



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

<12. December 2011>

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

Comments from: **Swissmedic**

Name of organisation or individual

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).



1. General comments

Stakeholder number <i>(To be completed by the Agency)</i>	General comment (if any)	Outcome (if applicable) <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>
§9.12, p.27		<p>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.</p> <p>Comment: From our experience we consider the 24 hour maximum time limit as too short and very difficult to enforce it in today's complex distribution channels. Therefore we recommend to extend the limit to 72 hours, reflecting a shipment to be hold in a transportation hub from Friday afternoon to Monday morning, without the need for a whole sale distribution authorisation for the hub. With regard to the risk for the product we consider this extension as acceptable, because refrigerated products are excluded from this waiver per se and it will still be the responsibility of the distributor to assure compliance of the shipment conditions also during the holding time in the hub. However, in order to avoid that this transportation hub is shifting smoothly to a real warehouse, which would require a wholesale distribution authorisation, we recommend to introduce a sentence requiring that the 72 hours should not repeatedly be extended on request of the wholesale distributor. Therefore we consider the package (72h, no refrigerated products, still within the responsibility of the distributor and limitation of extending the limit) as more practical and "enforceable" than the one proposed in the draft document which will lead to too many unnecessary OOS.</p>	

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		Proposed change (if any):a maximum time limit of normally 72 hours should be set to await the next stage of the transportation route. <u>This time limit should not repeatedly be extended on request of the wholesale distributor.</u> Where.....	

Please add more rows if needed.