



European Medicines Agency
Evaluation of Medicines for Human Use

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**OVERVIEW OF COMMENTS RECEIVED ON
'PROCEDURE ON MANAGEMENT OF PROPOSALS SUBMITTED BY INTERESTED PARTIES
FOR COMMUNITY LIST ENTRIES OR COMMUNITY HERBAL MONOGRAPHS'
(EMEA/HMPC/328575/2007)**

Table 1: Organisation(s) that commented on the draft 'Procedure on management of proposals submitted by interested parties for Community list entries or Community herbal monographs' as released for consultation on 31 October 2007 until 15 February 2008.

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

Table 2: Discussion of comments

GENERAL COMMENTS TO DRAFT DOCUMENT		
AESGP sees the merit of such proposal and appreciates the opportunity to comment on the draft HMPC procedure on management of proposals submitted by Interested Parties for Community list entries and Community herbal monographs.		
SPECIFIC COMMENTS ON TEXT		
8 Instructions		
Paragraph no. line no.	Comment and Rationale	Outcome
Submission of proposal by interested parties:	<ul style="list-style-type: none"> - We would suggest adding the link to the HMPC meeting dates. - We believe that proposals should preferably be channelled through the identified 'interested parties to the HMPC'. - It would be useful if the HMPC secretariat could <u>acknowledge receipt of the proposal</u>. 	<ul style="list-style-type: none"> - The link is already included under section 5 of the document. - Flexibility should be maintained; therefore the text is not changed. - Receipt of a validated proposal will be acknowledged as described in page 6.
1. Validation	<ul style="list-style-type: none"> - We agree that the request from an interested party should be explained. The priority setting for developing Community Monographs (CM) and Community List Entries (CLE) should be driven primarily by <u>commercial interests</u>. Market relevance should therefore come first in the criteria listed. In addition, the size and importance of the relevant (national) market(s) should be taken account of. - It would be useful to have the link to the CM and CLE templates. - Interested parties should be permitted to <u>suggest a country / expert's name as rapporteur</u>. Such preference should be taken into account when deciding for the rapporteurship. 	<ul style="list-style-type: none"> - Commercial interests are covered by the term 'market relevance'. All factors explained in the justification will be taken into account in a balanced way when preparing the recommendation and HMPC decision. - The link is already included under section 5 of the document. - Rapporteur appointment is the responsibility of HMPC and shall be made on the basis of objective criteria which will allow the use of the best available expertise in the EU on the relevant scientific area according to Article 6 of the HMPC Rules of Procedure.

<p>2. Discussion and decision by the HMPC on priority</p>	<p>- The fact that the development of the CM/CLE will start as soon as the rapporteur 'is ready' is a bit surprising in light of the priority given to the development of a CM/CLE on the given plant. We understand the heavy workload faced by members and especially appointed rapporteurs but in the present case, the role of the rapporteur would be somewhat facilitated by the submission of a draft 'CM/CLE' accompanied by the references already compiled. We suggest that the <u>assessment phase is initiated by the rapporteur as soon as possible and no later than at the next MLWP meeting.</u> Providing a timetable for the assessment to the interested party having made the proposal would certainly help predictability.</p> <p>- In case the proposed herbal substance, preparation or combination thereof is not added to the priority list, we believe that the interested party should be informed and be given the rationale for the decision. The interested party should be given the possibility to provide further justification/explanation of its proposal in writing within a month after reception of the notification stated above and/or to be invited at the next MLWP meeting for a hearing.</p>	<p>- It is recognised that that the provision of data will facilitate the procedure, however ongoing assessment work has to be taken into account before initiating new work, therefore the assessment phase will start as soon as possible. Clarification has been included in the text.</p> <p>- A good and complete justification is expected in first instance and therefore a low rejection rate. Therefore there would be no need for additional steps and hearing. In any case, the proposal will be included in the alphabetic inventory for future work (see page 6).</p>
<p>3. Interested party will be informed about the HMPC decision</p>	<p>- With reference to the comment made above, a draft timetable for assessment should <u>always</u> be communicated to the interested party.</p>	<p>In case of a positive decision from HMPC, a timetable will be provided. Clarification has been included in the text.</p>