EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Procedure for calls for scientific data for use in HMPC assessment works

Final

Adoption by HMPC	26 October 2006
Revision 2 adopted by HMPC	10 February 2009
Revision 3[2] adopted by HMPC	15 July 2010
Revision 4[3] adopted by HMPC	12 July 2011
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Keywords	Herbal medicinal products; HMPC; HMPC assessment work; European Union herbal monograph; European Union list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products; call for scientific data; systematic review; interested parties

[1] Corrected reference to legislation: e.g. 'Directive 2001/83/EC as amended' replaced with 'Directive 2001/83/EC'
[2] Most relevant changes in sections 3.2, 4.1 and in the template in annex
[3] Change in section 4.1 and introduction of calls for data to support the 5-year review of adopted monographs.
[4] Change in sections 3.2, 4.1 and templates

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1. Background and scope of the procedure

In accordance with Directive 2001/83/EC as regards traditional herbal medicinal products through Directive 2004/24/EC (1), it is the task of the Committee on Herbal Medicinal Products (HMPC) to establish a list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products (Article 16f). Furthermore, the HMPC shall establish European Union herbal monographs for herbal medicinal products (Article 16h(3)). The HMPC has also undertaken to ensure that monographs and list entries remain up-to-date (scientific state of the art) by assessing regularly the need for their revision (5, 6).

The legislation does not specify how scientific data relating to the assessment work for the monographs and list entries should be identified and compiled. The HMPC discussed a number of possibilities and agreed on a practice subject to 3 conditions:

1. The compilation of data will be a public procedure; and
2. The compilation will take place within a framework of criteria to be predefined by the HMPC (e.g. in relation to literature search strategy); and
3. The compilation shall seek to ensure that a complete set of bibliographic references and/or scientific data will be available to the Rapporteur(s).

2. Quality of bibliographic data to be submitted

No requirements for scientific standards are provided in the legislation and submission by interested parties of bibliographic references and/or scientific data is voluntary. However, some guidance as to the scope of data requested can be provided through the application of Directive 2001/83/EC:

- Bibliographic data submitted in relation to well-established medicinal use should provide evidence that the constituent or the constituents of the medicinal product has or have a well-established medicinal use with recognised efficacy and an acceptable level of safety within the meaning of Directive 2001/83/EC (Recital 2 of Directive 2004/24/EC).
- Bibliographic data submitted in relation to traditional-use should provide evidence that the medicinal product in question, or a corresponding product has been in medicinal use throughout a period of at least 30 years preceding the date of the application, including at least 15 years within the European Union (Article 16c(1)(c)).

In addition, the contributor is expected to submit both favorable and unfavorable data as well as to ensure that the newest publications are taken into account.

Further guidance on the requirements can be found in the HMPC ‘Guideline on non-clinical documentation for herbal medicinal products in applications for marketing authorisation (bibliographical and mixed applications) and in applications for simplified registration’ (2) and the HMPC ‘Guideline on the assessment of clinical safety and efficacy in the preparation of European Union herbal monographs for well-established and of European Union herbal monographs/entries to the European Union list for traditional herbal medicinal products/substances/preparations’ (3).

3. Procedure for publishing a call for scientific data

3.1. Identification of assessment work to be initiated or revised

An assessment work to be initiated by the HMPC is reported in a priority list of planned assessments that is published on the Agency website (4). The list is updated by the HMPC secretariat after each HMPC meeting, reflecting new assessments to be initiated as well as progress made with ongoing assessments.
The monographs undergoing a systematic review (assessment of the need for revision) and those subject to a revision are also tracked in this priority list.

3.2. Announcement of call for scientific data

3.2.1. Initial call for scientific data

The HMPC secretariat announces a call for scientific data in the HMPC meeting report at the time of the appointment of a Rapporteur and the call for scientific data is published on the Agency website (according to the template in annex 1).

3.2.2. Call for scientific data for systematic review of final monographs

The HMPC secretariat announces a call for scientific data for the systematic review of a monograph in the HMPC meeting report based on annual work plans and according to decision by the HMPC as recorded in the Table of decisions. The call is published on the Agency website (according to the template in annex 2)

The HMPC secretariat is responsible for taking care of any practical issues relating to such calls.

4. Collection of scientific data

4.1. Submission of contributions

Interested parties are given a period of **3 months** to submit data to the HMPC secretariat.

Interested parties are requested to send their contributions in electronic format by e-mail, Eudralink or by post to the HMPC secretariat. A list of attached documents and their references should be provided. The HMPC secretariat transmits one copy of the received material to the Rapporteur(s).

Unpublished proprietary data may be included. However, the consent of the data owner is a necessary requirement. The owner of the data will be given the opportunity to review the assessment report to remove any confidential data. The HMPC will consider such submissions on a case-by-case basis. Submitting parties are bound to obey existing copyrights. Contributors should also take duly into account the rights of interested parties, as the documentation provided will be used for the development of European Union list entries and European Union herbal monographs. Such development is underpinned by assessment reports, which will be made public in accordance with measures taken by the Agency to ensure an appropriate level of transparency.

4.2. Language requirements

Documents should be submitted in English where possible since this is the working language of the HMPC, but documents in other official languages of the European Union will be accepted. In order to

facilitate the assessment, the HMPC strongly recommends the submission of an abstract in English when original references are provided.

