EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 November 2018
EMEA/HMPC/328575/2007 Rev.2
Committee on Herbal Medicinal Products (HMPC)

# Procedure on management of proposals submitted by Interested Parties for European Union List Entries or European Union herbal monographs

Draft

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|---|---|
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| End of consultation (deadline for comments) | 30 July 2019 |

Comments should be provided using this template. The completed comments form should be sent to hmpc.secretariat@ema.europa.eu

[1] No comments received

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| | |
|---|---|
| Keywords | Herbal medicinal products (HMP); Traditional herbal medicinal products (THMP); HMPC; European Union list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products; European Union herbal monographs; Interested Parties |

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# Table of content

# 1. Purpose

The purpose of this document is to enable consistent management of proposals submitted by interested parties for:

- Entries into the 'European Union list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products' (thereafter called the 'European Union list entries');
- European Union herbal monographs on traditional herbal medicinal products;
- European Union herbal monographs on well-established herbal medicinal products.

The HMPC establishes draft entries to the European Union list and European Union herbal monographs following assessment of scientific publications/data and in accordance with adopted procedures.

Assessment of substances/preparations is determined by the HMPC work program and ultimately by resources available at the level of the Committee and at the level of the national competent authorities in the EU Member States.

The HMPC is responsible for identifying the herbal substances/preparations/combinations to be assessed in order to establish a monograph and, if applicable, a draft list entry. The process of identification, prioritization and assessment is reflected in two public tracking documents:

a) An alphabetic inventory of herbal substances proposed for assessment by the Committee in order to establish European Union herbal monographs and draft list entries;

b) An overview of status of assessment work by the HMPC (so called 'HMPC work list' (formerly 'priority list')) providing information for approximately 200 priority herbal substances.

The HMPC work list is updated after each HMPC meeting to reflect the progress achieved.

The preparation of draft monographs and list entries by the HMPC/MLWP follows a work program, which is established on an annual basis and published.

This document presents the procedure followed by the HMPC and its secretariat when proposals are submitted by an interested party. The validated proposals will be added in the alphabetic inventory of herbal substances proposed for assessment.

The details of the procedure for the management of proposals submitted by interested parties are described in the sections below and illustrated in Figure 1.

# 2. Scope

This procedure applies to the HMPC and to the HMPC secretariat for the management of proposals for European Union list entries and European Union herbal monographs.

The procedure does not apply to proposals concerning products, which have been used in the European Union for less than 15 years, but are otherwise eligible for the simplified registration. Procedures for such products are handled in accordance with the procedure laid down in Article 16c(4) of Directive 2001/83/EC (referrals procedure[2]).

Any interested party can make proposals.

[2] See Chapter 3 - Union Referral Procedures - of the Notice to Applicants Volumes 2A

# 3. Responsibilities

Members of the HMPC and HMPC secretariat must ensure the adherence to this procedure in the management of proposals for European Union list entries and European Union herbal monographs submitted by interested parties.

# 4. Related documents

HMPC Meeting dates (dates for HMPC meetings are published on the EMA website)

Inventory of herbal substances for assessment (EMA/HMPC/494079/2007)

Overview of assessment work – HMPC priority list (EMA/HMPC/278067/2006)

Guideline on the documentation to be submitted for inclusion into the 'Community list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products' (EMEA/HMPC/107399/2005 Rev. 1)

Template for a European Union herbal monograph (EMA/HMPC/107436/2005 Rev.7, *Corr.* 1)

Template for Assessment report for the development of European Union herbal monographs and European Union list entries (EMA/HMPC/418902/2005 Rev.5, *Corr*. 1)

Guideline on the assessment of clinical safety and efficacy in the preparation of European Union herbal monographs for well-established and traditional herbal medicinal products (EMA/HMPC/104613/2005 Rev. 1)

Part II.1 of Annex I to Directive 2001/83/EC

Establishment of European Union herbal monographs and European Union list entries and related documents (SOP/H/3163)

Procedure for calls for scientific data for use in HMPC assessment works (EMA/HMPC/1004/2006).

# 5. Definitions and abbreviations

**Definitions**

European Union list entry: document whose purpose is to provide structured information, including information laid down in Article 16f(1) of Directive 2001/83/EC, relating to specific herbal substances or herbal preparations or combinations of substances and preparations from a given plant[3] for use in traditional herbal medicinal products.

