' organisations in order to develop comprehensive mechanism throughout Europe.

In this respect, we would like to draw your attention to the fact that GIRP's members, in close partnership with the pharmacies, not only have the facilities to report but also have fast and reliable emergency and recall procedures in place, guaranteeing that within 24 hours all warehouses and all pharmacies are informed to remove the recalled products from sales and to store them in an isolated place until their return/destruction.

GIRP's members also contribute to the supply chain safety by ensuring the continuity of the cold chain and storage, the destruction of expired medicine in the recommended way as well as the safe handling and storage of narcotics.

Full-line wholesalers are in contact with community (and hospital) pharmacists several times a day at the occasion of orders and deliveries, as well as regularly with Marketing Authorisation holders and/or their representatives in the Member States. The EMEA could use the excellent communication channel pharmaceutical wholesalers have with the pharmacies as basis for post-authorisation communication activities in partnership with the pharmaceutical industry and patients' organisations.

Furthermore, we would like to remind you that the European Commission has direct access to GIRP's emergency contact list (on the GIRP website) in case of a bio-terrorism attack or health threat.

c. GIRP's interest in e-Health strategies

GIRP welcomes the Commission's e-health strategy and would like to express its interest in activities related to e-health. As mentioned earlier, some of GIRP members are involved in the provision of health relevant information over the Internet for pharmacies. Our association is therefore interested in issues related to the future EU health portal and the prior collection of data.

Finally, we would like to reconfirm our commitment and interest in taking part in the European Commission reflection processes. We appreciate the European vision of the EC strategy although the healthcare sector presents a wide heterogeneity of systems services and regulations. We believe that our members, because of the special requirements of the medicines we handle and the wide range of services we deliver, are directly concerned and very knowledgeable in the field of healthcare and healthcare services.

GIRP would be delighted to be associated to any future consultation or working group on health strategy and services and hereby would like to express our willingness to assist the European Commission's efforts to improve healthcare and health systems with our skills in the distribution sector.

We hope these brief comments will contribute positively to your reflection process and the European Commission's global health strategy.

Yours sincerely,

A handwritten signature in blue ink, appearing to read 'M. Derecque-Pois', written in a cursive style.

Monika Derecque-Pois
Secretary General

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