EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 July 2013

Draft Chapter 8 EU GMP Guide: Complaints, Quality Defects and Product Recalls

Comments from:

Name of organisation or individual
EFPIA

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)***
	EFPIA appreciate the opportunity to provide comments for the draft revision of Chapter 8 and consider the proposed text to be a positive improvement on the current chapter.	
	It is noted that the Concept Paper highlighted the risk-based classification of quality defects within the Compilation of Community Procedures. Whilst the proposed text does address different extents (8.25) and, partly, urgencies (8.26) of recall, the text does not clearly tie with the Class I – III urgency classifications within the Compilation of Community Procedures, nor is this document referenced. It would be beneficial to at least include a reference. To facilitate optimal interpretation of the text please ensure that terms are used consistent through the chapter and new terms and pertinent definitions are added to the Glossary.	

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)***
8.8 iii		Comment: This bullet has compound points within it currently and it is suggested that these be separated out Proposed change (if any): iii The need to request a sample of the defective product from the complainant and, where a sample is provided, the need for an appropriate evaluation to be carried out. iv The distribution information for the batch(es) in question. v The assessment of the risk(s) posed by the quality defect. And renumbering of subsequent points	
8.8 v		**COMMENT:** This step should be removed and added to the recall section since it is specific to recall actions and considerations and not part of complaint handling process **PROPOSED change:** Remove Step 8.8 v. from complaint handling section	
Section 8.12		Comment: Clarify statement "Such decisions should ensure that patient and animal safety is maintained in a timely manner, in a way that is commensurate with the level of risk that is presented by those issues." Proposed change (if any): "Such decisions should be timely to ensure that patient and	

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		animal safety is maintained, ~~in a timely manner,~~ in a way that is commensurate with the level of risk that is presented by those issues."	
Section 8.14		Comment: Clarify the phrase "abnormal restriction in the supply of the product". Proposed change (if any): Clarification and alignment with drug shortage expectations in draft Chapter 5.68	
8.16		**COMMENT:** If industry is using risk based principles, not all complaints will have an RCA performed. Special attention should be given to all complaints to establish whether it relates to falsification, not just those that have an RCA conducted. We need to consider falsification prior to identifying the root cause - Please strongly recommend that this remain in the complaint handling section. **PROPOSED change:** Change location of step 8.16. Step 8.16 was moved under the RCA and CAPA section but should remain in Complaints (Procedures for handling complaints) section e.g. 8.6.	
Section 8.21		Comment: Clarify distribution network, as it is not clear whether it is limited to external network, not within company control, or	

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		whether it is a wider scope to include internal company controlled distribution such as regional warehouses. Proposed change (if any):	
8.28:		**COMMENT:** When the disposition of recalled product following reconciliation is destruction, discussing the rationale with the competent authority is not warranted. However, it is reasonable that this discussion should occur when the disposition is to rework recalled product. Clarification is needed to differentiate when it is necessary to discuss the rationale for the disposition of recalled products with the competent authority. **PROPOSED change:** The recommendation is to revise as follows: "A formal disposition of all recalled batches should be made and documented. The rationale for any decision to rework recalled product should be documented and discussed in advance with the relevant competent authority".	

Please add more rows if needed.