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Health and Consumers Directorate –General, Brussels  
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**PROVIISORIIHDISTYS**

30 April 2013

To the Health and Consumers Directorate-General:

**Subject: Guideline on the Principles of Good Distribution Practices for Active Substances for Medicinal Products for Human Use**

The Finnish Pharmacists' Society would like to thank the European Commission for the opportunity to provide an input to the above-mentioned public consultation. The Finnish Pharmacists' Society is a professional association that presents 1,100 individual members in the field of pharmacy.

Overall we feel the guideline is well prepared and adequate for the purpose. We agree with the draft, however, we see the need to take into account the following sections:

#### **Quality System**

The quality system should include an emergency plan which ensures effective recall of Active Substances and the concerned medicinal products from the market ordered by the competent authorities or marketing authorisation holder for the medicinal product concerned.

#### **Personnel**

Because the Active Substance is in crucial role in the pharmaceutical products, the distributor of Active Substance must designate a certain person as Responsible Person. The Responsible Person should meet the qualifications and all conditions provided for by the legislation of the Member State concerned. An upper university degree in pharmacy (M.Sc.) is desirable because this particular education makes possible to assess a causal relationship between physico-chemical change and its effect to pharmacovigilance. The Responsible Person should have appropriate competence and experience as well as knowledge of training in GDP. The responsible person should be in direct employment to the distributor.

#### **Outsourcing**

Nowadays distribution chain is complex and long. Thus any activity covered by this GDP Guide that is outsourced should be correctly defined, agreed and controlled in order to avoid misunderstandings which could affect the characteristics of the Active Substance. There must be a written Contract between the Contract Giver and the Contract Acceptor which clearly establishes the duties of each party. The Contract Giver should always be responsible for the activities contracted out.

If you have any questions, please contact us.

With very best regards,  
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President

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