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**To:** SANCO GMP; 'gmdp@ema.europa.eu'

**Subject:** RE; Public consultation on: Guidelines on Good Distribution Practice of Medicinal Products for Human Use.

The European Commission has announced public consultation on: Guidelines on Good Distribution Practice of Medicinal Products for Human Use.

In this connection the Association of Danish Pharmacies has the following comments to the material:

The guidelines primarily relate to demands for pharmaceutical wholesalers' setup and operation of their business. In a number of points it is a matter of substantial expansions compared with the existing guidelines, which may be financially burdensome to the wholesalers. Especially during the present financial situation it should be reconsidered if the suggested changes are necessary to secure a safe handling of pharmaceuticals.

The Association of Danish Pharmacies has noted that the suggested guidelines also include a few regulations, which have direct and extremely far-reaching consequences to the pharmacies.

It relates to the suggested guidelines of return of medicine.

6.9 Medicinal products which have left the premises of the distributor should only be returned to saleable stock if:

- i)..
- ii) medicinal products returns from a customer not holding a wholesale distribution authorization should only be returned to saleable stock if they were returned within five days of original dispatch;
- iii)..

This condition involves that the pharmacies will have to return medicine within 5 days in order for the wholesaler to return the product to the saleable stock.

Such a condition will have severe consequences to the pharmacies' possibility of returning medicine. It will imply completely new logistic systems, in which both pharmacies and wholesalers can control precisely which packages have been supplied on which days. A change as suggested must therefore be expected to become financially burdensome as well as impose a large extra logistic burden to the pharmacies. Further such conditions will in practise be damaging to price and delivery rules as e.g. in Denmark, where we operate with a price period of 2 weeks and where the pharmacies are obligated to supply the cheapest alternative during the period. Obstacles in the access to return medicine may mean that the pharmacies will be reluctant having a stock which can fully meet the demand, in order to avoid a stock of unsaleable medicine. It will imply serious, negative consequences to the delivery degree and with that the service in relation to the patients.

Finally we point out that the pharmacies have rules which secure that quality problems of medicine stored at the pharmacy do not occur. Also medicine supplied from wholesaler to pharmacy typically has relatively long durability. In the light of this the condition seems unnecessary, when it is a matter of return from the pharmacies.

Therefore the Association of Danish Pharmacies strongly urges the Commission to change this condition so that it does not include returns from pharmacies.

Yours sincerely,

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