



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 July 2011
EMA/HMPC/495353/2011
Committee on Herbal Medicinal Products (HMPC)

Overview of comments received on 'Procedure on the publication of HMPC public statements when Community herbal monographs on herbal substances, preparations and/or combinations thereof are not established' (EMA/HMPC/84530/2010)

Table 1: Organisations and/or individuals that commented on the 'Procedure on the publication of HMPC public statements when Community herbal monographs on herbal substances, preparations and/or combinations thereof are not established' (EMA/HMPC/84530/2010) as released for public consultation on 15 February 2011 until 15 May 2011

	Organisations and/or individuals
1	The Association of the European Self-Medication Industry (AESGP)



Table 2: Discussion of comments

SPECIFIC COMMENTS ON TEXT

Section number and heading	Interested party	Comment and Rationale	Outcome
Lines 29-34	AESGP	<p>This paragraph gives the impression that one of the main purposes is to address the specific issue of essential oils, i.e. that public statements are mainly made for essential oils in case they are different from the respective herbal drug with regard to composition, safety profile and/or indication etc. As nowhere else in the entire text examples of specific groups of substances are mentioned, we propose to leave this paragraph out for a better flow of the document.</p> <p>Proposed change:</p> <p>Delete lines 29-34</p>	<p>Partially endorsed. The ORGAM DG moved the text to point '4. Procedure' and revised the text as follows:</p> <p><i>Note: The HMPC has a policy to establish <u>individual monographs on essential oils having regard to their chemical composition and the amount of data generated by their medicinal uses. Monographs on essential oils are often supported by an AR distinct from the AR on the herbal substance and <u>other</u> preparations thereof. Therefore public statements might be established specifically on essential oils, in line with this policy. For example, the HMPC has established a monograph on sage leaf and published a public statement on sage leaf essential oil.</u></i></p> <p>The section intends to clarify to the public why public statements on essential oils are published, even if a monograph on the herbal substance in question has been established.</p>