EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22/12/2011

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
Federal Ministry for Health (BMG), 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).

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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)*
	The document in general seems to be very detailed. It is encouraged that at least some of the "musts" should be replaced by "should" to emphasize the documents character as a guideline.	

…

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, 2.1 The wholesale distributor must designate a person as Responsible Person. The Responsible Person should fulfil his/her responsibilities personally and should be permanently available. The Responsible Person should meet the conditions provided for by the legislation of the Member State concerned.		Comment: The current wording could lead to the view that the responsible person should be present on site 24 hours per day. In addition there should be the possibility to delegate the responsibilities of the Responsible Person to another person having equal qualification and requirements. Proposed change (if any): The wholesale distributor must designate a Person as Responsible Person. The Responsible Person should fulfil his/her responsibilities personally and should be permanently ~~available~~ **reachable.** The Responsible Person should meet the conditions provided for by the legislation of the Member State concerned.	
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.	

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		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 a very extensive task. Qualification and approval of suppliers and costumers can be performed by other sufficiently trained and competent persons of the wholesaler. The Responsible Person should ensure that the approval and qualification of customers is correct. 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 Person is a very extensive task. 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. The Responsible Person should ensure this. Proposed change (if any):	

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		Replace "authorising the return to saleable stock of any returned medicines " by "ensuring that returned medicines are to be returned to saleable stock only if they have been examined and assessed by a sufficiently trained and competent person" or delete.	
4.5 Documentation		Comment: In addition to the current text, it should be added that documents should be retained a period one year after expiry date of the product, at least 5 years. Proposed change (if any):	
5.11		Comment: not the copy of the marketing authorisation should be required, but at least a verification that a marketing authorisation exists issued by the competent authority should be available.	
5.17 Medicinal products should be stored separately from other products and protected from harmful effects of light, temperature,		Comment: This requirement that products should be stored separately is related to the fact that the quality of each product should be not affected by any other product or storage condition. It is proposed to clarify the wording. Proposed change (if any):	

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moisture or other external factors. Particular attention should be paid to products where specific storage conditions are required.		Medicinal products should be stored separately from other products **which can affect the quality of the medicinal product** and protected from harmful effects of light, temperature, moisture or other external factors. Particular attention should be paid to products where specific storage conditions are required.	
5.32 …….. Records should be kept so that the actual physical journey undertaken by the product can be tracked.		Comment: There are several reservations to interpret this sentence insofar, that a tracking or monitoring of each step of the product during the journey is required. Proposed change (if any): …….Records should be kept so that the actual physical ~~journey~~ **delivery** undertaken by the product can be tracked.	
6.9		Comment: The guideline of GDP requires the attachment of the batch number of the copy of the original delivery note with regard to all medicinal products whereas the proposal for a Directive amending Directive 2001/83/EC as regards the prevention of falsified medicines requires this specification at least for medicinal products subject to safety features as set out in Article 54a. Proposed change (if any):	
6.9 ii		Comment: Asking that "medicinal products returns from a customer not	

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		holding a wholesale distribution authorisation should only be returned to saleable stock if they were returned within five days of original dispatch" is both unfounded and 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 from pharmacies to five days after original dispatch. Proposed change (if any): Delete.	
Chapter 7, Principles When outsourcing activities a written contract should be drawn up. Both the contract giver and the contract acceptor must hold a distribution authorization. The written and signed contract should cover all wholesale distribution activities and clearly establish		Comment: Outsourced activities subject to this requirement should be limited to activities relevant for distribution, storage and handling of medicinal products only. A distribution authorisation should not be necessary for the contract acceptor when the activities are not directly related to the core activities connected to the medicinal products, e.g. cleaning activities, etc.. Proposed change (if any): When outsourcing activities a written contract should be drawn up. **In case of outsourcing wholesale distribution activities** both the contract giver and the contract acceptor must hold a distribution authorisation. The written and signed contract should cover all **outsourced** wholesale distribution activities and clearly establish the duties and responsibilities of	

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the duties and responsibilities of each party. Written contracts should be established for any activity likely to impact on GDP related activities.		each party. Written contracts should be established for any activity likely to impact on GDP related activities.	
9.12		Comment: Asking that all transportation hubs where medicinal products are held for longer than 24 hours "will be […] required to obtain a wholesale distribution authorisation" seems to be very rigorous. The same comment goes for the demand "For refrigerated product any storage at a transportation hub for any period of time would require that premises to hold a wholesalers distribution authorisation." Proposed change (if any): Delete.	
Annex Glossary of Terms		The definition of "brokering" should be clarified/illustrated by examples. "purchase" covers divers meanings in different countries. It's a debatable point, how we shall supervise and register brokers as well as wholesalers located in third countries. The wording "validation", "risk Management system" and	

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		"computerized systems" lead to some questions in connection with GDP. Shall the wholesaler fulfil the same requirements as a manufacturer of medicinal products? Maybe we run into danger to set too high standards with this regard. From our point of view the standards have to be specified.	

Please add more rows if needed.