European Medicines Agency
Post-authorisation Evaluation of Medicines for Human Use

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OVERVIEW OF COMMENTS RECEIVED ON 'PUBLIC STATEMENT ON CHAMOMILLA CONTAINING HERBAL MEDICINAL PRODUCTS'

Table 1: Organisations that commented on the document as released for consultation

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

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Table 2:Discussion of comments

General comment	Comment and rationale	Outcome / Proposed change

Line no or section and paragraph no	Comment and rationale	Outcome / Proposed change
Section 4.8: Undesirable effects	A general remark on hypersensitivity reactions should be sufficient. According to commenting organisation, the case study reported by Jensen-Jarolim E. et al. (1998) does not give reason for the proposed amendment: "Some cases of anaphylactic shock or asthma have been reported".	Both proposals should be rejected because severe allergic reactions have been reported for chamomilla containing herbal medicinal products in different preparations. The literature survey presented by the Kooperation Phytopharmaka shows no relevant new publication compared to the report published

Section 4.8: Undesirable effects	Proposed change of the wording under this section as follows: ”Proven hypersensitivity reactions to (German) chamomile are very rare, especially with regard to the widespread use of this herbal drug in many different preparations. Cross reactions may occur in people with allergy to pollen of compositae (e.g. Artemisia/mugwort).” The proposal is based on a general rating of the sensitizing capacity by Hausen (1997) and an update of a report on allergies due to German chamomile published by the Kooperation Phytopharmaka (2002). This update (June 2005) adds one recently published clinical trial to the original report (Jovanovic M et al., 2004). In this study 30 adult patients suffering from "extrinsic" atopic dermatitis were patch tested with a sesquiterpene lactone mix and a Compositae mix. 9 (30%) patients had positive reactions to the Compositae mix. Among these 3 (10%) were positive to the sesquiterpene lactone mix as well. 5 of the 9 patients (55.5%) had a positive reaction to German chamomile.	

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		In addition there are further publications of type I systemic allergic reactions following the administration of chamomilla containing herbal medicinal products (see list of references in the Public statement) including - a second case report of allergic shock following rectal administration of a chamomile containing enema (Reider N et al., 2000), - two case reports of anaphylactic shock after oral use of German chamomile infusion (Subiza J et al., 1989, Florido-Lopez et al., 1995). Although the published case of anaphylactic shock after rectal administration of a pre-labour enema containing chamomile with fatal outcome for the newborn (Jensen-Jarolim E. et al., 1998) resulted from off-label use, the collected data from published literature and the BfArM pharmacovigilance data base point to a substantial risk of generalised type I allergic reactions for chamomile containing products in various preparations following internal use. Three of the above stated serious adverse events (2 severe asthma attacks, 1 anaphylactic shock) were related to clinical trials with the specific extract (including a total number of 477 exposed patients). The recently published study (Jovanovic M et al., 2004) does not allow a statement of the frequency of allergic reactions to chamomile in the general population.