28th April 2017

Submission of comments on

'Questions and answers on implementation of risk based prevention of cross contamination in production and "Guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities"

EMA/CHMP/CVMP/SWP/463311/2016

Comments from:

E.I.P.G. – European Industrial Pharmacists Group

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)*
	This Q&A document is appreciated by our members as it is considered useful for clarifying a number of points on the implementation of the corresponding guideline. In particular, our appreciation refers to the clarification on the following points: - Definition of highly hazardous products/active substances (Q2) - The circumstances where HBEL based on the 1/1000th minimum therapeutic dose approach can be applied (Q4) - The recommendations about the choice of the cleaning limits (Q6) - The adjustments of HBELs for paediatric population (Q11)	

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)*
Q2. 3rd paragraph Point 5.		A better definition of compounds with a high sensitizing potential is required. A list of these compounds and examples of how to deal with this category of hazardous materials would be useful.	

Please add more rows if needed.