<Apr. 4th, 2013>

Submission of comments on:

GUIDELINES ON THE PRINCIPLES OF GOOD DISTRIBUTION PRACTICES FOR ACTIVE SUBSTANCES FOR MEDICINAL PRODUCTS FOR HUMAN USE

Comments from:

Name of organisation or individual
LEEM

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)*
	Even if most of the items mentioned on the present Guideline are originated from ICH-Q7 §17, this Guideline complete for Europe requirements, and does not replace and does not supersede ICH-Q7 and EU-GMP Part II. This should be specified as introduction	

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) Introduction		The title should be "Directice 2011/62/EU or 2001/83/EC". Typpo error to be corrected	
§1 - Scope		Comment: to be addeded : Proposed change (if any):…/… Therefore, in the context of the present guideline, the term "Distributor" includes Trader and Broker	
§6 Personel		Comment:Management representative must also be present at headquarter office if appropriate Proposed change (if any): A management representative should be appointed in each distribution point, including procuring, supplying and exporting activity location; He should have defined authority …/…	
§ 7 Personnel		Comment: to be added distribution activities Proposed change (if any): Key personnel involved in the warehousing and the distribution of active substances should have …	

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§ 15, last sentence (Receipt)		Comment: Deliveries should also be checked for evidence of tampering as well as that the API name and quantities delivered are correct Proposed change (if any): Deliveries should be examined at receipt in order to check that containers are not damaged, all security seals are present with no evidence of tampering and adulteration and that the active substance (identity and quantities) and the consignment correspond to the order.	
§ 18 Storage		Comment: There is no GMP requirement to store APIs separately of Excipients, so this should not be a requirement added in the present guideline Proposed change (if any): Active Substances should be normally being stored apart from other non pharmaceutical goods, and in any case according to storage conditions which guaranty to be protected against external and cross-contamination.	
§24		This requirement is not a requirement of the directive 2011/62/EU. Remove paragraph 24, *or replace it by*: Supplies within the EU should be made only by registered distributors of active substances according to Article 52a of Directive 2001/83/EU or by authorized manufacturers according	

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		to Article 40 of Directive 2001/83/EU.	
§25-a		Comments to be added: a) their identification is not lost or adulterated, as well as original manufacturer name and address mentioned on container labels	
§ 39		Sentence to be added: All quality related complaints, whether received orally or in writing, should be recorded and investigated according to a written procedure. There should be a time limit defined in the procedure to ensure complaints are recorded and evaluated on timely manner	
§ 41		Sentence to be added: Complaints should be reviewed on periodic basis and reported at least annually to senior management	

Please add more rows if needed.