18 July 2013

GMP revision: Chapter 3 – Premises and Equipment

Comments from:

Name of organisation or individual
AESGP

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)*
	We refer to our comments on the 'EMA Guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities' (annexed to this document) and again ask that both the PDE approach and the current approach be equally acceptable. Companies should be left the choice of the approach they want to follow.	

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)*
Chapter 3 (Premises and Equipment), No. 3.6		Comment: With reference to our comments on the 'EMA Guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities' (annexed to the present document), applying the PDE approach to all APIs and finished products would be excessive and would be extremely cost and resources-demanding for companies (particularly those with a large portfolio of older/ well-established products or products with a small market share- those two kinds are very common in the self-care sector) whilst generating minimum value added. We believe that the performance of toxicological evaluation should be left to the decision of the company. Both the PDE approach and the 'current approach' should be equally acceptable. The PDE-approach may particularly benefit hazardous contaminants such as highly sensitizing materials (such as beta lactams), biological preparations (e.g. from live micro-organisms), certain hormones, cytotoxics and other highly active materials. Proposed change (changes in bold): 1.6 Cross-contamination should be avoided for all products by appropriate design and operation of manufacturing facilities. The measures to prevent should be commensurate with the risks. Quality Risk Management principles should be used to assess and control the risks. Risk assessment **may** include among others parameters a	

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)*
		toxicological evaluation of the products being manufactured, **as applicable, depending on the approach chosen by the company** (see guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities). Dedicated facilities are required when they present a risk: a) Which cannot be adequately controlled by operational and/or technical measures or b) Scientific data does not support threshold values (e.g. allergenic potential from highly sensitizing materials such as beta lactams) or c) Threshold values derived from the toxicological evaluation are below the levels of detection. Further guidance including some exceptions could be found in Chapter 5 and in Annex 2, 3, 4, 5 of the EU detailed guidelines on GMP and the guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities.	

AESGP comments on GL on setting health b