To whom it may concern

Ski, Norway December 23, 2011

Regarding Commission Guidelines on Good Distribution Practice of Medical Products for Human Use

We appreciate that we are given the opportunity to give comments to the proposed Guidelines on Good Distribution Practice of Medicinal Products for Human Use.

On behalf of Alliance Healthcare Norway AS, a pharmaceutical wholesaler, we have a few comments to the document. The comments are listed below:

1) **Chapter 2 Personnel**
   Personnel and responsible person:

The responsible person should fulfill his/her responsibilities personally and should be permanently available.
The responsibility of the responsible person is wide (2.5) and we suggest that written delegation of the handling of tasks, but not the responsibility, to qualified and trained personnel should be legal and described in the guidelines.

2) **Chapter 5 Operation**
   Products without a national MA:

We suggest patient based import of a very limited quantity of products without a national MA should not require documentation of release to the market (5.15). This is a service for a very few individual patient, judged by a physician to need the product, products the manufacturer have not marketed in all countries with few patients. Norway is a country with a little population and few patients. For some of these access to product without a Norwegian MA is required for optimal treatment - and in every case the prescription is approved or notified to the Norwegian authorities. Too strict requirement and regulations in this limited field may increase cost and decrease availability of products without a national MA which might be highly requested by a few patients.

3) **Chapter 6 Complaints, Returns, suspected falsified Medicinal Products and Medicinal Product Recall**
   Returns:

Medicinal products should only be returned to salable stock if they were returned within five days of original dispatch. We suggest this time period should be expanded, otherwise we fear, due to changes in the pharmacies sales patterns, that medicinal products for a lot of money have to be destroyed, being a big economical burden for the pharmacies.

4) **Chapter 9 Transportation**

Transportation:

a) If transportation is sub-contracted to a third party then the contract should encompass the requirements contained within Chapter 7 (9.11). Further, in chapter 7 it is stated that the contract acceptor must hold a distribution authorization.

It is not clear which kind of authorization that is required for companies only transporting medicinal products on behalf of a wholesaler. Should they be authorized as a wholesaler requiring a wholesaler distribution license or will a new kind of a distribution license be issued and required?

b) The required storage condition for medicinal products should be maintained during transportation within the defined limits as described on the packaging information.

We suggest that the packaging information is meant for the patients, and that this should in the guidelines be changes to "recommendations from the manufacturer" or similar, as some product might be shipped at room temperature although the long-term storage temperature, which is stated on the packs, is refrigerated!

Sincerely yours,

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