



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

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**OVERVIEW OF COMMENTS RECEIVED ON HMPC
DRAFT 'PROCEDURE FOR CALLS FOR SCIENTIFIC DATA FOR USE IN HMPC
ASSESSMENT WORK'
(EMEA/HMPC/1004/2006)**

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

	Organisation
1.	Association of the European Self-Medication Industry (AESGP)
2.	Biohorma
3.	European Scientific Cooperative on Phytotherapy (ESCOP)

Table 2: Discussion of comments

General comment	Comment and rationale	Outcome
	<p>With this publication the HMPC proposes a procedure for the collection of scientific data for use of their assessment. The call to interested parties is not restricted for papers only but includes also the search strategy, data of the search term etc. In our opinion this is a task for HMPC. They are responsible for literature search and everything that is needed to set up a search. The call for scientific data should publish and include the search results. If the articles are not ordered by a library, the call must lead to the submission of copies of the listed articles. Of course it should be allowed to send new or missing data.</p>	<p>The call for submission of data is not the only route used by HMPC Rapporteurs in order to obtain a complete set of bibliographic references and scientific data for a given assessment. Furthermore, submission(s) from interested parties take place on a voluntary basis. However, in order for the HMPC Rapporteur to better assess the submission(s) as part of the overall set of data, it is requested that the interested party outlines the search strategy and search terms used.</p>
	<p>Specification of literature search strategies, search terms and a list of used databases and the result of the search should be made available. The evaluation of the data will be done by the HMPC and should be made available too. This can published as part as part of the list or monograph.</p>	<p>This is addressed in the HMPC assessment reports relating to Community herbal monographs and draft entries to the Community list. An assessment report template is currently under finalisation.</p>
	<p>According to the title of the document, this paper should give a procedure for calls for scientific data in general. However, the focus of this document lay upon collecting data for the evaluation of the indication. Nothing is said about the evaluation (e.g. call for data, criteria for assessment) of the safety of herbals from the community list and community list.</p>	<p>The evaluation criteria used in relation to HMPC assessments fall outside the scope of this procedure.</p>

Line no or section and paragraph no	Comment and rationale	Outcome
<p>1. Background and scope of the procedure</p> <p>p. 3</p>	<p>It is stated under item 2 that compilation criteria will be predefined by the HMPC, for example, in relation to literature search strategy and the type of interested parties that is relevant. From our point of view, the literature search strategy is only relevant for database searches. References to support the ‘traditional use’ can be found in older textbooks, monographs, etc.</p>	<p>See answers to comments on Annex.</p>
	<p>With respect to identification of the interested parties to be addressed by the (published) call, we are of the opinion that submission of data by an interested party is made on a voluntary basis without any legal obligation to provide the HMPC with the complete literature search.</p>	<p>The text has been amended to reflect the fact that submissions are made on a voluntary basis.</p>
	<p>A call for scientific data does not necessarily mean a complete literature search. Individual submission of relevant and quality studies (e.g. recently published clinical studies), should still be useful for the assessment by the HMPC.</p>	<p>The procedure should be read as a guidance on how the HMPC would expect the interested parties to structure their submissions in order to facilitate the work of the Rapporteur(s).</p>
	<p>The last line of the second paragraph ends with “a practice subject to 3 main conditions”. This suggests that there are other or less conditions. If this is right, and there are other conditions that will be used for the assessment of scientific data, can those conditions be made public?</p>	<p>The word ‘main’ has been deleted. No other conditions apply.</p>
	<p>Point two of the conditions suggests that HMPC has additional criteria for the compilation of data. The literature search and interested parties are given as example. If this right, are those criteria should be published. In our opinion a call for scientific data does not mean a complete literature search (see general comment), individual submissions of literature might be useful for the assessment within the HMPC.</p>	<p>The HMPC is discussing the establishment of general literature search criteria. Once available, such a document would be published on the EMEA website.</p>

2. Quality of bibliographic data to be submitted, p. 3	<p>We agree that the data submitted will generally be connected to the indication. However, the document concerns call for scientific information in general; submission of literature should not be limited to this area. Possibility to submit other types of data should be mentioned.</p>	<p>The procedure has been amended to clarify that the calls are not restricted to data relating to the implementation but also encompasses other data relevant to the assessment.</p>
	<p>“All submitted of the assessment”. What is meant with the word “relevant” and are there criteria available after submission that are relevant?</p>	<p>The sentence has been rephrased with a view to better describing the expected quality of submissions.</p>
4.1 Submission of contributions, p. 4	<p>The second paragraph mentions that contributions should be sent by email, post or fax to the HMPC secretariat. From our experience, sending a large quantity of files by email is often not possible technically (as the file is beyond the size allowed by the recipient’s mailbox) therefore it may be useful to mention that in such a case sending them on a CD is preferred.</p>	<p>Included.</p>
	<p>We would suggest rephrasing the following sentence: <i>“As far as possible, the package should include a specification of the literature search strategy, the date of the search, search terms (inclusion/exclusion terms) as well as a listing of databases used for the search. As an alternative, a statement can be made that the best available knowledge has been included.”</i> (cf. comments on the annex).</p>	<p>The HMPC regards the criteria as being important to obtain the expected quality of bibliographic references/scientific data and will therefore not take the proposal on board.</p>
4.2 Language requirements, p. 4	<p>On the model of the annex, we would propose to add a sentence saying that: <i>“In order to facilitate the assessment, it is nonetheless recommended to submit original references together with an abstract in English”.</i></p>	<p>Included.</p>
Annex: 1. Conditions for data submission, Points 1 & 2	<p>It is unclear whether the decision about well-established medicinal use or traditional use should be made by the contributor or the HMPC.</p>	<p>The classification in relation to the assessment is the responsibility of the HMPC.</p>

<p>Annex: 2. General criteria, point 2</p>	<p>The differentiation between peer-reviewed and non-peer-reviewed papers is not feasible in practice. We assume that due to their expertise the HMPC members/Rapporteurs will be in the position to perform an assessment on whether or not a bibliographic reference can be included (e.g. to support indication claims or safety statements). Furthermore, references to support the "traditional use" can mainly be found in older textbooks, which did not go through a peer-review process. For these reasons we would like to suggest the following wording: <i>"Scientific contributions may be classified, if appropriate, by the interested party ..."</i>.</p>	<p>The procedure has been amended to better address the issues raised concerning peer reviewed and non-peer reviewed articles, taking into account the submission of information from older standard books of phytotherapy.</p>
<p>Annex: 2. General criteria, point 3</p>	<p>The submission of a document providing a specification of the literature search strategy, search terms and a list of databases can only be required for new literature searches and compilation of material made from a specific date on. There are many collections of literature existing for which these criteria have not been defined, which, however, might contain important documents and information for the HMPC. As an alternative to a document providing a specification of the literature search etc. it could be useful to include a disclaimer saying that the best available knowledge has been included: <i>"As far as possible, a document ... should be enclosed. As an alternative, a statement can be made that the best available knowledge has been included."</i></p> <p>Furthermore, taking into account references to support the "traditional use" which can be found in older textbooks etc., a sentence such as <i>"Quotations from established standard books of phytotherapy or other reliable sources might provide useful information on the traditional use"</i> should be included.</p>	<p>See above.</p>