20/12/2011

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
Leem (les entreprises du medicament)

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)*

Line number(s)	
General comments	The conditions to return to saleable stock medicinal products which have left the premises of the distributor become very strict. Furthermore, it seems to be impossible : to require a wholesale distribution authorisation for all transporter's hubs all around Europe, to monitor all equipments used to transport medicinal products in Europe and for France in the different overseas departments all around the world.
2. Specific comments on text	
Introduction	This chapter should reflect the evolution in technology used in the distribution industry (e.g. e-commerce) Proposed change (if any): e-commerce, Direct to Pharmacy and Direct to Patient deliveries should be included
Chapter 1	Liability of the wholesale distributors as regard to their stock for which their first objective is to supply the national territory before any exportation
Chapter 2	

Line number(s)	
Chapter 2 §2.16:	"Storage of food, drink ... should be prohibited in storage areas". Drinking **water** is sometimes allowed in the distribution sites (water fountains)
2.10	Comment: add training in QA principles Proposed change (if any): "All personnel (…) should be qualified in GDP requirements and **Quality Assurance principles"**
Chapter 3	
3.2	Comment: Does this mean that a separate licence is needed for an external storage facility or it is sufficient to include the external storage into the existing licence for the DC?
3.4	Comment:Physical segregation has not to be required if a validated Warehouse Management System is in place. this is also applicable for quarantined products Proposed change: "Medicinal products not intended for the Union market should be kept in segregated areas**, excepted if validated warehouse management system is in place**"
3.10	Comment: add request to have cleaning program Proposed change: "Premises and storage (…) litter and dust. Cleaning **program**, instructions and records should be in place. Cleaning equipment (…) contamination."
3.13	Comment: Humidity should be measured continuously but not controlled as temperature. Proposed change: "Suitable equipment and procedures should be in place to ensure adequate control or **measure** of the environment of medicinal products during storage. **A risk assessment should determine** the environmental factors to be considered include, but are not limited to, temperature, humidity, and cleanliness of the premises."
3.17	Comment: Risk assessment must be done to determine the necessity to have in place appropriate alarm systems, and associated alarm levels. Proposed change (if any): "**According to a risk assessment, if necessary,** appropriate alarm systems should be in place to provide alerts when there are deviations from pre-defined storage conditions. Alarm levels should be appropriately set and alarms should be regularly tested to ensure adequate functionality."
3.20	Proposed change (if any): Add at the end of paragraph: "**e.g. Validation**"

Line number(s)	
3.25	Comment: need for regular testing of data restoration Proposed change: "Procedures to be followed if the system fails or breaks down should be defined. This should include systems for the restoration of data **and regular testing of data restoration**"
4.8	Records ? proposed change : delete
Chapter 5 – 5.1	Proposed change (if any): Replace "… only from persons who are…" by "… **only from establishment which are**…"
5.22	Comment: after the last sentence, add "according to a predefined timing" Proposed change: "Medicinal products (…) segregation. Physical removal of unsuitable stock should be performed regularly **according to a predefined timing**".
5.28	need for a written destruction order from the MAH
5.32	Comment: Data of actual physical journey undertaken by the product are actually available for consultation but not recorded. Proposed change (if any): "For all supplies to a person authorised or entitled to supply medicinal product to the public, a document must be enclosed to ascertain the date; name and pharmaceutical form of the medicinal product, batch number at least for products bearing the safety features, where required; quantity supplied; name and address of the supplier, name and delivery address of the consignee (actual physical storage premises, if different) and applicable transport and storage conditions. **Data should be consultable to track the actual physical journey undertaken by the product.**"
6.3	Comment: need to inform also the MAH Proposed changes: Any complaint (…) investigated. The national competent authority should be notified without delay **and the manufacturer and/or the Marketing Authorisation Holder should be informed**"
6.9 ii)	Comment: -It seems curious that products can be returned from a customer **not holding** a wholesale distribution authorization….! Since this is a prerequisite for product distribution in the European Union.

Line number(s)	
	-Five days to return medicinal product after original dispatch seems to be too short to permit the receipt by the customer and return to the distributor. Proposed change (if any): "ii) medicinal products returns from a customer not holding a wholesale distribution authorisation should only be returned to saleable stock if they were returned within **fifteen** days of original dispatch"
6.10	One of the provision is not applicable (opening of packaging) once the safety feature apposition will be in place. This will overcomplicate the task as distribution centers that will not have the capacity (nor systematically the administrative authorization) to repack products, safety features inclusive….! Rather verification of the integrity as per the Directive should be sufficient by itself to guarantee authenticity of the product returned. The problem at stake remains cold chain maintenance demonstration. Proposed change : opening of the packaging **if no safety features**
6.11	Comment: need for the systematic information of the MAH Proposed change: "All handling of returned medicinal products including their return to saleable stock or disposal should be approved by the Responsible Person, recorded, **and the manufacturer/MAH should be informed**."
7.2	not propose to systematically audit the contractor before the beginning of the activities but according to a risk based approach
7.6	Comment: It is impossible to evaluate and approve a third party at any time, in particular for transportation. But it is possible to have a list of third parties used by the Contract Acceptor. Proposed change (if any): "Arrangements made between the Contract Acceptor and any third party should ensure that the wholesale distribution information is made available in the same way as between the original Contract Giver and Contract Acceptor. **A list of all third parties used by the Contract Acceptor should be available.**"
chapter 9	Comment: We have highlighted the hub storage requirements (distribution authorization). I will propose a comment asking the possibility to cover this requirement by using both risk assessment and a qualified monitoring.

Line number(s)	
9.1	Comment: -The monitoring of the temperature for all products in not realistic and not feasible (excepted dedicated vehicles) -Wider temperature ranges for transport should be possible if based on stability data. Proposed change: "The required storage conditions for medicinal products should be maintained during transportation within the defined limits as described on the packaging information **or based on the stability data**"
9.5	the verification that truck drivers are GDP trained seems complicate even if the intent of this is good.
9.12	Comment : That is not realistic in the current European transportation network that transportation hubs hold a wholesaler distribution authorisation.
9.12	Comment: Requirement difficult to be implemented by the carriers. Time limit of 24h is easily reachable the Week-End, bank holidays and far foreign countries Proposed change: 1) to delete the sentence 2) if 1) not accepted : "Where transportation hubs are utilised in the supply chain, a maximum time limit of normally **120** hours should be set to await the next stage of the transportation route." "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. For refrigerated product any storage at a transportation hub for any period of time would require that premises to hold a wholesalers distribution authorisation."
9.16	Comment: If information about the contents is available, this could increase thefts. Proposed change (if any): "Containers should bear labels providing sufficient information on handling and storage requirements and precautions to ensure that the products are properly handled and secured at all times. ~~The containers should enable identification of the contents of the containers and the source.~~"
Annex	Comment: Need to be clarified as the definition is not clear.

Line number(s)	
Glossary of terms Free zones and free warehouses – (a)	
	the notion of deputy qualified/ responsible person is not clearly defined The notions of" brokers", “data”, “container “need clarifications. define clearly "release to the market" to make a difference with the GMP/ pharmaceutical release
Others suggestions -	no point on transportation accidents of medicinal products

	Outcome *(To be completed by the Agency)*

Please add more rows if needed.