



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30.12.2011<Date of submission>

Submission of comments on 'Commission Guidelines on Good Distribution Practice of Medicinal Products for Human Use' (SANCO/C8/AM/anD (2010) 380358)

Comments from:

Name of organisation or individual

Apteekkitavaratukkukauppiat ry – Association of Pharmaceutical Distributors, Finland



1. General comments

Stakeholder number	General comment (if any)	Outcome (if applicable)
<i>(To be completed by the Agency)</i>		<i>(To be completed by the Agency)</i>

2. Specific comments on text

Line number(s) of the relevant text <i>(e.g. Lines 20-23)</i>	Stakeholder number <i>(To be completed by the Agency)</i>	Comment and rationale; proposed changes <i>(If changes to the wording are suggested, they should be highlighted using 'track changes')</i>	Outcome <i>(To be completed by the Agency)</i>
<p>9.12 Where transport hubs are utilised in the supply chain, a maximum time limit of normally 24 hours should be set to await the next stage of the transportation route. Where medicinal products are held on the premises for longer than this defined time limit, the hub will be deemed to be acting as a storage site and required to obtain a wholesale distribution authorisation. For refrigerated product any storage at a transportation hub for any period of time would require that premises to hold a wholesaler distribution authorisation.</p>		<p>Comment: Transport terminals are an integral part of the distribution system of pharmaceuticals in Finland. Due to the large size of the country, the expected promise of a 24-hour delivery time can only be met by using the terminals, or hubs. Typically the shipments stop in the terminals for a matter of hours, the exception being weekend, when they stop for a longer period as they will be delivered further on Mondays. The hubs and operations therein are also audited regularly to monitor the quality requirement compliance of the transport companies.</p> <p>To expect a pharmaceutical wholesale license in every transport terminal would clearly compromise the fluent distribution and availability of medicines in Finland. The requirement being as now proposed, the utilization of the terminals would cease and the delivery schedules of distributing wholesalers should be unfavourably rearranged to cover shipping only through weekdays.</p> <p>Proposed change: Suggestion: To allow use of transport terminals as currently, including GDP compliance supervision requirement (e.g. auditing) with country-specific decisions on acceptable shipment stopping time.</p>	
		<p>Comment:</p>	

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		Proposed change (if any):	
		Comment: Proposed change (if any):	

Please add more rows if needed.