

21.12 - 2011

Patricia Brunko
Unit D.3 Pharmaceuticals
Health and Consumers Directorate General
European Commission

RE: EEA Response to the Commission consultation on Guidelines on Good Distribution Practice of Medicinal Products for Human Use

Dear Mrs. Brunko,

With great interest has the European Express Association (EEA) reviewed the proposed GDP guidelines that were submitted for public consultation by the European Commission Health and Consumers Directorate General. In the attached document you will find our observations and recommendations for further clarification of the application of the guidelines to transportation. These recommendations are based on the current experience that our member companies have with the provision of transportation services for the pharmaceutical industry. This industry has become an important user of express delivery services over the past years and represents 8% of our customer base.

Our recommendations are aimed at clarifying the nature of certain types of handling that are performed during the normal process of transportation of goods in an express delivery mode. They are specifically targeted at the language used for the 24hr rule and loading, unloading and reloading of goods. These are our concerns:

- 1) Based on the current text in 9.12 one could come to the conclusion that goods that are in transport for more than 24hrs need to be moving all the time and cannot be temporarily staged for a period of more than 24hrs within the network of the express delivery service provider unless the depot or hub is licensed as a wholesale distribution facility. In the normal express delivery process it could happen that goods are sitting in a building before being loaded onto a vehicle or aircraft. This is part of the normal transportation planning process and in line with the so called planned flow of the goods once the shipper (pharmaceutical manufacturer) has selected a specific shipping option. The goods remain in full control of the express delivery company but could exceptionally sit for more than 24hrs in a secured building before moving on. In our view this would not qualify as "storage" and would therefore not require a wholesale distribution license for the transportation company. As staging of goods is not the objective of the express transportation process, we would like to seek confirmation that it is excluded from the license requirement as "normally" the 24 hrs limit is not exceeded. Another clarification required is that the term "refrigerated product" excludes passive temperature controlled packaging such as isothermic boxes. Otherwise, every express transportation hub may require a wholesale distribution license.
- 2) Express delivery operates using a so-called hub and spoke system. This implies that shipments can be loaded on a truck, moved to a depot to be sorted, reloaded on another vehicle or aircraft and

unloaded, sorted and reloaded on other types of transportation for delivery. In our view these activities do not qualify as the activities mentioned in article 9.13 and can be carried out without a wholesale distribution license.

It would in our view be helpful if this is clarified in the guidelines and we would welcome any changes that you can make to the text to accommodate our concerns. We would be available for further clarification and review if this would be of value to you.

Kind Regards

A handwritten signature in black ink, appearing to read 'Reinout', with a long horizontal stroke extending to the right.

Reinout Wijbenga

Chair EEA - CMR Committee

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EEA website:

www.euroexpress.org

Oxford Economics report, December 2011 - "Economic impact of express carriers on Europe":
http://www.euroexpress.org/uploads/ELibrary/EEA_RA2011_LR.pdf