<21 November 2011>

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

Comments from:

Name of organisation or individual
VAPI-UPIP Ninoofsesteenweg 2 1540 Herne Belgium Tel: +32 2 309 06 19 fax: +32 2 270 25 77 www.vapi-upip.be – www.upip-vapi.be – upip-vapi@telenet.be

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 *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	1. It is positive that this guidance gives more clarity; risk management is incorporated and gives more guidance compared to the text from 1994. 2. Description of Critical Processes can be added for clarity. Suggestion is to define Critical Processes as the outcome of a risk based approach and add some examples just for information 3. Are in Chapter 5 also Veterinary Medicinal Products in scope related to the qualification of customers? 4. Chapter 10: Specific Provisions for Brookers. The guidance is deviating to much compared to regular wholesalers/distributors. Comparable expectations for comparable activities should be established.	

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)*
1.4 & 1.6		Comment: There is overlap in these two paragraphs Proposed change (if any): Merge into one paragraph	
1.11		Comment: add "documented" Proposed change (if any): The outcome of this management review of the quality management system should be timely and effectively communicated and documented.	
2.3		Comment: "A degree in Pharmacy is desirable." Is not consistent with the rest of the document where Responsible Person is used. Proposed change (if any): Delete "A degree in Pharmacy is desirable."	
2.4		Comment: Rephrase the paragraph to reflect the effective content and liability. Proposed change (if any): The Responsible Person should carry out his/her activities in such a way to ensure the wholesale distributor can demonstrate GDP compliance and that public service obligations are met.	

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2.16		Comment: Change "storage" to "presence" to reflect better the intent. Proposed change (if any): The presence of food, drink, smoking materials or medication for personal use in the storage areas should be prohibited.	
3.3 & 3.4		Comment: These paragraphs should reference to 5.24 where a validated Building Management System can be used instead of physical separation Proposed change (if any):	
3.7		Comment: There are specific local requirements for Radioactive products not only related to pharmaceuticals. Proposed change (if any): Also refer to local applicable legislation.	
3.23		Comment: Not clear what is meant by "Durability", additional clarification would be useful. Proposed change (if any):	
Chapter 4 principle		Comment: specify that paper as well as electronic format can be used.	

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		Proposed change (if any): Instructions, procedures, and records should be free from errors and each employee should have access to such instructions and procedures in paper or electronic format.	
4.6		Comment: More specification is needed Proposed change (if any): All necessary documentation for the tasks executed should be readily available.	
4.8		Comment: text lay out, should be formatted as title Proposed change (if any):	
4.10		Comment: Add expiry date to the summation. Proposed change (if any): Records should include the following information: date; name of the medicinal product; expiry date; quantity received, supplied or brokered; name and address of the supplier, broker or consignee, as appropriate; and batch number where required.	
Chapter 5 principle paragraph 3		Comment: please revise sentence. It is not clear what exactly is meant. Is parallel import meant? Proposed change (if any):	
5.2 & 5.5		Comment: Replace "qualification" by "mutual verification of Distribution Licenses"	

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		Proposed change (if any):	
5.4		Comment: replace written by documented so paper based as electronic format can be used Proposed change (if any): Purchase of medicinal products should be controlled by documented procedures. The supply chain of medicinal products should be known and documented.	
5.7		Comment: "due diligence" is a heavy term. This paragraph is also related to 5.2 & 5.5 Proposed change (if any):	
5.17		Comment: It is not always possible for wholesalers with a lot of references to store all products "separately". A risk based approach should be used to guarantee the quality, efficacy and safety of the products. Proposed change (if any):	
5.18		Comment: It is not clear what is the definition of "Containers" Proposed change (if any): Add "Containers" to Glossary of Terms	

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5.21		Comment: Is not always possible. Some medicinal gasses are placed directly on the floor. Proposed change (if any):	
5.26		Comment: segregation and separation are used throughout the document. Both terms should be added to the Glossary of Terms for clarification. Proposed change (if any):	
5.32		Comment: Additional clarification needed Proposed change (if any): Records (paper based or electronic format that can made visible/printed) should be kept so that the actual physical journey undertaken by the product can be tracked.	
5.32		Comment: clarification needed on "at least for products bearing the safety features" Proposed change (if any):	
5.33		Comment: "operation" change into "operating" Proposed change (if any): A person exporting medicinal products must thus hold a wholesale distribution authorization or a manufacturing authorization. This is also the case if the exporting wholesale distributor is operating from a free zone.	

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6.9 ii		Comment: 5 days is very short, as pharmacies don't have wholesale licenses they can be added. Proposed change (if any): medicinal products returns from a customer not holding a wholesale distribution Authorization/pharmacy license should only be returned to saleable stock after thorough evaluation	
6.20		Comment: "available" can be replaced by "Accessible" Proposed change (if any):	
9.12		Comment: for consistency use of "2°-8°" instead of refrigerated. Proposed change (if any):	
9.12 & 9.13		Comment: Incorporate Risk Based evaluation in the use of HUB's Proposed change (if any):	
9.12		Comment: add HUB to the Glossary of Terms Proposed change (if any):	

Please add more rows if needed.