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

London, 24 October 2005
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OVERVIEW OF COMMENTS RECEIVED ON

'Guideline on the documentation to be submitted for inclusion in the List of herbal substances, preparations and combinations thereof' (EMEA/HMPC/107399/2005)

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

	Organisation
1.	Association of the European Self-Medication Industry (AESGP)

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Table 2:Discussion of comments

Line no or section and paragraph no	Comment and rationale	Outcome / Proposed change
Section 2, page 3	We do not think that the wording 'description of the structure' is a suitable terminology. The meaning is unclear. Therefore we propose to delete the content of the paragraph and to insert its content under 'description of formula'	Agreement in principle with the comment. However, in order to maintain the consistency with the CTD headings, decision to maintain the section 'Description of the structure' after the section 'Description of formula'.
Section 4, page 4	The first indent reads: "30/15 years medicinal use in EU in specified indication". Article 16c (1) (c) of Directive 2001/83/EC amended by Directive 2004/24/EC does not require a 'specified indication' for the proof of traditional use. According to Article 16c (3), 'the requirement to show medicinal use throughout the period of 30 years, referred to in paragraph 1(c), is satisfied even where the marketing of the product has not been based on a specific authorisation. In such cases, it is rather rare when reference is made to specific indication. In order to be consistent with Article 16 c (1) (c) of the Directive and the wording provided in the draft 'structure of the list of herbal substances, preparations and combination thereof', we believe the first indent should be rephrased as follows: "30/15 years traditional medicinal use in EU in specified therapeutic area"	Text modified as follows: "The documentation should demonstrate compliance with the requirements for traditional use laid down in Article 16c(1)(c) including: - 30/15 years medicinal use within **the Community** ~~EU in specified indication~~ - Bibliographical or expert evidence of medicinal use **in specified indication** - Bibliographical review of safety data"