Press Release

European pharmaceutical full-line wholesalers express serious concern about sky-rocketing costs entailed by the proposal to revise European Good Distribution Practice Guidelines

Lisbon, Portugal, 4th June 2012 – The 53rd Annual General Meeting of the European Association of Pharmaceutical Full-line Wholesalers (GIRP) is currently underway in Lisbon, Portugal where wholesale distributors have gathered for their annual conference. As the event opens, GIRP is keen to take the opportunity to comment on the on-going revision of the European Good Distribution Practice Guidelines (GDP) – a set of guidelines that aim to ensure that a harmonised level of quality is maintained throughout the distribution chain in all EU Member States.

A draft revision of the 'Guidelines on Good Distribution Practice of Medicinal Products for Human Use', which were first published in 1994, was proposed by the European Medicines Agency through its GMP/GDP Inspectors Working Group in the summer of 2011 and published by the European Commission's Directorate General for Health and Consumer Policy (DG SANCO) for public consultation.

The main intention behind the revision is to take into account new requirements for wholesale distributors and brokers established in Directive 2011/62/EU on falsified medicines. However, from the perspective of wholesale distributors, the draft covers a series of provisions which are only applicable to pharmaceutical manufacturers and as such entail GMP (Good Manufacturing Practice) orientated standards, which are only applicable to manufacturing processes and go far above what is required for the safe and efficient distribution of medicines. GIRP takes the view that principles of GDP should not include Good Manufacturing Practice requirements, as 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. Therefore, GIRP is calling for a distinction to be made between provisions applicable to manufacturers and wholesale distributors.

Today, the warehouses of wholesale distributors are equipped with heating and cooling systems to ensure the adequate storage temperature of medicines. The proposal asks for active humidity control throughout the entire warehouse, but in Europe humidity is not a problem for medicinal products in their secondary packaging. Humidity control is therefore not necessary and as such not justified at an estimated cost of EUR 430 million. While active humidity control may be necessary for the actual production of medicinal products and the storage of a couple of very specific products, this requirement should not be applied to the full space of wholesalers' warehouses.

Another example relates to transportation where wholesale distributors will be required to ensure that storage conditions according to the packaging information are maintained during transportation. The cost impact to adjust the delivery vehicle fleet of pharmaceutical wholesalers in Europe to temperature controlled transport would be a sky-high EUR 220 million while the impact on the quality of medicinal products is negligible, as the average delivery time in the 6 largest European countries is only 2.66 hours. Therefore, a distinction should be made between "storage" and "short-time transport temperature" for the purposes of delivering medicines from the warehouse to a pharmacy.

On top of these – the proposal also looks to introduce validation requirements of wholesale distributors' IT systems to an extent which currently no pharmaceutical wholesaler in Europe has in place. Depending on the extent of such first estimates show that costs may run into the region of EUR 1-2 billion.

Overall the proposal goes far beyond what is necessary to ensure the safe handling, storage and transportation of medicines. The proposed new requirements are overly burdensome to achieve a relatively limited step forward to overhaul a currently well-functioning quality system.

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GIRP and its members urge a thorough reflection and consideration on the cost implications of new GDP Guidelines on wholesale distributors as these costs cannot be covered by current remuneration systems for wholesale distributors in the Member States. Finally, it is important to highlight that the GDP requirements on European level represent a minimum standard. It is up to Member States to apply stricter provisions on their national territory. GIRP therefore takes the opportunity to remind national authorities, where specific problems exist on their national territory, that they can choose to raise the standard or correct the problem during their own implementation of the revised GDPs.

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