



European Medicines Agency
Evaluation of Medicines for Human Use

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**OVERVIEW OF COMMENTS RECEIVED ON
'COMMUNITY HERBAL MONOGRAPH ON AVENA SATIVA L., FRUCTUS'
(EMA/HMPC/368600/2007)**

Table 1: Organisations providing comments on 'Community herbal monograph on *Avena sativa* L., fructus' as released for consultation on 31 October 2007 until 15 February 2008

Organisation	
1.	The Association of the European Self-Medication Industry (AESGP)
2.	Kooperation Phytopharmaka, Germany

GENERAL COMMENTS	COMMENT AND RATIONALE	RAPPORTEUR'S COMMENTS
<p>4.8. Undesirable effects <i>Skin reactions occur frequently in atopic patients and in patients with contact dermatitis.</i></p>	<p>This seems in full contradiction with the traditional use of the herbal substance and there is no evidence for such undesirable effects. On the contrary, results of the enclosed study showed that repeated application of oat-based ointment in atopic patients sensitised and/or allergic to cereals is well tolerated and does not lead to worsening of the symptoms (cf. Jean-Decoster et al.). We therefore object to this statement and recommend its deletion.</p>	<p>Most probably the comment generated from the wording 'frequent', which means in more than 1% but less than 10% of the patients. The reference cited is not fully documented as the source is concerned. On the other hand, we calculated the frequency from one out of two references cited in the assessment report. El Bakali et al. (2000) did not find an enhanced frequency of allergic reactions in patients suffering from atopic dermatitis (n=114) or contact eczema (n=115). Although the findings were reported by Pierre-Fabre the number of patients is important. In a second reference (Rancé et al. 2001) positive patch and prick test reactions occurred with Avena (in 2.4% of the patients). This paper was published in a French journal. The number of patients is important (n=202), but they were all children. Therefore we should not generalise. Taking into account these different conditions the wording could be somewhat moderated. Proposal: ... <i>Skin reactions may occur in atopic patients</i></p>
<p>Comment on the list of references</p>	<p>The pharmaceutical quality of the herb (harvested before flowering season) or fruits is different and different data are relevant for each of both drugs; by combining the data for both drugs in one list of references, such detailed information is not more available for any assessment. Therefore, there should be a separate list of references for each of both monographs.</p>	<p>Not endorsed. The list of references is clear when read in conjunction with the Assessment Report.</p>