European Commission
Directorate General for Health and Consumers
Public Health and Risk Assessment, Pharmaceuticals

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COMMISSION GUIDELINES ON GOOD DISTRIBUTION PRACTICE OF MEDICINAL PRODUCTS FOR HUMAN USE (SANCO/C8/AM/AND(2010)380358) - SUBMISSION OF COMMENTS FROM THE NORWEGIAN ASSOCIATION OF PHARMACEUTICAL WHOLESALERS

The members of the Norwegian Association of Pharmaceutical Wholesalers affected by the above mentioned draft Good Distribution Practice (GDP) Guidelines are all Norwegian subsidiaries of major pan-European pharmaceutical full-line wholesaling companies. These parent companies are direct members of GIRP (the European Association of Pharmaceutical Full-line Wholesalers).

Our members have been providing their comments to these draft GDP Guidelines through internal processes, all summed up and presented in the comprehensive response by GIRP. Consequently, we make use of this opportunity to express our support to the GIRP response.

However, the Norwegian market for wholesale distribution of pharmaceuticals has some characteristics that we would like to emphasize in regard to the draft GDP Guidelines.

First of all, the Norwegian Pharmacy Act allows for vertical integration between wholesalers and pharmacies. As a consequence, vertical integrated pharmacy chains amounts to the vast majority of the market for distribution of pharmaceuticals in Norway. Vertical integration makes it easier to control routines and storage conditions in pharmacies. Given that fact, the proposed regulation set forth in section 6.9 (*"medicinal products returns from a customer not holding a wholesale distribution authorisation should only be returned to saleable stock if they were returned within five days of original dispatch"*) should be reconsidered for fully integrated pharmacy chains. The number of days from original dispatch seems to be irrelevant and in our opinion the risk assessment described in section 6.7 should reflect the limitations for such returns.

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Moreover, Norway is a country with very long distances and geographic as well as climatic challenges. The Norwegian wholesalers need to use local transport agencies in some areas. It is not quite clear if Chapter 7 ("Contract Operations") also implies transport when outsourced to a third party, and if this is the case what is meant by "distribution authorization"? Is this a full wholesale distribution authorization and is such authorization also required of any other contract operators?
We have had initial discussions about this with the Norwegian Medicines Agency, and the detailed implementation is very important for the Norwegian wholesalers. Hopefully, the final guidelines will offer some clarification in this respect.

Please do not hesitate to revert if you have any queries to the above comments.

Yours sincerely
Norwegian Association of Pharmaceutical Wholesalers

Øystein Askim
Chairman of the Board of Directors

Copy:

The Norwegian Medicines Agency

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