5. References

1. Directive 2004/24/EC of the European Parliament and the Council of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the European Union code relating to medicinal products for human use.
2. Guideline on non-clinical documentation for herbal medicinal products in applications for marketing authorisation (bibliographical and mixed applications) and in applications for simplified registration (EMEA/HMPC/32116/2005).
3. Guideline on the assessment of clinical safety and efficacy in the preparation of European Union herbal monographs for well-established and of European Union herbal monographs/entries to the European Union list for traditional herbal medicinal products/substances/preparations' (EMEA/HMPC/104613/2005).
4. 'Overview of status of HMPC assessment work – priority list' (EMEA/HMPC/278067/2006) http://www.emea.europa.eu/pdfs/human/hmpc/27806706en.pdf
5. Reflection paper on the reasons and timelines for revision of final European Union herbal monographs and European Union list entries (EMA/HMPC/326440/2007)
6. Procedure for the systematic review of European Union herbal monographs and related documents (EMA/HMPC/124695/2011)

<*date*>
<*document reference number*>
Committee on Herbal Medicinal Products (HMPC)

Call for scientific data for use in HMPC assessment work on <*plant, plant part*>

Submission period: <start date> - <end date>

The HMPC invites all interested parties such as pharmaceutical industry associations, health care professional groups, learned societies, consumers and patients' associations, governmental institutions as well as EU and EEA-EFTA Member States to submit any scientific data, which may be used in the assessment of <*plant, plant part*> as part of the establishment of European Union herbal monographs and/or European Union list entries.

<Please note that the Rapporteur is seeking to receive copies of scientific contributions other than those referred to in the annex to this call for submission of scientific data.>

Scientific contributions should be sent in electronic format by e-mail or Eudralink to hmpc.secretariat@ema.europa.eu

or by post to

European Medicines Agency

30 Churchill Place

Canary Wharf

UK-London E14 5EU

Att.: HMPC secretariat

If an interested party intends to send scientific contributions in response to several calls for scientific data, response should be sent separately to each call.

A list of all scientific contributions and their references should be enclosed.

The name and contact details of the interested party providing the scientific contributions is required.

Unpublished data may be included. However, the consent of the data owner is a necessary requirement. The owner of the data will be given the opportunity to review the assessment report to remove any confidential data. The HMPC will consider such submissions on a case-by-case basis. Submitting parties are bound to obey existing copyrights. Contributors should also take duly into account the rights of interested parties, as the documentation provided will be used for the development of European Union list entries and European Union herbal monographs. Such development is underpinned by assessment reports, which will be made public in accordance with measures taken by the Agency to ensure an appropriate level of transparency.

As regards **copyright**, it is important to clarify that the use by the HMPC of the bibliographic material is entirely for a non-commercial purpose. As its non-commercial use by the Committee is guaranteed,

any interested party will not incur in any liability as to the use intended by the HMPC by forwarding the bibliographic literature to the Committee. The HMPC is in all cases willing to confirm in writing the non-commercial use of documents sent in by interested parties.

Documents should be submitted in **English** where possible since this is the working language of the HMPC, but documents in other official languages of the European Union will be accepted. In order to facilitate the assessment, the HMPC strongly recommends the submission of an abstract in English when original references are provided.

Conditions for data submissions

Scientific contributions should be relevant to the purpose of the assessment, and their scope should address either:

Well-established medicinal use: Submitted data should provide evidence that the constituent or the constituents of the medicinal product has or have a well-established medicinal use with recognised efficacy and an acceptable level of safety within the meaning of Directive 2001/83/EC.

Traditional use: Submitted data should provide evidence that the medicinal product in question, or a corresponding product, has been in medicinal use throughout a period of at least 30 years preceding the date of the application, including at least 15 years within the European Union. (Details of herbal substance / herbal preparation, pharmaceutical form and posology in medicinal use should be given.)

Furthermore, the Agency encourages submission of peer-reviewed data/publications (not just the reference) as the most relevant and reliable documents. Non peer-reviewed data such as references from older standard books of phytotherapy or comparable scientific sources can be taken into consideration provided that they are of an adequate quality.

<*date*>
<*document reference number*>
Committee on Herbal Medicinal Products (HMPC)

Call for scientific data for the systematic review of the monograph on <*plant, plant part*>

Submission period: <start date> - <end date>

The HMPC invites all interested parties such as pharmaceutical industry associations, health care professional groups, learned societies, consumers and patients' associations, governmental institutions as well as EU and EEA-EFTA Member States to submit any scientific data that the HMPC should consider at the review of the monograph on <*plant, plant part*> towards a possible revision of the monograph and supporting documents. The publication of this call is the first step in the procedure established by the committee so that adopted monographs remain up-to-date (scientific state of the art).

To avoid submission of data which were already evaluated during the initial assessment work, interested parties are invited to carefully check the published 'List of references supporting the assessment' and 'Overview of comments received during the public consultation'.

The HMPC is looking to receive scientific literature published since the end date of the public consultation on the monograph and supporting documents.

Scientific contributions should be sent in electronic format by e-mail or Eudralink to hmpc.secretariat@ema.europa.eu

or by post to

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