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

Ms. Paola Testori Coggi
Director General
Directorate General for Health and Consumers
European Commission
B- 1049 Brussels
Belgium

Brussels, 07th December 2011

Subject: European Commission Consultation on a proposal for a revision of European Good Distribution Practice Guidelines (GDP)

Dear Ms. Testori,

As you are aware GIRP is the umbrella organisation of pharmaceutical full-line wholesalers in Europe. The activity of pharmaceutical full-line wholesaling consists of purchase and sale, warehousing, storage, order preparation and delivery of medicinal products in their secondary packaging. Pharmaceutical full-line wholesalers carry and distribute the full assortment of medicinal products (in range and depth) to meet the needs of those with whom they have normal business relations and deliver all medicines used in their geographical area of activity within a very short time period. As an organization, we represent the national associations of over 600 pharmaceutical full-line wholesalers serving 31 European countries, including major pan-European pharmaceutical full-line wholesaling companies. Through their network of operational facilities, GIRP members distribute over 130 billion Euros worth of medicines every year.

This makes GIRP the principal voice of the operators of the main channel for the distribution of medicinal products to pharmacies, hospitals and other persons authorised to dispense medicines to the public. As such, GIRP has a fundamental interest in Good Distribution Practice (GDP) guidelines which aim to ensure that a harmonised level of quality is maintained throughout the distribution chain in all EU Member States, so that medicinal products reaching the general public are safe and of unaltered, genuine quality.

The current Guidelines on Good Distribution Practice (GDP) of Medicinal Products for Human Use (94/C 63/03) have been implemented throughout the EU Member States and strictly adhered to by full-line wholesalers to ensure that all finished medicinal products are handled, stored and transported efficiently, and securely.

Your services have published for public consultation the draft proposal for the revised 'Guidelines on Good Distribution Practice of Medicinal Products for Human Use' as prepared by the European Medicines Agency through its GMP/GDP Inspectors Working Group.

While the intention to revise current GDP Guidelines to take into account new requirements for wholesale distributors as set out in the new Falsified Medicines Directive (2011/62/EU) is welcomed by our organization, many of the proposed new requirements presented in the consultation document raise significant concern for us and go far beyond the spirit of the changes contained in the Directive.

From our perspective, the proposed new requirements are overly burdensome to achieve a relatively limited step forward to overhaul a currently well-functioning quality system. Several of the proposed measures are from a cost perspective seriously disproportionate to the expected additional benefits. This is particularly surprising given the fact that EU Member States and economic operators find themselves in the midst of the worst economic and financial crisis of the past 80 years and therefore neither the

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economic hardship nor the consequential decrease in service level arising from the need to implement proposed new obligations can be justified. On this point we would call on your services to fully reflect on the cost / benefit balance in the exercise of revising the GDP.

We would like to take the opportunity to also briefly and constructively outline in this letter some these main concerns which are more extensively covered in the enclosed reply of GIRP to the consultation, which has equally been submitted to the services of DG Health and Consumers.

GDP overly influenced by GMP standards

The proposal covers a series of provisions which are only applicable to pharmaceutical manufacturers and are GMP (Good Manufacturing Practice) orientated standards. GIRP is of the view that principles of GDP should not include Good Manufacturing Practice requirements, especially when wholesale distribution authorisation holders are not permitted to interfere in any way with the actual medicinal product and are only handling, storing and delivering medicinal products in their secondary packaging. A distinction has to be made between provisions applicable to manufacturers, distributing their products and wholesale distributors (also considering the fact that the Directive equally refers to distribution of Active Pharmaceutical Ingredients (API)). There is no indication made which provisions are applicable to which actors and therefore the proposal in its current state goes far beyond what is necessary to ensure the safe handling, storage and transportation of medicines.

Responsible Person requirements

Currently wholesale distributors ensure the availability of a Responsible Person as part of their operations. The wording in the proposal suggests that a Responsible Person should be physically present 24 hours per day at each wholesale distribution site. As our members operate over 1,600 warehouses in Europe the new requirement would result in an annual cost increase of approximately 20 million Euros (a detailed calculation is available in our office) and deliver little improvement to the current system, which allows delegation of responsibilities in most Member States. In addition the coverage of these costs is not covered by current remuneration systems for wholesale distributors in the Member States.

Environmental controls proposed

The distribution sites of full-line wholesalers are equipped with heating and cooling systems to ensure the adequate storage temperature of medicinal products in their secondary packaging, which provides sufficient protection. The proposed changes concerning humidity controls are therefore a disproportional measure. While strict humidity controls are deemed necessary for the actual production of medicines products, humidity is not a problem for medicinal products in their secondary packaging (in Europe) and therefore not necessary and not justified.