European Union herbal monograph: document whose purpose is to provide a scientific summary of all data available on the safety and efficacy of a herbal substance/preparation intended for medicinal use, as referred to in Article 16h(3) of Directive 2001/83/EC.

Interested Parties: parties concerned with the use of medicinal products such as pharmaceutical industry associations, health care professional groups, scientific, consumers and patients' associations, governmental institutions as well as EU Member States and EEA-EFTA States.

[3] It will be indicated if more than one plant is used and if hybrids are also used.

Interested Parties to the HMPC: specific interested parties identified[4] as having an interest in (traditional) herbal medicinal products at European level.

Key references: references considered relevant for the proposal by interested parties and submitted as a full text.

**Abbreviations**

EMA European Medicines Agency

HMPC Committee on Herbal Medicinal Products

MLWP Working Party on European Union Monographs and European Union List

EEA European Economic Area

EFTA European Free Trade Association

# 6. Records

All documents, including correspondence, will be filed at the EMA in electronic format.

The HMPC secretariat will keep records of all proposals received.

# 7. Instructions

## *7.1. Submission of proposal by interested parties*

Interested parties are welcome to submit a proposal at any time, using the template (Annex 1). The proposal should be a maximum 2-3 page document (A4 format) and should include the justification to add that substance, preparation or combination to the HMPC priority list.

To ensure that a proposal is discussed by the HMPC at a specific meeting, the proposal should be received by the HMPC secretariat at least 2-3 weeks before the start of that meeting. The dates of HMPC meetings are published on the EMA website.

Proposals can be submitted by any interested party or can be channeled through the identified 'Interested parties to the HMPC'.

Submitting parties are bound to obey existing copyrights. Rights of third parties should be duly taken into account, as the documentation provided might 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. Unpublished proprietary data may be included. However, in this case the consent of the data owner is a necessary requirement and therefore it must be provided simultaneously with the contributions. If the party submitting the data is not the data owner, the consent of the latter is needed. If the data owner is the interested party itself, the voluntary submission of the data as a contribution to the HMPC assessment constitutes consent that the HMPC may evaluate and use the submitted data in the course of following assessment procedures.

Upon receipt at the EMA, proposals will be subject to the following steps:

- Validation of the submitted proposal by the HMPC secretariat;

[4] http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/document_listing/document_listing_000223.jsp&mid=WC0b01ac05807fa576

- Discussion and decision by the HMPC;

Informing interested party about the decision by the HMPC secretariat.

## *7.2. Validation of the proposal*

The HMPC secretariat will verify the proposals received from the interested parties if:

a) The template (Annex 1) is filled with the required information and the view of the interested party on the level of interest of the given herbal substance, preparation or combination, justifying that such substance, preparation or combination should be added to the HMPC work list, including information on European Union interest, public health protection, market relevance, etc.;

b) The key references are provided as full text.

If the provided data are considered sufficient, the HMPC secretariat will validate the proposal within two weeks from the submission of the documentation. The proposal will be added in the next HMPC Agenda for discussion/decision.

For justification of proposals related documents should be considered:

- Part II.1 of Annex I to Directive 2001/83/EC;
- 'Guideline on the assessment of clinical safety and efficacy in the preparation of European Union herbal monographs for well-established and traditional herbal medicinal products' (EMA/HMPC/104613/2005 Rev. 1);
- 'Guideline on the documentation to be submitted for inclusion into the 'Community list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products' (EMEA/HMPC/107399/2005 Rev. 1) (specific for traditional use).

As regard the documentation submitted, the requirements in terms of **copyright**, **confidentiality** and **language** are those laid down in the 'Procedure for calls for scientific data for use in HMPC assessment works' (EMEA/HMPC/1004/2006 Rev. 6).

The HMPC secretariat will acknowledge receipt of each proposal within two to three weeks from the submission and clarify whether sufficient information is available for an informed decision by the Committee.

## *7.3. Discussion and decision by the HMPC*

The Committee will consider the views of the interested party, the validation by the secretariat and the supporting documentation (key references) provided and takes a decision.

All new herbal substance, preparation or combination proposed for assessment by the HMPC will be added to the alphabetic inventory of herbal substances.

