EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25/08/2011

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:

Name of organisation or individual
Rico Schulze GMP / GDP Inspector DE-09221 Neukirchen-Adorf Germany

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)*
	None	

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)*
Chapter 2, 2.5 i)		Comment: Implementation and maintenance of a quality management system are not within the Responsible Person's field of responsibility. Senior management is responsible for implementation and maintenance of quality management. Proposed change (if any): Replace "management" by "assurance" or delete.	
Chapter 2, 2.5 vi)		Comment: Assigning the responsibility for performing the qualification and approval of suppliers and costumers to the Responsible Person is inadequate. Qualification and approval of suppliers and costumers can be performed by other sufficiently trained and competent persons of the wholesaler. Proposed change (if any): Replace "performing the qualification and approval of suppliers and customers" by "ensuring that suppliers and costumers are qualified and approved".	
Chapter 2, 2.5 vii)		Comment: Assigning the responsibility for authorising the return to saleable stock of any returned medicines to the Responsible	

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)*
		Person is inadequate. As stated in Chapter 6, 6.9 iv), it is sufficient if these medicines have been examined and assessed by a sufficiently trained and competent person of the wholesaler. Proposed change (if any): Replace "authorising the return to saleable stock of any returned medicines " by "ensuring that returned medicines should only be returned to saleable stock if they have been examined and assessed by a sufficiently trained and competent person" or delete.	
Chapter 6, 6.9 ii)		Comment: Asking that "medicinal products returns from a customer not holding a wholesale distribution authorisation should only be returned to saleable stock if they were returned within five days of original dispatch" is unfounded, inadequate and will lead to a disproportionally high loss of values. Pharmacies, e.g., which usually do not hold a wholesale distribution authorisation should generally be able to demonstrate that the medicinal products have been continuously stored under suitable conditions. Therefore there is no reason to limit medicinal product returns to five days after original dispatch. Proposed change (if any): Delete.	

Please add more rows if needed.