EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 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:

Name of organisation or individual
GKFI (Groep Kwaliteitsbewustzijn Farmaceutische Industrie), The Netherlands (Group Quality Awareness Pharmaceutical Industry)

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).

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom

An agency of the European Union

Telephone +44 (0)20 7418 8400 Facsimile +44 (0)20 7418 8416
E-mail info@ema.europa.eu Website www.ema.europa.eu

1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*

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)*
In general		Comment: A new guideline on GDP is highly appreciated. However, the scope of the current draft is broad. It applies to both manufacturers and wholesalers. And although some activities are similar, others are not. A more clear distinction between requirements for manufacturers and wholesalers is needed. Proposed change (if any): Refer to above.	
§ 2.3		Comment: *"A degree in Pharmacy is desirable" (for a responsible person).* This is rather vague. What if the preferred Responsible Person has no degree in Pharmacy? What other qualifications are required? Proposed change (if any): Clarify what other qualifications are required.	
§ 3.4		Comment: *"Medicinal products not intended for the Union market should be kept in segregated areas."* In 5.24 is stated that an electronic system replacing physical segregation is allowed. Is this also allowed for the products	

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		referred to in 3.4? Proposed change (if any): Electronic systems should be considered equal to physical segregation.	
§ 4.10		Comment: *" ….; and batch number where required."* This is not clear. Proposed change (if any): Clarify when a batch number is needed, when not.	
Ch. 5 Principle, last alinea		Comment: *"…..imports …..from another member state…".* The word "import" is confusing. Moving product from outside the EU into the EU is import. Proposed change (if any): Rephrase wording.	
Ch. 5 Principle, last alinea		Comment: *A distributor not being the MA-holder who receives a product from another Member State, shall inform the MA-holder and the competent authority of the receiving Member State.* This does not seem practical. E.g.: the product is authorized in all EU countries and the MA-holder for all these products is located in EU country A. Manufacturing is also in EU country A, but the central European warehouse (distributor) is situated in EU country B. Should the warehouse in EU country B inform the	

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		authority in country B of every product that is received from country A? Proposed change (if any): Refer to above.	
§ 5.4		Comment: *"Supply chain should be known and documented".* What is exactly meant by this sentence? What is the beginning and the end of the supply chain? What does it add to the obligations to know supplier (e.g. manufacturer) and the customer? Proposed change (if any): Refer to above.	
§ 5.10		Comment: *"Wholesale distributors should monitor transactions and investigate irregularity in sale patterns."* Wholesale distributors already check the authorization of their customers on a regular basis. Monitoring transactions and investigating irregular sale patterns seems to be overdone. Proposed change (if any): Refer to above.	
§ 5.25		Comment: *"The products and the areas concerned should be appropriately identified."* In 5.24 is stated that segregation via a computerized system is	

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		possible. What kind of identification of products and areas is needed when it's already identified in a computerized system? Is physical identification still needed? Proposed change (if any): Clarify is physical identification is needed when a computerized system is in use.	
§ 5.30		Comment: *"Containers in which medicinal products are shipped should be sealed."* The word "sealed" is not unambiguous. Does it mean containers should be closed, or should they be tamper evident sealed? Is an outer carton closed with tape allowed? Proposed change (if any): Clarify word "sealed".	
§ 6.9 ii)		Comment: *Products returned from customers not holding a wholesalers license and going back to saleable stock, should be returned within 5 days of original dispatch.* This is not achievable in practice, this is too short. Beside this, days should be defined as working days or calendar days. Proposed change (if any): Change 5 days into 14 calendar days.	
§ 6.9 v)		Comment: *" the distributor has reasonable evidence that ~~th~~ the product*	

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		was supplied to that….." Proposed change (if any): Refer to track changes in red.	
§ 6.11		Comment: *"All handling of returns should be approved by the Responsible Person. "* Following an SOP approved by the Responsible Person, it should be possible for an organization to destroy a return or return to stock without the approval of the Responsible Person every single time. Proposed change (if any): Refer to above.	
§ 7.2		Comment: *In the introduction of chapter 7 is described that any outsourced activity that could have impact on GDP related activities should be covered by a contract. In 7.2 is described that audits are required.* Is this also necessary for GDP related activities outsourced, but performed within the facility, such as pest control, cleaning, calibrations? Such activities should be part of self-inspection. Proposed change (if any): Describe in more detail, or add self-inspections as means of audits.	
§ 9.12 and 9.13		Comment:	

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		We urgently request the authorities to reconsider the obligation for hubs etc. to have a wholesaler distribution authorization. The number of hubs in the EU is huge. This would lead to an unworkable situation for authorities, wholesalers and distributors. Audits of terminals (e.g. at airports) is also difficult to accomplish. And what if an airplane is forced to fly to another airport (e.g. due to fog), should the terminal be audited prior to deployment? It is also unrealistic to presume that changes made to these premises will be communicated to the wholesaler or distributor. Proposed change (if any): Delete obligation for hubs to have a wholesaler distribution authorization.	
§ 9.19		Comment: This paragraph implies that transport of non-temperature sensitive products (e.g. medicinal products without storage condition) should also be performed with temperature controlled transport. This paragraph lacks the use of a risk assessment. Proposed change (if any): Use of risk assessment should be allowed.	