Validation and Qualification aspects

All wholesale distributors have an existing Quality Management Systems in place, which covers all aspects of handling, storing and distributing medicinal products. While wholesale distributors accept in principle the notion of validation, the scope, extent and level of the validation in the draft proposal needs to be clearly defined. The proposal suggests that GMP validation levels be applied to GDP activities, which is overly disproportionate.

Storing medicinal products separately proposal

Today medicinal products are stored in the warehouses according to their demand frequency (slow-moving items, fast-moving items, etc.) to commission the medicinal products ordered by the pharmacy at maximum speed and least possible time delay with a high degree of efficiency and security. As

pharmaceutical wholesale distributors are only involved in the handling, storage and distribution of medicinal products in their secondary packaging, no product contamination can occur and therefore a requirement to store medicinal products separately from other products needed by pharmacies and health care professionals is in no way justified. The proposed requirement to "store medicinal products separately from other products" would entail a complete restructuring of wholesalers' warehouses and current operations and decrease the current speed of delivery and make patients wait unnecessarily for their medicines.

Tracking of delivery route requirements

As pharmaceutical full-line wholesale distributors do not deliver bulk quantities of medicinal products but bundle several manufacturers' products and deliver very small quantities of medicinal products – in many cases one unit piece only – to customers in a highly predicable and in a non varied manner, the proposed notion of tracking delivery routes is disproportionate and the installation of tracking devices adds extra costs which are not justified.

Requirements to deliver into the care of the consignee

Wholesale distributors operate out of hours and night deliveries and frequently do not hand the deliveries directly into the direct care of the consignee, but have special provisions to leave the medicinal products within the premises of the pharmacy. The proposed provision that the delivery must be handed into the care of the consignee is especially problematic. If adopted, full-line wholesalers will not be able to continue to operate out of hour and night delivery services, thus reducing the speed of delivery of vital medicinal products to the points of dispensation and ultimately to patients.

Transport requirements

Wholesale distributors deliver ordered medicinal products to their customers within a very short time frame (average European delivery time between 2–4 hours). The extremely short delivery time and the very low number of products within a delivery, which require temperature control, have to be taken into account when establishing provisions on temperature control during transport. In addition full-line wholesalers can only comply with requirements available on the secondary packaging of medicinal products. Otherwise manufacturers would have to be required to provide information on the transport conditions of their products or temperature parameters and stability data to wholesale distributors. Moreover, a distinction should be made between "storage temperature" and "transportation temperature" for the purposes of defining the requirements for transportation. A further distinction should be made between requirements for the transportation of medicinal products and their delivery from the warehouse to the pharmacy.

Wholesale distribution authorisations for subcontractors / outsourced activities

The activities which are outsourced, such as cleaning, security and pure transport, would become subject to the requirement that the provider of the services holds a wholesale distribution authorisation. This is a highly impractical requirement and should be constricted to only those activities, which are directly related to the handling and storage of medicinal products.

Returned products

The proposal also presents new requirements for returned medicinal products. Specifically problematic for full-line wholesalers is the requirement to ensure that returned medicinal products have been maintained correctly during the time they were outside the control of the full-line wholesaler as it cannot be ensured that medicinal products have been handled and stored according to the proper condition during the period that they were in the care of a third party.

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Batch number recording proposal

It is exceptionally important to point out that the requirement on the recording of batch numbers as foreseen in the Falsified Medicines Directive "at least for medicinal products carrying safety features" can only become effective once the information is available on the secondary packaging of medicinal products in a harmonised, machine-readable format. As the modalities and technical specifications of the safety features have yet to be established through the "Delegated Acts" arising from the Falsified Medicines Directive, it is important that the national inspectorates do not require wholesale distributors to fulfil the provision of the new GDP Guidelines ahead of it being required by national legislation.

In sum, while we understand that the proposal presented for consultation may indeed only be a first reflection for a revision, the proposals are deeply concerning for our members. We believe that it is extremely important that we have the opportunity to meet with you and your services as part of the consultation process once the replies have been revised. This would allow for us to gain a better understanding of the rationale behind many of the problematic proposals, share with you the reasons behind our concerns and suggest alternative measures which best reflect the operational approaches of wholesale distributors and how to achieve the desired outcome of improved patient safety. We would therefore kindly ask you that decisions are only taken once we had the occasion to express ourselves and discuss our concerns.

For transparency reasons we would also like to inform you that we will ask Commissioner John Dalli for a meeting with the CEOs of our sector to discuss amongst other issues our concerns in respect of the revision of the GDP guidelines.

We thank you in advance for taking up our concerns.

Yours sincerely,

René Jenny
President

Monika Derecque-Pois
GIRP Director General

CC. Patricia Brunko, DG Health and Consumer Protection, European Commission

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