If the Committee concurs with the interested party that the herbal substance, preparation or combination should be included amongst those substances/preparations/combinations to be assessed by the HMPC, the proposal will be included in the HMPC priority list.

Simultaneously with the inclusion in the HMPC priority list, the HMPC appoints a Rapporteur in charge of the assessment and in accordance with standard operation procedure for establishment of European Union herbal monographs and European Union list entries (SOP/H/3163) starts the Procedure for calls for scientific data for use in HMPC assessment works (EMA/HMPC/1004/2006).

If the proposed herbal substance, preparation or combination is not added to the HMPC priority list, it will be kept to the alphabetic inventory of herbal substances for future work.

### *7.4. Informing interested party about the HMPC decision*

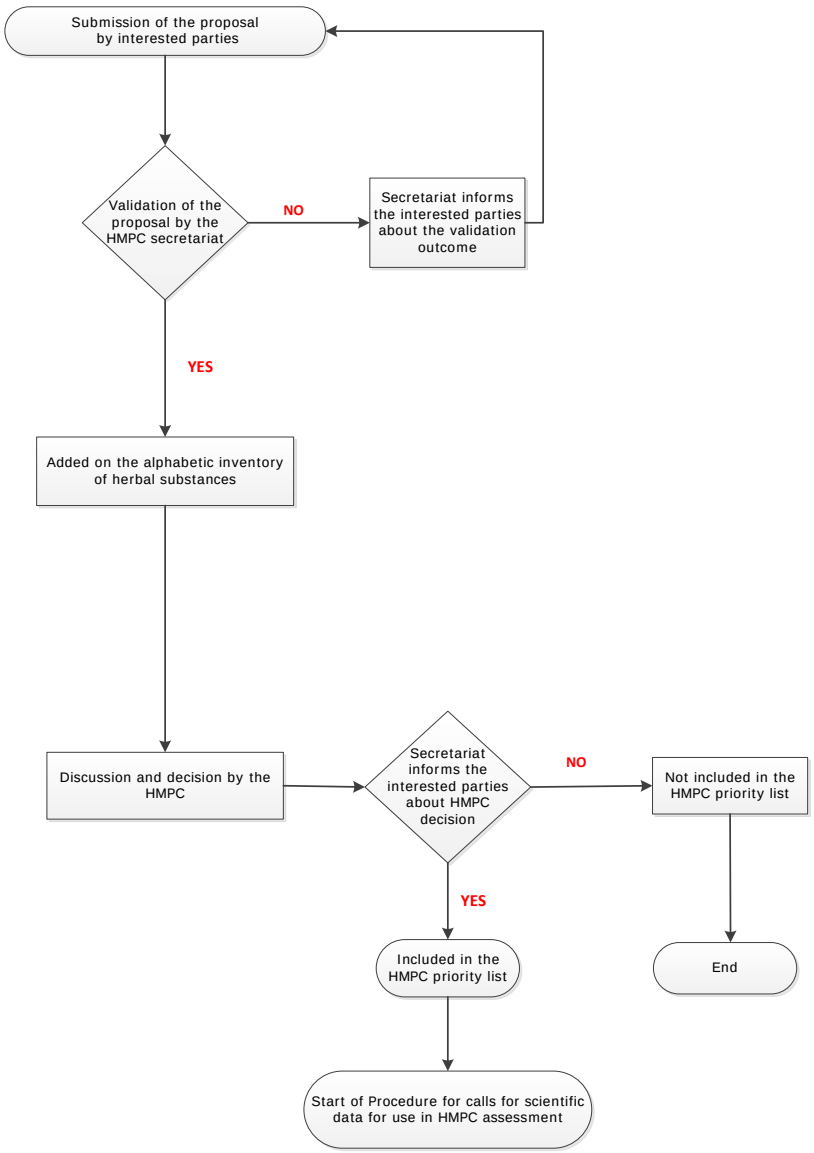
The HMPC secretariat will inform the interested party on the HMPC decision. In case of a positive decision, the estimated timetable for the assessment will be provided. Usually, for the development of a new European Union herbal monograph, including the call for scientific data and the public consultation period for the draft, it takes up to two years.

Remark:

Please note that requests for access to such proposals from interested parties will be handled in accordance with the Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001, the European Medicines Agency policy on access to documents and Rules for the implementation of Regulation (EC) No 1049/2001 on access to EMA documents.

