30 September 2015

Submission of comments on 'Questions and answers on sodium laurilsulfate in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use' (CPMP/463/00 Rev.1)' (EMA/CHMP/606830/2014)

Comments from:

Name of organisation or individual
PAINT-Consult Dr. Jörg Fuchs Wenigenjenaer Ufer 12 07749 Jena, Germany Phone: +49 3641 549396 Fax: +49 3641 549397 E-mail: info@paint-consult.com

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 excipients labelling statement must be clear, precise, brief and without difficult terms in order to achieve the highest benefit for patients. We at PAINT-Consult are a provider of readability tests of package leaflets and a researcher of this important patient information, with several published studies involving more than 10000 participants. See http://www.paint-consult.com/en/publikationen/publikationen/. The suggestions provided in "2. Specific comments on text" consider the findings of our extensive practical knowledge with package leaflets.	

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)*
93 first column "Name"		Comment: Please also include the other common name of "sodium dodecyl sulfate", as many people are only familiar with this name for the substance as opposed to "Sodium laurilsulfate or E487". Proposed change: **Sodium laurilsulfate** **or sodium dodecyl sulfate** **or E487**	
93 fourth column "Information of the package leaflet"		Comment: The sentence "This product contains sodium laurilsulfate x% w/w." contained in the proposal dated 23 July 2015, must be deleted. It is a repetition of the QRD template heading "X contains sodium laurilsulfate". Furthermore, the abbreviation "w/w" is unfamilar for most people and difficult terms must be avoided according to the readability guideline. Last but not least, what is most important is the information that this excipient is contained; therefore, information relating to the concentration "x% w/w" is unnecessary and not helpful for patients, particularly as lines 84 ff. state: "Skin sensitivity to SLS varies according to the concentration of SLS, contact time, patient population and experimental approaches...	

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)*
		Recommending a threshold for SLS in topical products is difficult to establish... It is, therefore, proposed to have a threshold of 0% for SLS in topical medicinal products for all age groups." The examples of skin reactions provided in the text bracket "(such as stinging or burning sensation)" should be deleted as - according to lines 72 and 73 - many further symptoms, such as itching or redness, may occur. In addition, it is impossible and unnecessary to provide all possible symptoms. Research experience with package leaflets informs us that mentioning "local skin reactions" is absolutely sufficient. Examples are not required as patients have an idea of what constitutes local skin reactions. The beginning of the last sentence should be shortened, with a stronger connection to the preceding sentence as suggested below. Proposed change: Sodium laurilsulfate may cause local skin reactions, in particular if you have sensitive skin. This may increase if other medicines are applied to the skin in the same area.	