EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22nd of July 2015

Submission of comments on "Concept paper on the development of a guideline on quality and equivalence of topical products" (EMA/CHMP/QWP/558185/2014)

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 concept paper is to be welcomed, taking into account the increasing knowledge in the biopharmaceutical assessment of topical products and its impact on the formulation development work. In particular, the possibility of using an in-vitro test or an ex-vivo test to prove bioequivalence between two formulations is appreciated. However, the following comments can be made in view of the preparation of the corresponding guideline: - a validation procedure of the in-vitro and ex-vivo tests is to be described, including the appropriate test conditions to be used - considerations about the discrimination criteria of an in-vitro study with respect to the expected in-vivo activity are to be reported, including the statistical evaluation approach to be applied - specifications are required whether an in-vitro assessment can be used only for identical topical pharmaceutical dosage forms or not The issue of the guideline is waited with great interest.	

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)*
Line 14 and following		Comment: “Problem statement”: it would be preferable to limit the scope of the new guideline to topical products for cutaneous use. Including other surfaces like eyes, ears, etc. would complicate the selection and definition of bioequivalence models. Proposed change (if any): /	
Lines 24, 25		Comment: To modify: “In addition, it is known that the vehicle itself may influence the condition to be treated e.g. moisturisers and emollients.” Proposed change (if any): “In addition, it is known that the vehicle itself e.g. moisturizers and emollients may influence the condition to be treated”	
Line 32		Comment: To modify “sensitivity, reproducibility, in vitro in vivo correlation…”	

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): “sensitivity, reproducibility, in vitro and in vivo correlation…”	
Line 44 and following		Comment: “Equivalence of Topical Products”: it should be mentioned that identical topical solutions can be considered equivalent by default, which is scientifically reasonable and will reduce the effort from industry to comply with this new guideline. Proposed change (if any): /	

Please add more rows if needed.