## 8. Date of compilation / last revision

20 November 2018

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185 **Figure 1.** The process flow map of the procedure for the management of proposals submitted by
186 interested parties

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# Annex 1

## Proposal to HMPC for assessment to establish EU herbal monograph / list entry

Key facts and justification for addition to HMPC priority list and work plan (need for EU harmonized standard)

**(A) Key facts**

**Herbal substance(s) (Latin/English, specific on plant part):**
<Insert text here>

Ph. Eur Monograph available: ☐ yes ☐ no

*In case of combination, precise in the text box below, the available Ph. Eur. Monograph for each substance*
<Insert text here>

**Botanical name of the plant(s) (likely):**
<Insert text here>

**Therapeutic area /Therapeutic indication (likely)[1]:**
<Insert text here>

**Proposed by:** name/date

**(B) Justification**

**(1) Available documentation on period of medicinal use[2] derived from:**

| | As a single active substance | As a combination | |
|---|---|---|---|
| Medicinal products authorised in the EU >10 years | ☐ yes ☐ no | ☐ yes ☐ no | Countries: |
| Medicinal products on the market in the EU >15/30 years | ☐ yes ☐ no | ☐ yes ☐ no | Countries: |
| Medicinal products on the market >30 years outside EU | ☐ yes ☐ no | ☐ yes ☐ no | Countries: |
| Other product categories with medicinal use >15/30 years in EU or >30 years outside EU | ☐ yes ☐ no | ☐ yes ☐ no | Countries: |
| Recent traditional use registration[3]/marketing authorization in EU MSs | ☐ yes ☐ no | ☐ yes ☐ no | Countries/years: |
| Other reliable literature/ information | ☐ yes ☐ no | ☐ yes ☐ no | |

[1] Including nature of the tradition in question (see also Article 16g(2) of Directive 2001/83/EC)
[2] Key references supporting available evidence on period of medicinal use should be listed in (C) references and attached to the proposal (D) attachments
[3] Traditional use registration in accordance with Art 16(a) of Directive 2001/83/EC

Comments/rationale:
<Insert text here>

**(2) Available documentation on indication with specified strength/posology[4] derived from:**

| | As a single active substance | As a combination | |
|---|---|---|---|
| Medicinal products authorised in the EU >10 years | ☐ yes ☐ no | ☐ yes ☐ no | Countries: |
| Medicinal products on the market in the EU >15/30 years | ☐ yes ☐ no | ☐ yes ☐ no | Countries: |
| Medicinal products on the market >30 years outside EU | ☐ yes ☐ no | ☐ yes ☐ no | Countries: |
| Other product categories with medicinal use >15/30 years in EU or >30 years outside EU | ☐ yes ☐ no | ☐ yes ☐ no | Countries: |
| Recent traditional use registration[5]/marketing authorization in EU MSs | ☐ yes ☐ no | ☐ yes ☐ no | Countries/Years: |
| Other reliable literature/ information | ☐ yes ☐ no | ☐ yes ☐ no | |

[4] Key references supporting available evidence on indication with specified strength/posology should be listed in (C) references and attached to the proposal (D) attachments

[5]Traditional use registration in accordance with Art 16(a) of Directive 2001/83/EC

Comments/rationale:

<Insert text here>

**(C) List of key references**

**List only key references here** *(no exhaustive literature, usually not more than 3-10 references)*

<Insert text here>

*E.g.*

*1. Muszyński J. Ziołolecznictwo i Leki Roślinne (Fitoterapia). Państwowy Zakład Wydawnictw Lekarskich, Warszawa 1954*

*2. Ożarowski A, łańcucki J, Gąsiorowska K. Leki roślinne. Zjednoczenie Przemys łu Zielarskiego. Herbapol, Warszawa 1978*

*3. Autorizatie de punere pe piata nr. 7804/2006/01-02, Anexa 2-Rezumatul caracteristicilor produsului PERSEN 210 mg, drajeuri*

*4. British Herbal Pharmacopoeia. British Herbal Medicine Association, Bournemouth, Exeter 1976.*

*5. Indian Materia Medica. Revised and Enlarged by Nadkarni AK Bombay Popular Prkashan Private Ltd, 1976.*

**(D) Attachments (full text key references)**

Attach full text key references as pdf *(no exhaustive literature, usually not more than 3-10 references)*