European Association of Pharmaceutical Full-line Wholesalers (GIRP) response to the European Commission Consultation regarding Community action on Health Services

Introduction

Firstly, GIRP welcomes the move of the European Commission to establish this consultation in an effort to provide legal certainty over the application of community law to health services and health care and help co-operation between member states' health services. GIRP and its members endorse the aim of the consultation regarding the establishment of an EU framework on healthcare services to ensure access to safe, high-quality and efficient care across Europe.

GIRP and its members fully recognize that finding the balance objectives of health-care systems and those of the internal market is not an easy task and is willing to join the European Commission and stakeholders alike to find a balanced solution with the ultimate aim of ensuring that patients have safe, efficient and equitable access to healthcare continuously.

Some general remarks:

It is our belief that all European citizens should have equal access to high quality health services. In this respect the distribution and consequently the continuous access to medicines in the EU should be subject to the same high quality standards throughout all EU Member States. In this regard Article 81(2) of Directive 2004/27/EC, as amended by Directive 2001/83/EC, once implemented in Member States foresees a joint obligation between manufacturers and wholesalers to ensure the adequate and continuous supply of medicinal products to pharmacies so that the needs of patients in the Member States are covered and oblige manufacturers to ensure adequate and continuous deliveries to wholesalers and pharmacies to guarantee the availability of all medicines in the Member States. However, this provision has been either ignored or insufficiently implemented in several Member States and therefore does not guarantee the access to all medicines in all Member States alike.

Furthermore, the Guidelines of Good Distribution Practice of Medicinal Products for Human Use 94/C 63/03 have not only to be fully and properly implemented in the Member States (which is the case in most Member States), but also properly enforced.

Therefore the provision of medicines is an area for which a Community regulatory framework should be properly supervised to ensure full and

accurate implementation and provisions enforced thereafter by the Member States.

Please find below GIRP's answers to the various questions raised in the consultation paper and it is important to note that the answers provided below are with specific reference to the sector of pharmaceutical full-line wholesaling.

Question 1: What is the current impact (local, regional, national) of cross-border healthcare on accessibility, quality and financial sustainability of healthcare systems, and how might this evolve?

Current funding of medicines is organised on the basis of the principle of sudsidiarity and in this respect the pharmaceutical full-line wholesaling sector, as part of the pharmaceutical sector, is largely national and even in some countries only regional in scope.

The medicine available in one Member State is not necessarily available in another Member State. The current European system shows significant differences in the number of medicines available on the national markets, a complex web of regulatory environments, differing largely from one Member State to another, major differences with respect to packaging, prices, labelling, access to medicines and finally the way medicines are paid for in the Member States.

Advancing a Single Market for medicines in Europe is a possible evolutionary factor that could lessen current differences between Member States.

Notwithstanding, the progress already made with respect to the Single Market, much work still needs to be done in the area of free movement of medicines. GIRP fully acknowledges that medicines are special goods. They are an integral part of all public health strategies as they are necessary for the protection of the health and wellbeing of every citizen. Irrespective of their financial capacity the National Governments of the Member States of the European Union must ensure the availability of safe and effective medicines for the treatment of their citizens.

GIRP believes that a balance is to be found between the needs of governments and health care systems to contain health care spending and the need to provide the most efficient and innovative medicines to all European citizens through the advancement of the Single Market for medicines. GIRP asks decision makers and stakeholders to embrace the objective of advancing the Single Market for medicines in Europe and to help finding a balanced way forward.

Question 2: what specific legal clarification and what practical information is required by whom (e.g.; authorities, purchasers, providers, patients) to enable safe, high-quality and efficient cross-border healthcare?

The EMEA in London provides for a centralized authorization procedure for innovative medicinal products, which allows for a single marketing authorization to be granted to new products valid throughout the European Union. Its ultimate aim should be that every European citizen has equal access to the most innovative medicines. Since its inception, the EMEA has issued almost 400 European marketing authorisations for medicines for human use.

