EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

2 December 2011

Submission of comments on 'Commission Guidelines on Good Distribution Practice of Medicinal Products for Human Use' (EMA/…/…)

Comments from:

Name of organisation or individual
Pharma Industry Finland

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF).

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1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	These guidelines should be different for manufacturers and wholesaler/distributors. It is understandable to have precise and strict guidelines for wholesalers who deal with many products from different manufacturers and distribute those in relatively small areas. The only way for a wholesaler to handle large variety of products is to have precise guidelines and procedures. In comparison, a manufacturer usually deals with limited variety of products and may distribute those to many areas globally. For an example, manufacturer (QP) knows its products and stability data for the products. Therefore, e.g. it should be possible to manufacturer ship/transport products in a wider temperature range than printed on packaging material (if it is justified according to stability data) to the wholesalers/distributors. **How should manufacturers interpret the GDP? To what extent does the GDP concern manufacturer's actions? This should be very clearly determined in the guideline because especially the nature of transportation from manufacturer to distributor/wholesaler and from wholesaler to pharmacies is totally different.**	

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
page 26.		Comment: Chapter 9 Transportation, Principle: "Medicinal products should be transported in accordance with the storage conditions indicated on the packaging information. This instruction is only for wholesaler/distributors. From the manufacturer's point of you, what is meant by packaging information? Information on shipment or in individual product package? Proposed change (if any): The temperature limits for transportation conditions can be wider than the described storage condition, if the limits are based on product stability data.	
page 26.		Comment: "9.1 The required storage conditions for medicinal products should be maintained during transportation within the defined limits as described on the packaging information." This instruction is only for wholesaler/distributors The limits for conditions during transportation from manufacturer to wholesaler can be wider than described storage conditions, if the limits are based on stability data. Proposed change (if any): The temperature limits for transportation conditions can be wider than the described storage condition, if the limits are based on product stability data.	
page 26.		Comment:	

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		” 9.5 Delivery drivers (including contract drivers) should be trained in the relevant areas of GDP.” This instruction is only for wholesaler/distributors. In a global distribution chain it is quite impossible to make sure that every driver in the chain, including air and sea cargo, is trained for GDP. Proposed change (if any):	
page 27.		Comment: “9.12 Where transportation 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 wholesalers distribution authorisation.” This instruction is only for wholesaler/distributors. Temporary storing for 24 hours or more should be acceptable in the supply chain. This kind of delays and waiting times are normal in a global distribution chain due to e.g. ferry schedules. The wholesaler authorisation should not be required from all parties in supply chain. Proposed change (if any):	
page 27.		Comment: “9.13 In the event that the transportation of medicinal products requires unloading and reloading e.g. at terminals and hubs, these premises should be audited and approved	

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		prior to deployment." This instruction is only for wholesaler/distributors. Whose responsibility it is to audit these? If each manufacturer, who act as a distributor, needs to audit every terminal and hub, it will cause unacceptable amount of work in the terminals and hubs. Proposed change (if any):	
page 11.		Comment: "3.4 Medicinal products not intended for the Union market should be kept in segregated areas." What is meant by segregated areas? All parties in a supply chain cannot have separated areas for different marked areas. Proposed change (if any):	
		Comment: Proposed change (if any):	
		Comment: Proposed change (if any):	
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		Comment:	

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		Proposed change (if any):	

Please add more rows if needed.