<Date of submission>

Submission of comments on Eudralex Vol 4 GMP – Chapter 8

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).

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom
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)*
	The modernization of this chapter should reflect the registration status of the products in general, either national, centralized or mutual recognition procedures whereas the current text does not distinguish among them. A more uniform aspect of treatment is expected from the industry for the same type of event affecting a product and adoption of risk management shall be used through this integrated approach to prevent distorted measures taken at the EU level for the same issue. Several clarifications of terminology are expected between the frequent use of Authorities/Authority, a Quality defect or a Quality problem, or a Quality issue. A defect can result from a problem or an issue, but all issues or problems does not results into defects or necessitate external communication to Authorities or Authority; This has to be unambiguous for the reader to prevent unsolicited time consuming declaration. Integrating the term Quality Defects into the title of the chapter is a strong message, however this message has to be crystal clear in its definition and understanding by both the Industry and the Regulator for preventing future misunderstandings in its application.	

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)*
Title of the chapter Principle		**Comment:** "Quality defects" is now added as a generic term within the title of Chapter 8. This is an importance addition to the previous version. The wording in the description under "Principle", is still using the term "**potential** quality defects" in the list of events subject to communication. Further to the above *"All concerned competent authorities should be informed in case of a quality defect (faulty manufacture, product deterioration, detection of falsification, non compliance with the marketing authorisation or product specification file, or any other serious quality problems) .../..."* There should be a clearer description throughout this entire draft in the meaning of Competent Authorities, which is used alternatively in the plural and singular mode. Further ***"other serious quality problems"*** is now highlighted in the list of declarative events which will add further confusion. "Serious quality problems" may be over-interpreted either by the pharmaceutical industry and/or their respective inspectorate, leading to misalignment/misinterpretation with the original intent of this draft. As a general opinion "serious quality problems" are managed under the responsibility of the Production and Quality departments who are in charge of implementing, maintaining	

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)*
		and working GMP principles and shall not fall under the declaration mode to Authorities. As a further example, "*non compliance with the marketing authorisation"* may result in the restriction for use of the 2009 Concept paper about QP discretion. In general the "Principle" should clearly explain what Quality Defects means with unambiguous examples and be not confused with Quality problems. The current version applicable of chapter 8 already describes this (see 8.8 ".../...any other serious quality problems with a product") whereas this draft is embedding "Quality Defects" in its Title and remains vague under "...any other serious quality problems"). A definition of Competent Authorities (plural) and Competent Authority (singular) is desirable to avoid confusion. This should also clarify Authority outside the meaning of EU members. Guidance is also required for declaration according to the registration mode of products (MR, centralised and national). Proposed change (if any):	
Personnel and organisation		Comment: The Qualified Person having certified product for sale and engaged his responsibility should be directly involved	

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)*
8.1		in the decision making process, in particular for "*...any recall operations* ". The fact that the QP is made aware of etc...is insufficient within the meaning of his responsibility. Proposed change (if any): The QP is directly involved in the recall decision making process.	
8.21		Comment: *"Any retrieval of product from the distribution network as a result of a quality defect should be regarded and managed as a recall"* This is a too restrictive approach as the industry will see this as a technicality. As long as product has not reached the pharmacy level or patient, there is no need to treat such situations as recalls. Proposed change (if any): Paragraph to be removed.	
8.25		Comment: This has to be read in conjunction with comments made above on Principle. Competent Authoriti**es** are consulted for the determination of the level of a potential recall, and *the Competent Authori**ty** informed in situations in which no recall action is being proposed.* The industry would prefer to have a limited number of Authorities to work with such as the National Authority where the defective product has been manufactured and the Authority designated in the RMS or Centralised registration procedure.	

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)*
		Proposed change (if any):	
8.26		Comment: A product cannot be recalled at the sole initiative of the industry and usually has to receive the approval of the Authority(ies). Proposed change (if any):	
8.27		Comment: There is still confusion between Authorities and Authority Proposed change (if any):	

Please add more rows if needed.