Many believe that centrally registered medicines can freely circulate Europe wide. However, none of the almost 400 products for human use, which have received a central marketing authorisation, can circulate freely throughout the European Union, without first having to acquire additional authorisations.

Currently, national laws require specific information to be placed on the packages of the medicines before the products can be dispensed in their territory, such as a national registration number, for example the "Pharmazentralnummer" in Germany or the “Vignette“ in France. Adaptations to these national requirements are pre-conditions for placing the product on the market and subject to a manufacturing authorisation.

In this respect the information specific to a Member State has to be accommodated in the boxed area (the so-called ‘blue box’), which appears on one side of the medicine pack. Manufacturers should be able to present European or multi-country packs with the national requirements for the countries in which they will be dispensed, so that the same medicines can be traded throughout the European Single Market.

This could be a first step towards a Single Market for medicines and would guarantee immediate access to the most innovative medicines for all European citizens.

The concept, once successfully implemented with the EMEA, could be later on extended to products, which are mutually recognised

However, to guarantee immediate access to medicines it must be possible for a manufacturer to set their ex-factory prices (whether a single European price or different national prices) before a decision on reimbursement is made by the Member State authorities.

Question 3: which issues (e.g.: clinical oversight, financial responsibility) should be the responsibility of the authorities of which

country? Are these different for the different kinds of cross-border healthcare described in section 2.2 above?

With further reference to the answer provided to question two and from the perspective of the pharmaceutical full line wholesalers a centralised body should, as it is currently the case, assume the responsibility for the registration of new innovate medicines, take the responsibility for the approval of European or multi country packages and facilitate product information which can be down loaded from its Web site in all of the Community languages.

The responsibility for the ex factory price of new medicines should be initially determined by the manufacturers (either single European price or national ex factory price) until the decision, whereas the decision on reimbursement of the medicine, respecting the principle of subsidiarity, is taken by Member States authorities. This would ensure immediate access to the most innovative medicines for all European citizens.

Question 4: who should be responsible for ensuring safety in the case of cross-border healthcare? If patients suffer harm, how should redress for patients be ensured?

Pharmaceutical full-line wholesalers have a B2B function and therefore do not directly deal with patients.

GIRP members believe that issues concerning safety should be determined according to the stages of production, distribution and dispensation of the medicines:

Concerning production, the manufacturer of the medicine takes the responsibility for safety.

Concerning storage, handling and distribution, the pharmaceutical full-line wholesaler, takes the responsibility from the time they receive the medicines from the manufacturer until the time that the medicines are delivered to the pharmacies thereby ensuring the safety and timely provision of medicines with respect to the aforementioned aspects.

The physician and pharmacist remain the responsible party for the dispensing of the medicines.

In case of the necessity of the recall of a medicine to prevent a defective product from being dispensed, or in the case of an incident of serious pharmacovigilence, from reaching the patient, pharmaceutical full-line

wholesalers assume the responsibility with their customers (pharmacies) to remove the product safely and effectively from the supply chain.

The Member State authorities should assume the overall responsibility for ensuring that medicines manufactured, distributed and dispensed on their national territories comply with Good Manufacturing Practice, Good Distribution Practice, Good Pharmacy Practice and that the provisions are fully enforced.

Question 5: what action is needed to ensure that treating patients from other Member States is compatible with the provision of a balanced medical and hospital services accessible to all (for example, by means of financial compensation for their treatment in 'receiving' countries?)

The core role of full-line wholesalers does not relate to the subject matter of this question. Therefore, GIRP is not in a position to provide particular comments on this question.

Question 6: are there further issues to be addressed in the specific context of health services regarding movement of health professionals or establishment of healthcare providers not already addressed by Community legislation?

The core role of full-line wholesalers does not relate to the subject matter of this question. Therefore, GIRP is not in a position to provide particular comments on this question.

