



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 December 2011

Submission of comments on 'the revised 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



Distribuzione Primaria Farma & Salute
Associazione Operatori Commerciali e Logistici

Contacts:

Via Pietro Cossa, 41 – 00193 - Roma
Tel: +39.06.32.14.007
Fax: +39.06.32.15.888
email: info@assoram.it
web: www.assoram.it

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>
	<p>Introduction Ref. Art. 1 (17) Directive 2011/83/CE</p> <p>As a general comment, it should be clarified the existing difference between Logistic Providers/Pre-Wholesalers or Concessionaries (Depositari e Concessionari) and Wholesalers (Grossisti).</p> <p>In Italy there are different distribution-rules for Logistic Providers/Pre-Wholesalers or Concessionaries (Primary Distribution) and Wholesalers (Intermediate Distribution).</p>	

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>
2.3 Responsible Person		<p>Comment: <i>A degree in Pharmacy is desirable</i></p> <p>Proposed change: It should be better to mention a “Degree in Farmacy and... Chemistry or Biology” (as actually required by the Italian law).</p>	
5.17 Storage		<p>Comment: <i>Medicinal product should be stored separately from other products and protected from...</i></p> <p>Proposed change: As in the Pharmacy, medical products normally are not stored separately from other products as cosmetics, food supplements, medical devices, ... even if particular attention should be paid to products were specific storage conditions are required.</p>	

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>6.9 Returned medicinal products</p>		<p>Comment: <i>ii – medicinal products returns from costumer not holding a wholesale distribution authorisation should only be returned to saleable stock if they were returned within five days of original dispatch;</i></p> <p>Proposed change: To what kind of criteria does the choice of only five days refer? It would be better to mention: “as quick as possible” with a declaration of proper storage. The strictly time of five days couldn’t be respected because of the difference between Wholesalers and Logistic Providers/Pre-Wholesalers or Concessionaries (see our proposal in the Introduction). In fact it could be that a Logistic Providers/Pre-Wholesalers or Concessionaries has just one warehouse for the whole national territory.</p>	

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 Transportation</p>		<p>Comment: <i>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.</i> <i>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.</i></p> <p>Proposed change: It should be more reasonable to mention a time limit of 24/32 working hours (taking into account Weekends and National holidays). After this time limit the hub should be required to obtain a special "Storage authorization", without the requirement of the presence of a "Responsible Person (see 2.3)".</p>	