Question 7: are there other issues where legal certainty should also be improved in the context of each specific health or social protection system? In particular, what improvements do stakeholders directly involved in receiving patients from other Member States – such as healthcare providers and social security institutions – suggest in order facilitating cross-border healthcare?

The core role of full-line wholesalers does not relate to the subject matter of this question. Therefore, GIRP is not in a position to provide particular comments on this question.

Question 8: in what ways should European action help support the health systems of the Member States and the different actors within them? Are there areas not identified above?

With reference to GIRP's answers to Question 1 and 2, the single European or multi country pack for medicines should be addressed at the Community level.

Some Member States impose Public Service Obligations on pharmaceutical full-line wholesalers. This is to ensure that patients receive their medicines in a timely and safe manner from reliable and certified sources, thereby guaranteeing permanently an adequate range of medicinal products, to meet the requirements of a specific geographical area and to deliver the supplies requested within a very short time over the whole of the area in question throughout the European Union

Provisions on public service obligations for persons active in the distribution of medicines should be compulsory in all Member States.

A European framework providing for Public Service Obligations for pharmaceutical full-line wholesalers would enhance and strengthen the guarantee to patients in obtaining their medicines.

Question 9: what tools would be appropriate to tackle the different issues related to health services at EU level? What issues should be addressed through Community legislation and what through non-legislative means?

Careful implementation and re-enforcement of the current pharmaceutical legislation would be sufficient to tackle some of the problems related to health services at the EU level in relation to the activities of pharmaceutical full-line wholesalers. However, concerning Public Service Obligations a stronger specific European framework would be beneficial for the continuous availability of medicines. Concerning market access for innovative medicines a revision of Regulation 2004/726/EC would be the appropriate solution.

Brussels, January 2007

Annex I

GIRP, "Groupement International de la Répartition Pharmaceutique Européenne" or in English "European Association of Pharmaceutical Full-line Wholesalers", is the umbrella organisation of pharmaceutical full-line wholesalers in Europe. Founded in 1960, GIRP represents the national associations of over 600 pharmaceutical full-line wholesalers serving 32 European countries, including all major pan-European pharmaceutical wholesaling companies. GIRP members employ about 140,000 people and distribute medicines with an annual value of over 100 billion EUR.

The pharmaceutical full-line wholesalers achieve a general public mission as they contribute to global improvement of health. Therefore, their distribution activities are being developed to the benefit of all in the communities they serve.

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-coordinating informed opinions on all matters relevant to the efficient and safe distribution of medicines throughout Europe.

GIRP “Full Members” are the national associations of pharmaceutical full-line wholesalers in each European country as well as the three Pan-European companies and a cooperative uniting six European countries. There are two other classes of membership - the “Associate Professional Members” are full-line pharmaceutical wholesalers that are members of their national association, but also wish to have direct representation, and the “Associate External Members” who may be companies or organisations whose business interests are related to the pharmaceutical industry and its distribution. These latter members do not need to be based in Europe.

Members of GIRP are required to: (i) carry a full range of products continuously, (ii) ensure product availability to patients within a matter of hours continuously, (iii) create and maintain quality standards that ensure the safety and integrity of the medicine when delivered to the retail pharmacist.

The significance of rapid availability of medicines has a heightened importance in today’s world where events such as the threat of bio-terrorism attacks or sudden viral disease outbreaks require rapid response.

Each GIRP member has a network of warehouses providing several daily and, in some cases, overnight deliveries to hospitals and retail pharmacies. Members employ state-of-the-art information technology and physical infrastructure to undertake this service with a level of intensity, sophistication,

quality and efficiency required by manufacturers, pharmacies, hospitals and government health authorities.
GIRP members also play a role as an information conduit and supplier to industry players. This information is not only a critical analysis tool for industry participants, but plays a vital role in allowing wholesalers to efficiently effect withdrawal of a defective product from the market.